Kalorama Information

The Worldwide Market for IVD Tests, 19th Edition

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Chapter 1: Executive Summary

About Kalorama Information

Kalorama Information, part of Science and Medicine Group Inc., is a trusted publisher of market research exclusively focused on the healthcare industry. For over 25 years, Kalorama has delivered accurate, timely, and strategic intelligence to leaders in biotechnology, clinical diagnostics, in vitro diagnostics (IVD), pharmaceuticals, medical devices, and broader healthcare sectors.

Originally launched in 1998, Kalorama Information quickly established itself as a premier source of insight into U.S. and global medical markets. Today, Kalorama remains a leading authority on healthcare market dynamics, with a particular emphasis on IVD.

Kalorama is best known for its flagship title, The Worldwide Market for In Vitro Diagnostic Tests, an internationally recognized benchmark in the diagnostics field. Other reports published throughout the year cover these and other healthcare topics in greater detail. Our innovative approach to research, combined with deep industry expertise, has made Kalorama a go-to resource for top healthcare companies, strategic planners, investors, and media seeking authoritative market data and trends.

With a singular focus on healthcare, Kalorama continues to shape informed decision-making across the industry through comprehensive, evidence-based analysis.

Kalorama also works in coordination with other Science and Medicine Group brands, including BioInformatics, which focuses on life science markets and marketing, SDi, the leading source of information on the laboratory life science and analytical instrumentation industry and publisher of IBO, its twice-monthly newsletter, and IMV, which publishes reports and data on the medical imaging and clinical markets.

For more information about Kalorama Information and other services offered by Science and Medicine Group, please visit our website.

Overview

Kalorama Information's market analysis reveals encouraging news: the in vitro diagnostics (IVD) market is poised for positive growth over the forecast period, with incremental gains expected in each year. However, growth will not be uniform across all companies or market segments. While some routine testing areas may experience flat or modest revenue increases, segments leveraging novel technologies such as molecular diagnostics, mass spectrometry, genetic testing, and advanced point-of-care (POC) systems are expected to outperform the overall market average.

At the heart of clinical testing growth is the persistent threat to human health. This extends beyond individual diseases like diabetes or cancer to the growing prevalence of multiple chronic conditions occurring in the same individual. Current estimates indicate that approximately 40% of Americans and 33% of the global population suffer from at least one chronic condition, with nearly 20% of U.S. adults living with two or more. Conditions such as hypertension, chronic lung disease, asthma, heart disease, and cancer rarely exist in isolation. Their co-occurrence drives increased healthcare utilization, including more provider visits, longer hospital stays, and growing demand for home-based diagnostics, all of which fuel IVD test volume growth.

However, the IVD market faces several limitations. Although advancements in instruments, assays, and innovative technologies initially drive higher testing demand, this is often tempered by cost-containment efforts from payers and governments worldwide. Healthcare budgets are under constant pressure, with many governments actively seeking to curb spending growth.

Key factors shaping the IVD market include:

- Technological Innovation: Automation, faster turnaround times, real-time alerts, enhanced quality control, and integrated software systems are improving laboratory efficiency and test reliability.
- Syndromic and Multiplex Testing: These approaches have gained favor with payors in some markets and enjoy increasing adoption by providers for their ability to deliver comprehensive diagnostic insights from single samples.
- Artificial Intelligence (AI) and Robotics: Expected to enhance diagnostic precision and workflow efficiency, though AI in IVD still needs to robustly demonstrate

clinical and economic effectiveness comparable to its impact in imaging and other medical fields.

- Novel Biomarkers and Specialty Analyzers: The steady introduction of new biomarkers is expanding test menus and enabling more personalized and precise diagnostics.
- Healthcare Delivery Expansion: Increasing focus on smaller clinics and home-based testing presents new opportunities targeted by major IVD vendors.
- Reimbursement Landscape: Favorable reimbursement continues for tests that prove clear clinical value, though not all assays benefit equally.
- Global Market Expansion: Emerging markets are experiencing increased private insurance penetration and healthcare access, driving demand for diagnostics.

Looking ahead over the next five to ten years, moderate and gradual shifts in the IVD product markets are anticipated. Manufacturers can expect growth driven primarily by fundamental demographic and epidemiological trends, specifically an aging global population, a rising disease burden, and expanding international healthcare infrastructure. However, these positive trends will be partly offset by fiscal challenges, including government funding cuts in the United States, budget constraints in the European Union, and limited hospital spending in China.

Infectious diseases remain a top global priority, particularly in developing countries where diagnostic testing is essential and in developed nations facing emerging pathogen threats.

Additional challenges include geopolitical factors, such as tariffs and trade policies, that may disrupt supply chains and affect IVD vendors worldwide.

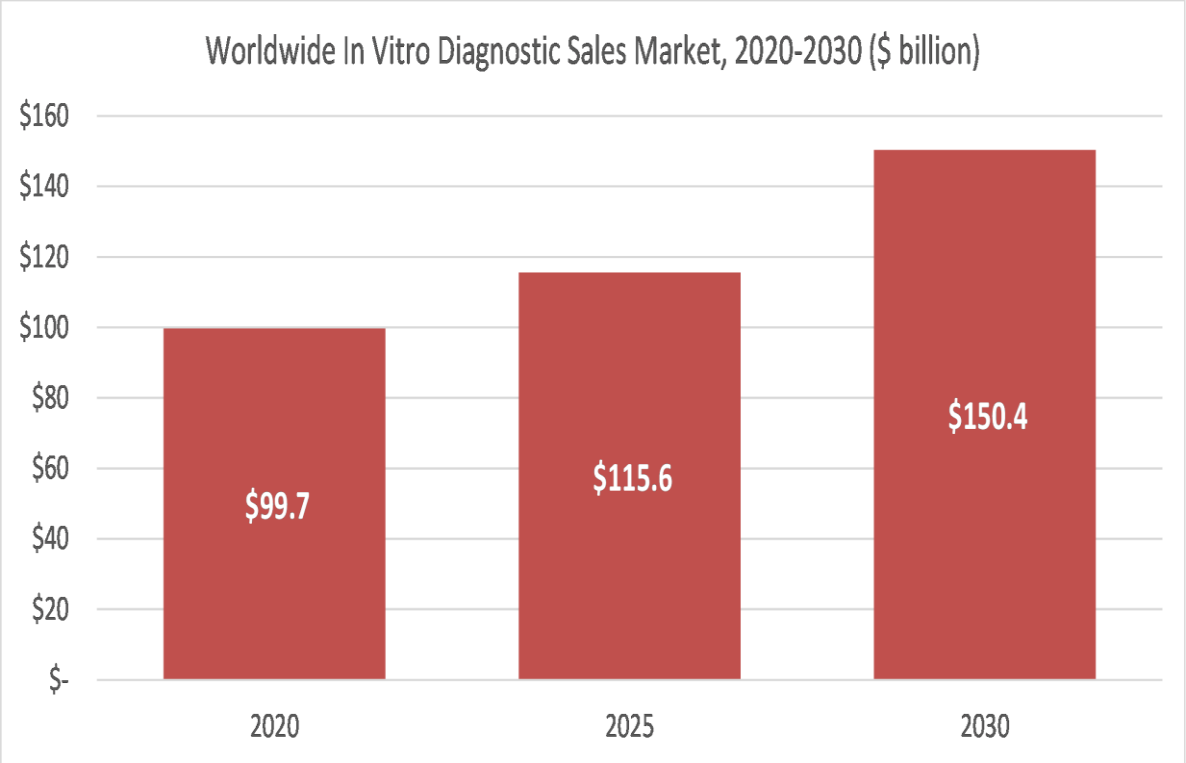
AI has the potential to enhance diagnostic accuracy and support higher-value pricing, but its long-term impact in the IVD market will depend on its ability to deliver measurable gains in clinical outcomes and overall cost efficiency.

Having weathered the disruption of the pandemic, the IVD market has emerged stronger and more growth-oriented, driven by new technologies and expanding opportunities. The COVID-19 pandemic led to an unprecedented demand for in-vitro diagnostic expertise. This led to a surge in demand for PCR, NGS, and serology-based rapid-test products. As a result, the market has opened several new areas of advancement, including microfluidic technologies, next-generation sequencing, microarrays, and the growing significance of

precision medicine, including companion diagnostics and multiplex testing, which will drive significant growth opportunities.

This report, ***The Worldwide Market for In Vitro Diagnostic (IVD) Tests***, now in its 19th Edition, details this activity on a global scale. The report examines the entirety of the in vitro diagnostic market and makes forecasts; assesses trends and scrutinizes vendor activities. The worldwide market for in vitro diagnostics in 2025 is $116 billion, as shown in this figure.

Figure 1-1: Worldwide IVD Market Sales, 2020, 2025, and 2030 ($ billion)



Source: Kalorama Information

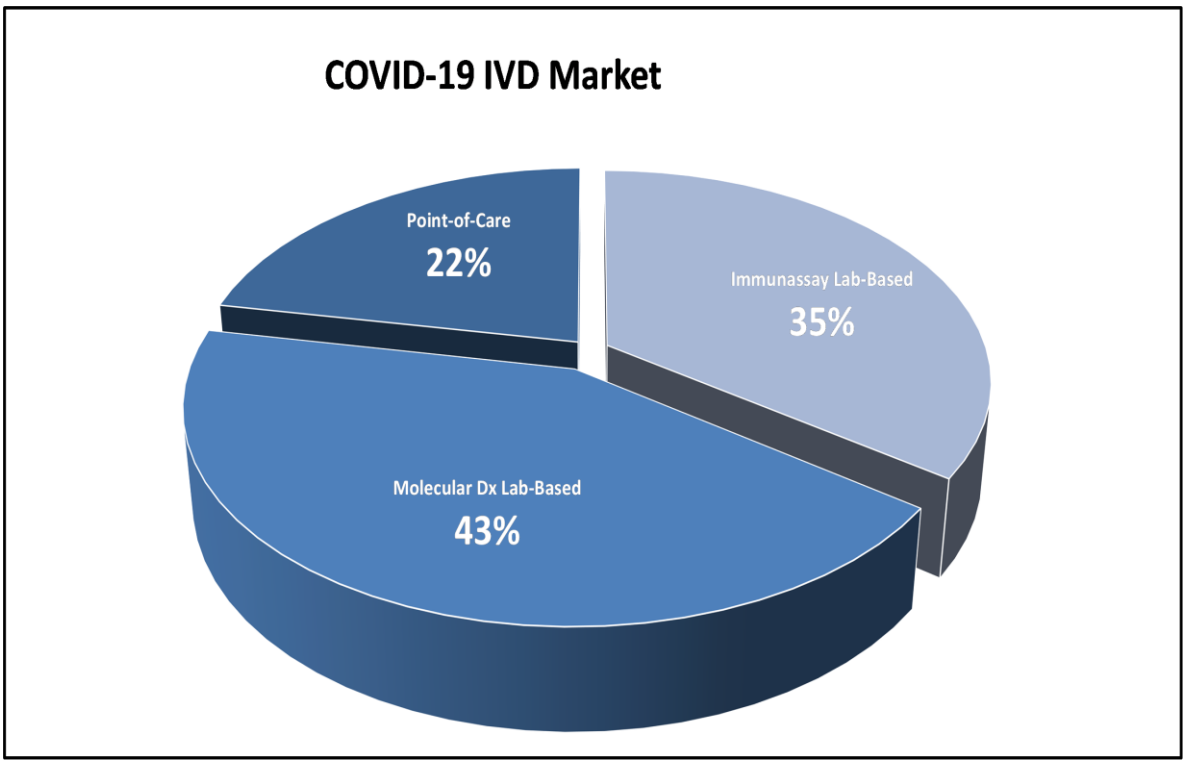
Chapter 5: Point-of-Care, Chapter 7: Immunoassays, and Chapter 11: Microbiology/Virology were most affected by demand for COVID-19 tests. These chapters cover multiplex respiratory panels, which have been increasingly used to rule out COVID-19. As anticipated, the urgency and swift response to COVID-19 testing solutions resulted in a strong uptick in the installed base of instruments for both immunoassay and molecular infectious disease diagnostic platforms. The capital investment in these systems has expanded overall use and

extended capabilities beyond the pre-COVID-19 era. This is particularly true of advanced molecular, molecular point-of-care and automation systems that may not have been purchased without the urgency and funding as a result of the pandemic.

As reflected in the COVID-19 market value for 2025 ($4.0 billion) compared to 2024 ($5.3 billion), the market is slowing and becoming more stable, more predictable for future market forecasting.

Figure 1-2: COVID-19 IVD Market, Share by Segment, 2025 (%)

[Immunoassay Lab-Based, Molecular Dx Lab-Based, Point-of-Care]



Source: Kalorama Information

To some degree, the issues the IVD industry was experiencing before the pandemic have worsened. The opioid crisis has not gone away. In fact, there is growing evidence that the crisis may have worsened as a result of economic woes, high unemployment (which has

lessened since this report), and rising inflation prompted by the COVID-19 pandemic. For 2026, these issues remain a concern but are diminishing.

New companies entered the IVD market space at a rapid pace throughout 2020, 2021, and 2022, largely introducing emergency use authorization (EUA) products to detect and guide care for COVID-19. Changes by the FDA and other regulatory entities reducing EUA-type approvals have resulted in some contraction in vendor participation, but participation has remained stable. In some cases, bankruptcy and funding challenges have closed some doors. Discontinued COVID-19 product lines and participation have also emerged throughout 2023-2025, as these segments are less profitable than during the height of the pandemic.

Top-tier IVD companies accounted for the majority of IVD product sales in 2025. This has been a continuing trend. Even in COVID-19 testing, consolidation is reflected. About ten companies (Roche, Abbott, Cepheid, bioMérieux among them) were among the labs' favored tests, at least in the United States, per an AMP survey. Top-tier and next-tier companies listed in the market tables in Chapter 2 of this report account for the majority of the global IVD market.

That does not mean there are not billions of dollars available for other concerns. The remainder of the market is held by 100s of companies, some of which specialize in specific test segments and others that serve their local markets. IVD remains dynamic. There are constant innovations. This report documents these innovations in each market chapter. The IVD industry is a high-R&D-spend industry, and there is ongoing interest from venture capital firms in diagnostic products.

Kalorama's report is global, industry-focused, elevating corporate developments and financials over academic modeling. This 19th edition of ***The Worldwide Market for In Vitro Diagnostic (IVD) Tests*** presents the current view of the changes these investments have brought in the various market chapters and company profiles in the report. One cannot look at a market without being aware of long-term trends. Trends such as artificial intelligence, next-generation sequencing, gene editing, and microbiome studies are detailed in Chapter 4 of this report.

Scope and Methodology

The world market for in vitro diagnostics is provided in U.S. dollars for the years 2025-2030. Financial data in foreign currency is translated into US$ using the average annual exchange rate as the base. Therefore, previous editions of this report may not align due to the readjustment in company revenues.

Please note that market events change quickly, and vendors release information at different times, either publicly or through private channels. In some cases, the market evaluations presented in this edition of the report will differ from those in the 18th edition of this report and other reports prepared by the author and Kalorama Information. This is because the market evaluations are based on reported company revenues that were available at the time of writing. They are also based on anticipated market penetration of new tests and an increase in the usage of incumbent tests. This does not always proceed as expected. Thus, information changes with time and influences the market estimates. This methodology, as imperfect as it is, is the most rational strategy. At the same time, this approach results in variations in market estimates. Kalorama makes every effort to maintain transparency in the market information contained in this report. Furthermore, the market data presented in this report should be viewed as estimates. Although Kalorama strives to publish market evaluations and projections as close as possible to the market's true value, there is a measure of uncertainty involved in the estimation and forecasting process.

Market analysis in this report covers world markets for in vitro diagnostics; however, the reader will find a bias toward the developed areas of the globe in North America, Japan, and Western Europe. All market data are based on manufacturer revenues and not on retail pricing or reimbursement payments. Data for the in vitro diagnostic market are presented in U.S. dollar market size by test category and, where possible, by specific analytes. The dollar value of a market segment is directly proportional to the number of tests performed, because the cost of the instrumentation is generally buried in the per-test price.

The report discusses tests and technologies that are currently available and those that are expected to take their place. Generally, current products and technologies establish the standard of care and their value to payers.

Kalorama Information based its analysis on currently available information regarding international trade policies, trade restrictions, and tariff structures as of the date of this report. Rapidly evolving dynamics of global trade regulations, particularly those

impacting medical devices, reagents, and diagnostic instrumentation, are considered in this analysis and pose significant uncertainty surrounding forecasting and potential impact. While reasonable assumptions have been made to account for current conditions in trade policy affecting IVD manufacturers and suppliers, there can be no assurances that these assumptions will account for future changes in trade policy.

Tariff commentary is based on tariff policies in effect as of April 30, 2026.

The information presented in this report is derived from publicly available information sources such as company, government, and medical organization reports. The analysis is based on the author's industry knowledge combined with literature searches and interviews with industry professionals and experts in the IVD industry.

Major information sources include, but are not limited to, the following:

- Association for Diagnostic Laboratory Medicine, www.adlm.org (previously AACC)
- American Association of Blood Banks, www.aabb.org
- Association for Molecular Pathology, www.ampweb.org
- Centers for Medicare & Medicaid Services
- CAP Today Online, http://captodayonline.com/
- China Cancer Registry
- Clinical Lab News
- Croatian Institute of Public Health, Department of Epidemiology
- EDMA (the European Diagnostic Manufacturers Association), www.edma-ivd.be
- FDA, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), www.fda.gov/cdrh/oivd/index.html
- The Freedonia Group Economic Data
- FX Investors, historical currency exchange rates (www.oanda.com)
- GenomeWeb
- Interviews and surveys conducted by Kalorama Information

- Institute of Health Information and Statistics of the Czech Republic
- India Public Sector News
- IVD company websites, annual reports, financial statements, investor conferences, press conferences
- Japan Analytical Instruments Manufacturers Association, IVD Committee
- Joint Commission International, Mexico
- Kalorama Information's Knowledge Center and previous reports
- Laboratory Equipment, www.laboratoryequipment.com
- Medec Canada
- MDDI Magazine
- National Bureau of Statistics of China
- Surveys, Science and Medicine Group/Bioinformatics
- Strategic Directions International (SDi)
- The New England Journal of Medicine
- Oncology KnowledgeBASE, http://oncologyknowledgebase.com
- World Health Organization databases and fact sheets
- World Bank

Size and Growth of the Market

The worldwide IVD market is valued at $115,559 million ($116 billion) in 2025. The following table presents the worldwide IVD market across all segments.

Table 1-1: Global In Vitro Diagnostic (IVD) Sales, by Product Segment, 2025-2030 ($ million)

[Blood Bank Molecular; Blood Bank Screening; Drugs of Abuse; Blood Grouping/Typing; Circulating Tumor Cells; Clinical Chemistry; Coagulation; Histology/Cytology; Continuous Glucose; Diabetes HbA1c Immunoassays, Lab-Based; Hematology; HPV, Molecular; Immunoassays - Infectious Disease; Immunoassays - Other; Mass Spectrometry; Microbiology (ID/AST); Molecular Microbiology; Nucleic Acid Assays; POC, OTC Diabetes; POC, OTC Other; POC, Professional; Other]

Product Segment	2025	2030	CAGR 2025-2030
POC Professional	13,537	16,751	4%
Immunoassays - Infectious Disease	13,165	15,494	3%
Immunoassays - Other	12,610	15,267	4%
Continuous Glucose	12,458	20,600	11%
Clinical Chemistry	10,978	13,308	4%
Molecular Microbiology	8,672	10,631	4%
POC, OTC Diabetes	6,693	7,020	1%
Microbiology (ID/AST)	5,586	6,314	2%
Hematology	5,495	7,455	6%
Histology/Cytology	5,017	6,597	6%
Molecular Oncology	4,705	9,500	15%
POC, OTC Other	3,642	4,489	4%
Coagulation	1,794	2,098	3%
D-dimer	1,475	1,710	3%
HbA1c Immunoassays, Lab-Based	1,342	1,700	5%
Molecular Genetic/Inherited	1,332	1,950	8%
Blood Bank Molecular	1,330	1,790	6%

Product Segment	2025	2030	CAGR 2025-2030
HPV, Molecular	1,270	2,145	11%
Blood Grouping/Typing	1,045	1,150	2%
Mass Spectrometry	1,032	1,580	9%
Blood Bank Screening	834	885	1%
Drugs of Abuse	333	353	1%
Circulating Tumor Cells	152	185	4%
Other	1,062	1,474	7%
Total	**115,559**	**150,446**	**5%**

Source: Kalorama Information

Market Highlights

Here are some highlights of the report:

- **Continuous Glucose Monitoring Drives POC Markets:** Device innovation and new product launches by key players such as Abbott, Dexcom and Trinity will support 11% (CAGR) growth through 2030.
- **Molecular Oncology:** Molecular oncology has expanded beyond diagnosis into minimal residual disease (MRD) detection, where highly sensitive assays identify trace levels of circulating tumor DNA after treatment, allowing earlier detection of recurrence and more informed decisions regarding adjuvant therapy supporting 15% CAGR 2025-2030
- **Mass Spectrometry Benefitting from Precision Medicine Demand:** High demand in specialized diagnostics, including precision medicine and oncology testing, will support growth of 9% CAGR 2025-2030.
- **Multiplex Testing Moving Beyond Just the Respiratory Arena:** In the post-pandemic era, multiplex tests help to meet laboratory needs created by personnel shortages, less hands-on time, fewer reagents, and fewer laboratory resources. There has been a proliferation of respiratory testing involving SARS-CoV-2, flu A & B and RSV. Now, multiplex testing is moving into other areas, such as differentiating between bacterial and viral microorganisms to help physicians prescribe the proper treatment. As an example, Spindiag's proprietary microfluidic technology enables the company's Rhonda to deliver quick, accurate, and convenient results for an array of infectious diseases.
- **HPV Molecular Markets Holding at Double-Digit Growth**: HPV molecular markets remain strong and will continue to demand 11% CAGR (2025-2030), driven by expanded preventive programs and a wider adoption of core lab integration.
- **Molecular Transplant Testing Market Gaining Momentum**. After a slow couple of years, the molecular transplant market has recently grown and is expected to continue growing through the forecast period (2025-2030), increasing at a 10% CAGR.
- **U.S. Percentage of World Market Holds Strong:** COVID-19, mass spectrometry, continuous glucose testing, and nucleic acid testing are contributing to the product segment in maintaining a steady market share.

- **Hematology Markets Outpace Expectations**: Growth in the hematology core lab market is trending stronger than previously anticipated due to demand for integration in core lab platforms (CAGR, 6.3%). Instrument replacements during the COVID-19 pandemic bode well for hematology markets, with upgrades that allowed high-throughput hematology analyzers and market expansion opportunities on the table.
- **Nucleic Acid Assays Show Strong Promise**: The nucleic acid assay segment is increasing with double growth and is expected to post 13.7% CAGR performance through the forecast period 2025-2030.
- **Bio-Rad Remains Top Contributor to Growing Quality Control Market:** This 19th edition continues to estimate quality control in support of immunoassay and molecular IVD use. The market for quality control is estimated at $1.2 billion for 2025, with 68% of the market utilizing immunoassay techniques and the remainder molecular. As it does not reflect direct in vitro diagnostic test revenue, this number is not included in the IVD market totals, but it is important for advancing the technology and testing.
- **Sepsis Concerns Still High Priority:** Sepsis continues to be a growing problem and has only increased the attention of caring for infected patients. Early detection is crucial for patients. The industry has responded by increasing rapid sepsis testing options and continuing steady utilization for lab-based techniques. This industry push in rapid sepsis testing is contributing 14% growth in the market. Approximately 1.7 million individuals in the US develop sepsis each year. Procalcitonin (PCT) and lactate are two established biomarkers for sepsis.

Market Assumptions

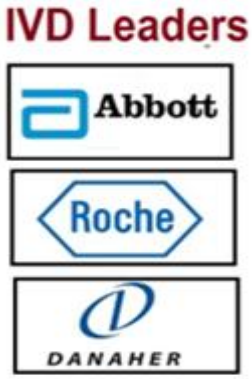
The IVD industry faces a mix of risks and opportunities shaped by global economic conditions, policy shifts, and evolving healthcare needs. To provide context for the market estimates and forecast, Kalorama Information considers some key assumptions driving the market outlook. These assumptions include, but are not limited to, trade and tariff uncertainties, regulatory challenges, and ongoing supply chain vulnerabilities. Combined these factors create uncertainty in the market and could shift market results from the forecasts presented in this edition of the IVD market. At the same time, favorable currency movements, rising investment in R&D, and rapid advances in digital and AI integration are creating positive momentum for long-term growth.

Table 1-2: IVD Market Assumptions 2025 Outlook

Transitioning to 2026 Outlook Assumptions	Impact/Comment	Company Examples		Weight of Impact on IVD Market
Trade tariff uncertainty	Negative impact on operating revenue - persistent but stabilizing	Abbott flagged cost risks from U.S.-China tariffs.	bioMérieux noted ongoing EU import concerns.	Moderate to high
Currency fluctuations	Mixed impact	Roche benefited from FX in early 2025 but noted normalization.	Siemens Healthineers continues to benefit from euro weakness in exports.	Low to moderate
Regulatory changes	Continued delays and increased compliance burden under IVDR transitions	bioMérieux is still impacted by IVDR bottlenecks.	BD highlighted ongoing EU compliance costs and SKU rationalization.	Moderate
Supply chain disruptions	Global risk is low; however, localized constraints remain	Siemens Healthineers reported improved reagent availability/supply.	Thermo Fisher is still managing select raw material sourcing challenges.	Low to moderate
R&D investment levels	Continued increase to support innovation pipeline - stronger focus on AI-enabled workflows	Thermo Fisher sustained high R&D increases.	Roche is expanding AI, digital pathology, and molecular platforms with advanced technologies	Moderate
Pricing pressures in key markets	Margin compression expected, with increasing tender pressure and value-based pricing	BD reported continued pricing pressures in APAC.	Abbott cited competitive pricing in LATAM and the US, reducing margins.	Moderate
Demand for COVID-19 testing	Significant decline vs. prior years - transitioned from a revenue driver to a baseline diagnostic category	QuidelOrtho revenues stabilized at a lower base.	Roche COVID-19 revenue is now a minimal contributor.	Varied: High for COVID-invested portfolios
Growth in chronic disease testing	Positive long-term demand driver - accelerating with aging populations and decentralization strategies	Danaher (Cepheid) is expanding test menus beyond infectious disease.	Siemens Healthineers launched new kidney disease assays.	High

Source: Kalorama Information

Competitive Picture in IVD



The sheer size and breadth of reach, both product-wise and geographically, allow IVD giants such as Abbott, Roche, and Danaher to contribute to the overall growth of the IVD market worldwide. At the top of the IVD list, **Abbott Diagnostics** (2025 IVD revenues of $16,935 million) is the market leader in the POC market, which generates an estimated $11 billion of the company's total IVD revenues. Abbott is expected to maintain a leading position in POC with a wide market share margin

Roche Diagnostics (2025 estimated IVD revenue is $16,607 million), is the second largest global provider of IVD products. As the IVD landscape continues to evolve, Roche also adapts and grows its presence in key markets. The company recently expanded its commitment to sequencing technologies through strategic collaborations and is using AI-enabled technologies to enhance its diagnostic product lines, including companion diagnostics. Roche is the leading vendor in core molecular diagnostics and generates revenue in nearly every broad segment of IVD clinical products.

The diagnostic companies of **Danaher Corporation** (2025 IVD revenue $9,940 million) include Beckman Coulter, Cepheid, Leica Biosystems, Radiometer, and SCIEX Diagnostics. The result of the company's acquisition strategy of key IVD players (most specifically Beckman Coulter and Cepheid) catapulted Danaher into the number three market position. Danaher generates a large proportion of its sales in North America, Europe, and Asia/Australia.

The significant gains made by companies that market infectious-disease immunoassays, cardiac markers, cancer diagnostics, histology, and molecular diagnostics illustrate several important market phenomena. One is that these areas have been the growth engines in the past and will continue to be so for the near future. On the other hand, companies including **bioMérieux** (2025 revenue $3,756 million) and Sysmex (2025 revenue $3,216 million) have capitalized on their investments in emerging markets in molecular and infectious-disease testing. Companies such as **Exact Sciences** (2025 revenue $3,247 million) remain strong in niche market segments, providing the company with a strong growth stream.

Chapter 2 provides more details on the competitive situation, and Chapter 14 details the major companies in the market.

Finding What You Are Looking For in the 19th Edition

Table 1-3: Finding What You Are Looking For in the 19th Edition

Looking For…	Location
Blood Donation Testing	Chapter 12
Cancer Testing Markets	Chapter 13 – **Histology**, Chapter 7 – **Immuno Biomarkers**, Chapter 8 – **Genetic Cancer Markers**
China IVD Market	Chapter 3
Clinical Chemistry	Chapter 6
COVID-19 Testing	Chapter 5, Chapter 7, Chapter 11
Distribution Agreements	Chapter 2
Flu Tests, Respiratory Tests	Chapter 11
Glucose Testing	Chapter 5
hbA1c	Chapter 5 – **POC** and Chapter 7 – **Lab-based**
Hematology	Chapter 9
HIV, Hep. Other Pathogens	Chapter 11
ID/AST and Blood Culture	Chapter 11
IHC and In Situ Hybridization	Chapter 13
LATAM IVD Market	Chapter 3
Market Share of Top Companies	Chapter 2
Point of Care	Chapter 5
PT and Other Coagulation Tests	Chapter 10
Test Services	Chapter 2 and Chapter 28 [not included in market data]
US IVD Market	Chapter 3

Source: Kalorama Information

Chapter 2: Introduction

IVD Landscape

Scope

This report offers a comprehensive analysis of all major segments within the in vitro diagnostics (IVD) industry, with detailed discussions of the global factors shaping each segment, including demographic, social, and economic trends. Each segment analysis includes insights into relevant regulatory developments, clinical practices, and recent market approvals, as well as sales data for 2025 with projections through 2030. The report also profiles key market leaders and companies active within each segment. Broader population and healthcare delivery trends in major world regions are evaluated for their impact on diagnostic laboratory markets.

While the report emphasizes the market impact of current and emerging diagnostic technologies, it does not delve into the technical specifications of testing modalities such as molecular assays, immunoassays, or flow cytometry, nor does it provide extensive clinical background on disease etiology, physiology, or manifestations, except when necessary to explain the role of diagnostics in patient care. Current products and technologies are evaluated based on their role in establishing or enhancing standards of care and their value propositions to payers. However, despite the potential of new diagnostic approaches to improve outcomes, adoption may be constrained by cost-benefit considerations within healthcare systems.

Market estimates and forecasts presented in this edition may differ from those in the 18th edition or other Kalorama publications due to updates in company-reported revenues and the latest financial and interview-based information available at the time of writing.

While the acute phase of the COVID-19 pandemic has passed, its aftereffects continue to impact the IVD industry in 2025, particularly with the decline in pandemic-related testing revenues. In response, many companies have shifted their focus to multiplex respiratory panels that include COVID-19, influenza A & B, and, in some cases, RSV, to sustain

relevance and utility. Several segments are emerging as key growth areas through 2030, including HPV molecular, molecular diagnostics, mass spectrometry, POC testing, and molecular HLA testing. Ongoing global health threats such as obesity, diabetes, cancer, cardiovascular disease, and infectious diseases are driving demand for increasingly specific and sensitive diagnostic tools. However, as advanced technologies such as genomics, microfluidics, and IT integration expand testing capabilities, the cost associated with these tests has drawn scrutiny from payers and regulators.

Still, the overall IVD market has improved since the previous year of Kalorama's global diagnostics report, fueled by continued technological progress, the proliferation of syndromic/multiplex testing, greater use of robotics and AI, ongoing biomarker discovery, and increased investment in R&D. Diagnostics that reduce long-term treatment costs or hospital stays remain favored, particularly in settings where reimbursement is favorable. Looking ahead, the IVD industry is expected to experience moderate, gradual growth over the next 5–10 years, with modest gains in developed countries and faster expansion in emerging markets. In these regions, growth is driven by a rising middle class, expanding private insurance coverage, and greater access to healthcare. Particular attention is being paid to infectious and chronic diseases, including rising rates of cancer, cardiac, and autoimmune conditions. Global initiatives such as those led by the Clinton and Gates Foundations have also expanded access to diagnostics for diseases such as TB, HIV, malaria, and STDs. In addition, the rise of emerging infectious diseases, including Chagas, dengue, chikungunya, monkeypox, and continuing COVID-19 variants, has underscored the persistent threat of infectious diseases in an increasingly interconnected world.

Edition-Specific Notes

Shifting Areas of Concentration

Since the 18th edition was published, Kalorama Information has identified specific areas of concentration. These include

- Portfolio expansion
- Customization
- Digital health

During research for the 19th edition, Kalorama Information identified that companies seem to be focusing on expanding their portfolios rather than investing in new products. This is not to say that IVD companies are replacing innovation with portfolios, but rather that they are shifting toward portfolio expansion, menu expansion, and acquisitions to drive primary growth, rather than relying on new platforms or products.

Portfolio expansion is a core strategy, achieved by offering larger test menus on existing platforms and venturing into adjacent disease areas. Acquisitions are playing a bigger role as companies acquire test portfolios or companies, such as Abbott's acquisition of Exact Sciences, to expand cancer diagnostics, and BD's restructuring to focus on other strengths in its portfolio.

Digital health is expanding through connectivity, data management and AI. Digital health has enabled companies to move toward a more integrated solution approach that supports revenue streams, strengthens customer relationships, and creates differentiation in an increasingly competitive market.

New products are still entering the market, especially in certain key growth areas like proteins, but so far, there have not been as many entirely new instrument platforms or disruptive technologies. True innovation is continuing in molecular diagnostics, companion diagnostics, POC molecular diagnostics, digital pathology, and AI-driven diagnostics but even in these areas, companies are acquiring or partnering with other companies instead of building internally.

Report Design

In this 19th edition of ***The Worldwide Market for In Vitro Diagnostic (IVD) Tests,*** Kalorama Information provides an enhanced report format designed to align with its integration into the Kalorama Knowledge Center. This platform provides subscribers with full access to Kalorama's extensive library of market research reports, along with downloadable content, including spreadsheets and Word documents, from these and other reports. While the layout has been updated for improved usability within the Knowledge Center, the report maintains the familiar structure and chapter organization of previous editions, including dedicated sections profiling key IVD market areas. Notably, this edition features expanded profile chapters on companies engaged in circulating tumor cell diagnostics, prenatal testing, and test service offerings, and segments that reflect the most prominent and emerging trends within the IVD industry. This edition has attempted to remove historical and product data

that are not relevant to understanding the information contained in the study. For more details on the Knowledge Center, visit *www.kaloramainformation.com*.

PAMA and CMS

PAMA is intended to introduce a more organic methodology for reimbursement adjustments for lab testing under Medicare and will replace uniform cuts implemented across the Clinical Laboratory Fee Schedule (CLFS) under the Affordable Care Act (ACA) and other prior legislation.

PAMA created a new category of assays, called advanced diagnostic laboratory tests (ADLTs), which CMS has defined as tests developed and offered by a single lab that use a unique algorithm to analyze multiple DNA, RNA, or protein markers, and which provide new clinical diagnostic information that can't be obtained by any other test. Each test is identified by unique codes, but the ADLT definition remains controversial among industry players. Test developers are awaiting further clarification from CMS regarding the requirement that ADLTs must provide new clinical diagnostic information. These tests will be paid full list price for three quarters after their introduction, then payment will be based on weighted median private payor rates, like all other tests.

In the ADLT category, Veracyte's Afirma Gene Expression Classifier (CPT code 81546), for distinguishing which thyroid nodules are benign and which are suspicious of cancer, had a price increase from $3,222 to $3,600, while CareDx's AlloMap test for gauging cardiac transplant rejection risk (CPT code 81595) increased from $2,841 to $2,917.

PAMA has been challenging for POC participants. The cost of the test is a factor in use. POC tests, traditionally higher-cost, would be particularly affected by reimbursement cuts. Industry participants feel that one way to address the issue would be to assign POC tests a different billing code rather than lumping them together with high-volume, low-margin tests. This is a trend that the industry needs to keep abreast of to develop strategies to counter reimbursement cuts for POC testing.

CMS releases new waived tests annually. Some of these additions include:

- 83036QW September 27, 2023, Abbott Diagnostics Technologies AS AS100 Analyzer
- 87635QW August 10, 2023, Abbott ID NOW Instrument (Nasal and Nasopharyngeal Swabs)

- 80061QW, 82465QW, 83718QW, 84478QW September 20, 2023, Alere San Diego Inc. Cholestech LDX {Lipid Profile cassette} (Whole Blood)
- 80305QW May 15, 2023, American Screening Corporation Discover Plus Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation G-Card Drug Test Dip Card
- 80305QW May 15, 2023, American Screening Corporation G-Cup Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation Onescreen Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation Precision DX Drug Test Dip Card
- 80305QW May 15, 2023, American Screening Corporation Precision DX Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation Precision Plus Drug Test Dip Card
- 80305QW May 15, 2023, American Screening Corporation Precision Plus Multi-Panel Drug Test Cup
- 85610QW July 27, 2023, ARKRAY USA Assure PT Care Prothrombin Time PT/INR Monitoring System Professional Use
- 80305QW July 11, 2023, Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M2000
- 80305QW July 11, 2023, Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M300
- 80305QW July 11, 2023, Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test
- 87631QW May 5, 2023, Biofire Diagnostics SPOTFIRE Respiratory Panel Mini
- 80305QW August 23, 2023, BTNX Inc. Rapid Response Multi-Drug One Step Cup
- 80305QW July 11, 2023, BTNX Inc. L-Cup Home Rapid Test (Urine)

- 80305QW May 19, 2023, Carethetic Group Corporation Carethetic Marijuana test kit (THC urine test)
- 80305QW May 19, 2023, Carethetic Group Corporation Carethetic Multi Drug Test Cup
- 80305QW May 19, 2023, Carethetic Group Corporation Carethetic Multi Drug Test Panel
- 80305QW August 28, 2023, Citest Diagnostics Inc. Citest Multiplex DOA Home Test Cup (Urine)
- 80305QW August 28, 2023, Citest Diagnostics Inc. Citest Multiplex DOA Home Test Panel (Urine)
- 80305QW August 24, 2023, Clarity Diagnostics LLC. Clarity Multi-Drug Urine Test Cup (Urine)
- 87635QW June 20, 2023, Cue Health Inc. Cue Health Monitoring System (For use with Anterior Nasal Swabs)
- 80305QW October 2, 2023, Dochek USA Inc. Amazewell Multi-Drug Urine Test Cup
- 80305QW August 2, 2023, Easy Healthcare Corporation Easy@Home Single Drug Screen Test (Cocaine Urine Test)
- 80305QW August 28, 2023, Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit For Cannabis
- G056QW June 27, 2024, Infectious agent detection by nucleic acid; hepatitis C, screening, amplified probe technique
- 81515QW January 1, 2025, Cepheid GeneXpert Xpress
- 87563QW January 16, 2025, Infectious agent detection by nucleic acid, Mycoplasma genitalium, amplified probe technique
- 87491QW January 16, 2025, Infectious agent detection by nucleic acid, Chlamydia trachomatis, amplified probe technique
- 0563UQW July 1,2025, Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets and 4

bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative

- 87494QW January 1, 2026, Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis and gonorrhea, multiplex amplified probe technique
- 87812QW January 1, 2026 Infectious agent antigen, detection by immunoassay with direct optical observation; severe acute respiratory syndrome coronavirus 2 and influenza types A and B.

PAMA remains an ongoing concern. The precedent set by funding reductions in other areas of healthcare suggests that similar cost-cutting mechanisms could be reintroduced to laboratory reimbursements, potentially reviving PAMA-related cuts. Industry groups in diagnostics and laboratory medicine have cautioned that 2025 and 2026 may not benefit from the same legislative relief or deferrals that Congress has granted in prior years.

Market Analysis of IVD Market Segments

The global market for in vitro diagnostics is estimated at $116 billion in 2025 and is expected to grow 5% annually to $150 billion by 2030. This includes all commercial laboratory- and hospital-based products, some research-use products used in clinical laboratories, and OTC product sales (not test services).

The reader is reminded that this is an estimate; the number of tests performed is expected to increase as more of the population has access to healthcare and aging populations in developed countries require medical care. However, with pricing pressures in the major markets, the dollar value of market segments does not automatically increase in direct proportion to the increase in the number of tests performed. The next chapter assesses the world market situation, and the following chapter presents major market trends. A comprehensive analysis of each IVD product segment is found in the appropriate chapter.

Table 2-1: Global In Vitro Diagnostic (IVD) Sales, by Product Segment, 2025-2030 ($ million) (%)

[Blood Bank Molecular; Blood Bank Screening; Drugs of Abuse; Blood Grouping/Typing; Circulating Tumor Cells; Clinical Chemistry; Coagulation; Histology/Cytology; Continuous Glucose; COVID-19 Dx; Diabetes HbA1c Immunoassays, Lab-Based; Hematology; HPV, Molecular; Immunoassays - Infectious Disease; Immunoassays - Other; Mass Spectrometry; Microbiology (ID/AST); Molecular Microbiology; POC, OTC Diabetes; POC, OTC Other; POC, Professional; Other]

Product Segment	2025	Market (%)	2030	Market (%)	CAGR 2025-2030
POC Professional	13,537	11.7%	16,751	11.1%	4%
Immunoassays - Infectious Disease	13,165	11.4%	15,494	10.3%	3%
Immunoassays - Other	12,610	10.9%	15,267	10.1%	4%
Continuous Glucose	12,458	10.8%	20,600	13.7%	11%
Clinical Chemistry	10,978	9.5%	13,308	8.8%	4%
Molecular Microbiology	8,672	7.5%	10,631	7.1%	4%
POC, OTC Diabetes	6,693	5.8%	7,020	4.7%	1%
Microbiology (ID/AST)	5,586	4.8%	6,314	4.2%	2%
Hematology	5,495	4.8%	7,455	5.0%	6%
Histology/Cytology	5,017	4.3%	6,597	4.4%	6%
Molecular Oncology	4,705	4.1%	9,500	6.3%	15%
POC, OTC Other	3,642	3.2%	4,489	3.0%	4%
Coagulation	1,794	1.6%	2,098	1.4%	3%
D-dimer	1,475	1.3%	1,710	1.1%	3%
HbA1c Immunoassays, Lab-Based	1,342	1.2%	1,700	1.1%	5%
Molecular Genetic/Inherited	1,332	1.2%	1,950	1.3%	8%
Blood Bank Molecular	1,330	1.2%	1,790	1.2%	6%
HPV, Molecular	1,270	1.1%	2,145	1.4%	11%
Blood Grouping/Typing	1,045	0.9%	1,150	0.8%	2%
Mass Spectrometry	1,032	0.9%	1,580	1.1%	9%

Product Segment	2025	Market (%)	2030	Market (%)	CAGR 2025-2030
Blood Bank Screening	834	0.7%	885	0.6%	1%
Drugs of Abuse	333	0.3%	353	0.2%	1%
Circulating Tumor Cells	152	0.1%	185	0.1%	4%
Other	1,062	0.9%	1,474	1.0%	7%
Total	**115,559**	**100.0%**	**150,446**	**100.0%**	**5%**
COVID-19	4,727	--	5,090	--	1%

Note: Values rounded, may not add to 100%

Source: Kalorama Information

Table 2-2: Additional Global In Vitro Diagnostic (IVD) Markets of Interest (Not in Totals), Sales by Product Segment, 2025-2030 ($ million) (%)

[Clinical Sequencing; Drugs of Abuse, Criminal; Drugs of Abuse, Employment (non IVD); DTC Genetic Testing; Flow Cytometry; Prenatal Test Services]

Markets of Interest (Not in Totals)	2025	2030	CAGR 2025-2030
Clinical Sequencing	7,505	11,550	9%
Flow Cytometry	1,765	2,230	5%
DTC Genetic Testing	1,195	1,970	11%
Prenatal Test Services	1,040	1,500	8%
Drugs of Abuse, Employment (non IVD)	818	876	1%
Drugs of Abuse, Criminal	374	395	1%
Total	**12,697**	**18,521**	**8%**

Note: *Clinical sequencing total includes related services

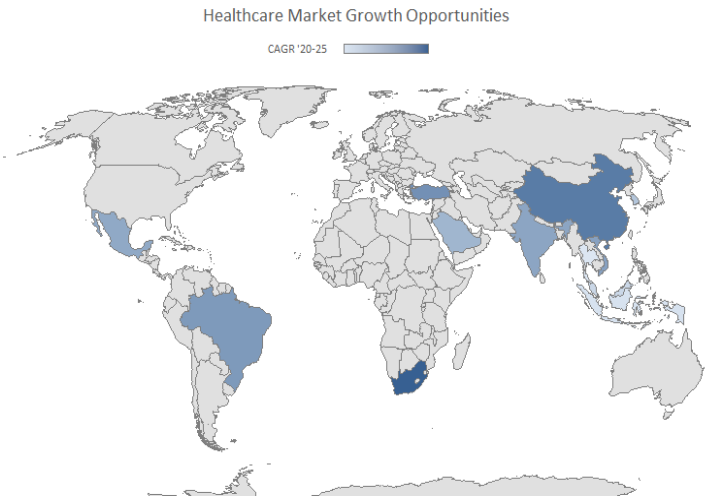
Source: Kalorama Information

Top Suppliers and Niche Players

Introduction

In 2025, the top IVD companies are estimated to account for $92 billion in IVD product sales, compared with $88 billion in 2024 and $85 billion in 2023. These product sales represent approximately a 4.9% increase in top-tier revenues for 2024-2025. This research shows that revenues generated by the major IVD companies account for almost 80% of the global IVD market in 2025. The remaining 20% is held by hundreds of companies worldwide, some of which specialize in specific test segments and others that serve local markets.

There is no doubt that the top and second-tier companies will continue to dominate the IVD industry due to their global reach and multi-segment participation and/or concentrated excellence in a particular test segment. This market power is evident in the latest revenue expansion.



Most of the companies profiled in this report attribute much of their revenue growth to the commercialization of advanced-technology products for cancer and infectious disease testing. More importantly, their continued penetration of routine and specialized test markets in the top 12 emerging countries (Brazil, China, India, Indonesia, Korea (South), Malaysia, Mexico, Saudi Arabia, South Africa, Thailand, Turkey, and Vietnam) is a significant driver of revenue growth.

As IVD markets in North America and Europe offer limited growth opportunities for the vast number of tests, even top-tier companies have begun to count on emerging markets for growth. Several factors influence growth opportunities within these markets, including a growing clinical market, nascent consumer demand, and increased government investment. Specific factors by emerging country include:

- Brazil - rising private healthcare, BRICS debate centrality
- China - aging population, rising healthcare services demand (cautiously optimistic, government spending controls)
- India - growing pharma exports, government support of medical tourism, chronic disease uptick, testing demand increases fueled by consumer and professional demand
- Indonesia - universal coverage, insurance expansion
- Malaysia - specialized treatments and medical tourism growth, growing fertility markets
- Mexico - launch of specialized drug treatments, growing middle class, urbanization
- Saudi Arabia - government infrastructure and strategy - Vision 2030 reform program allocates funding for healthcare infrastructure and private sector partnerships; rising chronic diseases, strong e-health, AI-enabled devices, molecular technology growth and telemedicine market demand
- South Africa - health investment, burgeoning medical tourism presence
- South Korea - advanced elective procedures, medical tourism, advanced technology adoption
- Thailand - long-established, high-volume medical tourism market; increasing demand for advanced technologies
- Turkey - cosmetic and specialized medical tourism growth, growing middle class
- Vietnam - rapid healthcare expansion, fueled by increases in both public and private sector healthcare spending, growing middle class, POCT markets expanding

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Overview of the Top Tier Companies

The following company abstracts are presented in relation to their ranking among the top companies in the IVD market: largest to smallest; see the table below. In some cases, specific IVD revenues are not reported by vendors and estimates are provided.

Table 2-3: Clinical Diagnostic Revenues of Selected Top 20 IVD Companies, 2024 and 2025 ($ million)

Company*	2024	2025	% Change 2024-2025
Abbott Diagnostics	16,146	16,935	4.9%
Roche Diagnostics (all)	15,866	16,607	4.7%
Danaher (all)	9,787	9,940	1.6%
Thermo Fisher Scientific	4,512	4,742	5.1%
Dexcom	4,033	4,662	15.6%
Siemens Healthineers	4,577	4,659	1.8%
bioMérieux	3,497	3,756	7.4%
Illumina	3,671	3,709	1.0%
Exact Sciences	2,760	3,247	17.6%
Sysmex Corporation	2,947	3,216	9.1%
Becton Dickinson	3,416	3,117	-8.8%
QuidelOrtho	2,783	2,708	-2.7%
Werfen	2,300	2,407	4.7%
Natera	1,694	2,307	36.2%
Mindray	2,208	1,908	-13.6%
Hologic	1,805	1,821	0.9%
Agilent	1,688	1,771	4.9%
Bio-Rad Laboratories	1,538	1,562	1.6%
QIAGEN	1,021	1,435	40.5%
Revvity	1,428	1,424	-0.3%
Top Tier Total	**87,677**	**91,933**	**4.9%**

*Note: Public companies

Source: Kalorama Information

Abbott Diagnostics

Abbott Diagnostics is the leader in the IVD market in 2025. There are several reasons why Abbott has remained a strong IVD leader in the market due to:

- Strong presence in the POC market, demonstrating 30% market share, with a target on cardiometabolic disease, infectious disease, and toxicology. Abbott's portable strip tests, along with its benchtop systems and analyzers, can provide immediate, actionable test information.
- Focus on the development of advanced diabetes care products with 38% market share
- Core focus on infectious disease testing, with a significant portion of sales generated in the European Union, emerging markets, and the U.S. The company is preparing for the future by developing next-generation systems, informatics to help labs manage and retrieve test data, new infectious disease diagnostics, and gene-based oncology tests for targeted therapeutics. Although demand for COVID-19 testing has waned, Abbott still maintains a strong market presence.

Abbott is a leader in immunoassays (number 2 worldwide) and is translating this expertise into molecular assays. Abbott is making a huge effort to improve its molecular test menu. Abbott Molecular analyzes DNA, RNA, and proteins at the molecular level. In general, Abbott Molecular focuses on tests for the evaluation and management of cancer, prenatal disorders, infectious diseases, and other genetic diseases.

Roche Diagnostics

Roche is a world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in personalized health care and diabetes management. Roche's personalized healthcare strategy aims to provide medicines and diagnostic tools for patients' disease management.

Technological advancements in molecular (PCR) IP, chemistries, immunoassays, HPV testing and its diabetes franchise (even though it is not as strong as it once was) are pushing the company forward. The company has reinforced its molecular and sequencing offerings, and branched out into prenatal analysis, genomics, hematology, microbiology and cfDNA for cancer testing. This strategy has secured Roche's leading presence in lab-based molecular markets.

Danaher Corporation

Danaher Corporation is a diversified company whose business segments include Professional Instrumentation, Medical Technologies, Industrial Technologies and Tools & Components. The Medical Technologies segment encompasses three key businesses: Dental Equipment and Consumables, Life Sciences, and Diagnostics. The diagnostic companies of Danaher Corporation include Beckman Coulter, Cepheid, Leica Biosystems, Radiometer, and SCIEX Diagnostics. Danaher is the third largest IVD manufacturer with the combined diagnostic group of companies.

Cepheid

Cepheid is a molecular diagnostics company that is dedicated to easy-to-use molecular systems and tests. The company made its mark with rapid molecular tests for tuberculosis, hospital-acquired infections, and respiratory diseases. Cepheid has roughly 11% market share of molecular diagnostics.

Radiometer

Radiometer is the world's leading provider of blood gas analyzers. Radiometer's products and solutions are used in hospitals, clinics and laboratories in over 130 countries, to provide information on the most critical parameters in acute care testing. Radiometer also provides accessories, IT systems and support services for blood gas testing, POC systems and immunoassays.

Beckman Coulter

Beckman Coulter is a subsidiary of Danaher Corporation (DHR), develops, manufactures and markets IVD tests for more than 80 years. Beckman Coulter is a leading provider in the clinical chemistry; they compete strongly with Roche. Strength in the market includes routine chemistry and UA segments.

Thermo Fisher Scientific

Thermo Fisher Scientific is a major manufacturer and distributor of clinical diagnostics reagents, instruments and supplies. The Thermo Fisher conglomerate serves healthcare, drug discovery, academia, government and industrial laboratories. Thermo Fisher offers a range of scientific instruments from basic equipment to advanced mass spectrometers. It also sells chemicals, agents, and antibodies for biotech research. Thermo Fisher has a strong presence in immunoassays and core laboratory segments. The company also participates in microbiology markets.

Dexcom

Dexcom is a medical device company that specializes in the design, development, and commercialization of continuous glucose monitoring (CGM) systems for people with diabetes and healthcare providers. The company conducts manufacturing activities at its San Diego, CA headquarters facility. Dexcom is the second-largest provider of POC glucose testing devices, with a 22% market share in 2025.

Siemens Healthineers

Siemens Healthineers is a major player in medical imaging, laboratory diagnostics, and medical information technology. The diagnostics division includes products for clinical chemistry, drug testing, hematology, coagulation, immunoassay, infectious diseases, microbiology, molecular diagnostics, plasma proteins, point-of-care testing, blood gases/electrolytes, and urinalysis. In addition, Siemens operates a clinical laboratory and offers laboratory informatics and automation. Siemens Healthineers holds the third-largest market share in lab-based immunoassays.

bioMérieux

bioMérieux provides diagnostic solutions (reagents, instruments, software), which are used for diagnosing infectious diseases, blood bank screening, blood culture, cancer screening and monitoring and cardiovascular emergencies.

bioMérieux is leveraging its dominant position in microbiology to build a molecular testing business focused on oncology and infectious diseases. The company is the second largest provider in the molecular segment, following closely behind Danaher.

Illumina

Illumina is a leading developer, marketer, and manufacturer of integrated systems for large-scale analysis of genetic variation and function. The heart of its business, Illumina's sequencers, offer a broad range of genomic applications, including whole-genome sequencing, targeted resequencing, de novo sequencing, amplicon sequencing, SNP discovery, identification of copy number variations, and chromosomal rearrangement. The company's sequencing products have been developed to meet the growing demand for next-generation sequencing. Illumina generates $4.3 billion in total revenues.

Exact Sciences

Exact Sciences was founded in 1995 through a collaboration with the Mayo Clinic. The company expects continued growth from Cologuard and its Oncotype products. The company was acquired by Abbott.

Sysmex Corporation

Sysmex Corporation is an integrated manufacturer of laboratory software and diagnostic systems involved in the development, production, marketing, and servicing of clinical laboratory testing devices and reagents. Since its establishment in 1968, Sysmex has concentrated on hematology and urinalysis. More recently, Sysmex has expanded into hemostasis, immunochemistry, and clinical chemistry, and has expanded its global operations in hematology, coagulation, immunochemistry, and urinalysis. Sysmex is expanding its presence in molecular analysis and liquid biopsy testing, primarily for cancer.

Sysmex is the undisputed leader in the hematology market, with a 33% worldwide market share. The company made its mark by introducing the first 5-part differential and then marketing several innovations. Sysmex has gained market share in the U.S. by establishing its own sales force and negotiating contracts with reference labs and hospital systems.

Becton Dickinson & Co

Becton Dickinson is a leading global medical technology company that develops, manufactures and sells medical devices, instrument systems and reagents. The company serves healthcare institutions, life science researchers, clinical laboratories, the pharmaceutical industry and the general public.

BD's legacy IVD involvement is in infectious disease testing and flow cytometry, where the company is an industry leader. BD is a leader in cervical cancer screening.

QuidelOrtho Corporation

QuidelOrtho Corporation markets POC and lab-based products, including immunoassays, under the QuickVue, D3 Direct Detection, and Thyretain brand names, as well as under the new Sofia brand. The portfolio includes tests for influenza, respiratory syncytial virus, fecal occult blood, Strep A, pregnancy, thyroid disease, bacterial vaginosis, infectious mononucleosis, HSV, H. pylori, and chlamydia.

Werfen

Werfen maintains its position in the IVD industry by concentrating on reinforcing its main areas of expertise in coagulation and autoimmune testing and has added to its acute care diagnostics.

Werfen specializes in the areas of clinical chemistry (8% global market share), clinical software, hemostasis (20% market share) and acute care diagnostics through its acquisition of Instrumentation Laboratory. In the area of autoimmunity, it specializes through its company, Inova Diagnostics. Werfen also provides OEM manufacturing for third parties (reagents and biomaterials) and infectious disease serology through its company, Biokit. Additionally, the company strengthened its presence in the transfusion and transplant markets with the acquisition of Immucor in March 2023.

Natera

Natera is a genetic testing and diagnostics company specializing in genetic diseases. Natera established a solid presence in the non-invasive prenatal testing market by developing and

offering a suite of tests, including the Panorama Prenatal test, Horizon Carrier Screen, Anora Miscarriage test, and Spectrum Pre-implantation Genetic Screening and Diagnosis tests. The company is among the fastest growing IVD companies worldwide.

Mindray

Mindray is the leading developer, manufacturer and marketer of medical devices in China, with a presence globally. Mindray's products are available in over 190 countries and regions. Mindray reported it has developed a more advanced biochemistry analyzer, an upgraded hematology analyzer, other biochemistry analyzers and several reagents, as well as a number of upgraded urine sediment analyzers.

Hologic

Hologic, Inc. is active in several markets: diagnostic products, medical imaging systems, and surgical products. The company operates four core business units focused on diagnostics, breast health, gynecological surgical and skeletal health. Hologic is a microbiology molecular manufacturer, generating nearly $1.3 billion in 2025; it is also the leading provider in the traditional PAP market.

Agilent

Agilent Technologies Inc is a technology leader in chemical analysis, life sciences, electronics and communications. Agilent operates in three business segments – life science and applied market, diagnostics, and genomics. The company is among the market leaders in the histology/cytology market, generating revenues of over $1 billion annually.

Bio-Rad Laboratories

Bio-Rad Laboratories, Inc. markets a broad range of products for the life science research and clinical diagnostic markets. The company offers more than 3,000 products covering more than 300 clinical diagnostic tests to clinical diagnostic customers, including hospital laboratories, reference laboratories, transfusion laboratories, and physician office laboratories. Bio-Rad has more than $1.5 billion in IVD sales and continues to stand out as one of the market's most reliable growth leaders.

QIAGEN N.V.

QIAGEN N.V. is a holding company with subsidiaries in Germany, the United States, China, Japan, the United Kingdom, Switzerland, France, Italy, Australia, Norway, Austria, Canada, Sweden, and the Netherlands. QIAGEN is a leading global provider of molecular sample and assay technologies.

Revvity

Revvity is focused on human and environmental health and has been a leader in prenatal and newborn screening for more than 30 years. Revvity also provides immunoassays, genetic screening, drug discovery, life science research, and analytical solutions.

Revvity's diagnostic offerings include prenatal, neonatal and infectious disease screening, along with molecular diagnostics solutions, through its wide range of instruments, reagents and assay platforms, and software. Revvity also provides DNA/RNA sequencing services to accelerate target identification, biomarker discovery, and diagnostic applications. The lab provides end-to-end sequencing and bioinformatics services. The company's $1.4 billion in estimated IVD sales is driven by strong contributions across immunoassay and molecular microbiology testing, positioning it as a reliable player in key diagnostic markets.

Overview of Selected Second-Tier Companies

Niche players in histology, molecular assays, and rapid tests for infectious diseases play their part as drivers of IVD industry growth. The table below presents the revenue growth of a selection of niche players from 2024 to 2025.

These second-tier companies have developed innovations in their respective diagnostic areas that have significantly enhanced the strength and efficiency of clinical diagnostic products.

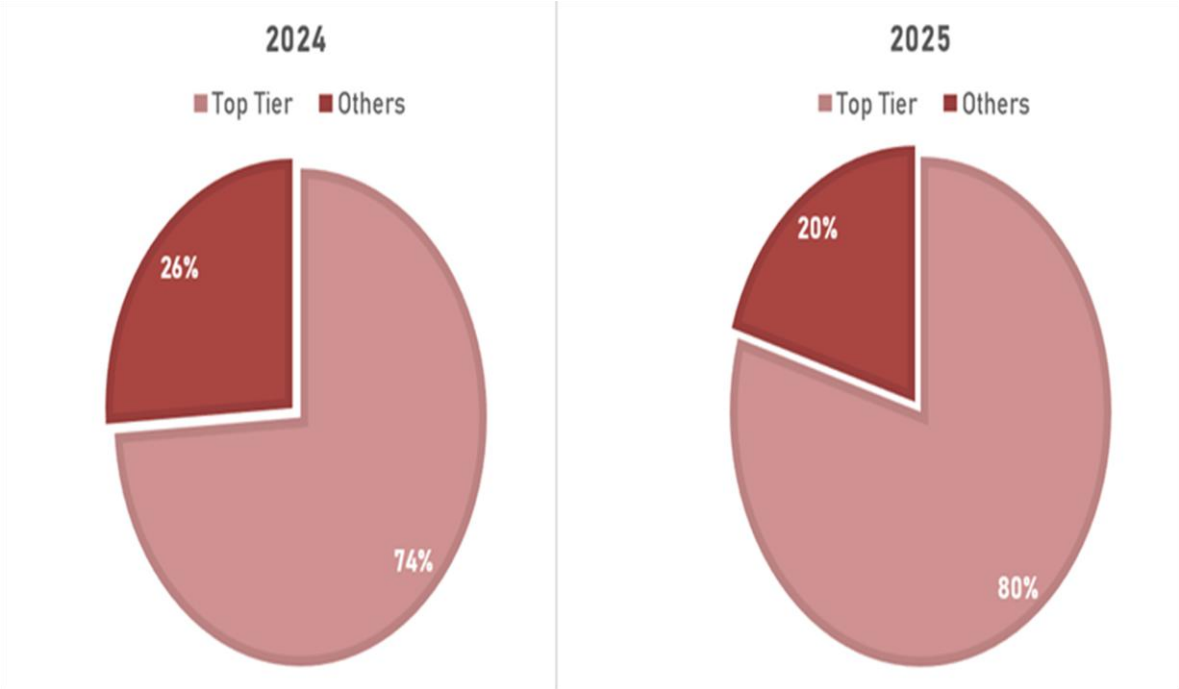
Table 2-4: Revenues of Selected Top 20 Niche IVD Players, 2024 and estimated 2025 ($ million)

Company*	2024	2025	% Change 2024-2025
Diasorin	1,282	1,352	5.5%
Bruker - CALID	1,094	1,211	10.7%
Guardant Health	738	981	32.9%
Myriad Genetics	838	825	-1.6%
Grifols	718	708	-1.4%
Diagnostica Stago	617	695	12.6%
BGI Genomics	618	606	-1.9%
Sekisui Diagnostics	498	552	10.8%
Arkray	400	422	5.5%
GeneDx	295	416	41.0%
Fujirebio	397	397	0.0%
Fulgent Genetics	284	323	13.7%
Seegene	304	333	9.5%
Horiba	223	282	26.5%
Randox	320	280	-12.5%
Eiken Chemical Co.	243	272	11.9%
Nihon Kohden	220	269	22.3%
Meridian	248	257	3.6%
Menarini Diagnostics	187	192	2.7%
Haemonetics	131	168	28.2%
Second Tier Total	**9,655**	**10,541**	**9.2%**

*Note: Public companies

Source: Kalorama Information

Figure 2-1: Top Tier Market Distribution, 2024 and estimated 2025 (%)



Source: Kalorama InformationThe following is a summary of the top 20 selected second-tier companies.

Diasorin Group

The Diasorin Group develops, produces, and markets immunoassay kits and instrumentation worldwide. Diasorin offers a broad range of specialty tests in the immunodiagnostics market and new tests in the molecular diagnostics market. Diasorin's acquisition of Luminex strengthened its presence in molecular microbiology. Diasorin maintains a strong presence in immunoassays, the core of its global reach.

Bruker/CALID Group

Bruker's microbiology and diagnostics products are part of the company's CALID group, which includes Bruker Daltonics, Bruker Detection, and Bruker Optics Divisions. These divisions cover mass spectrometry, chromatography, and life-science automated sampling and sample-preparation robots, reagent kits, and other disposable products used to conduct tests or assays, as well as bioinformatics software.

Guardant Health

Guardant Health develops and commercializes liquid biopsy diagnostic tests that utilize the company's proprietary "Digital Sequencing" technology. The company provides innovative products that offer unique IVD testing.

Myriad Genetics

Myriad Genetics is a publicly traded personalized medicine company that focuses on the discovery, development and commercialization of molecular diagnostic tests for various diseases, including cancer, rheumatoid arthritis, and neuropsychiatric disorders.

The company focuses on six medical specialties - oncology, urology, preventive care, dermatology, neuroscience and autoimmune diseases – for which it has developed several molecular diagnostics tests that aid patients and medical professionals in diagnosing and treating various diseases. Myriad's tests are based on its proprietary technologies, which include DNA sequencing, RNA expression analysis, and protein analysis.

Grifols S.A.

Grifols S.A. offers in vitro diagnostic products for laboratory analyses, including blood transfusion testing, blood typing, coagulation, and automatic immunoassay analyzers, as well as reagents for hospital blood banks and transfusion centers.

Diagnostica Stago

Diagnostica Stago has dedicated all its resources to developing the field of coagulation. With more than 350 coagulation products, Stago offers a wide product portfolio through its highly effective commercial network. The companies belonging to the Stago Group are Stago, Tcoag, Agro-Bio, BioCytex, Thrombinoscope, Synapse and DSRV.

Stago's product line extends from routine PT/INR tests to the investigation of highly specialized coagulation parameters. Stago also offers a complete range of analyzers and systems designed to meet the requirements of all laboratories that can be integrated into a Laboratory Automation System.

BGI Genomics

BGI, known as the BGI Group and BGI Genomics in the U.S., is a genome sequencing company headquartered in Shenzhen, Guangdong, China. BGI's stated mission is to support the development of science and technology, build strong research teams, and promote the development of scientific partnerships in the genomics field.

Sekisui Diagnostics

Sekisui Diagnostics product lines include clinical chemistry and coagulation systems and reagents as well as infectious disease rapid tests, LINE immunoassays and ELISA kits. Sekisui Diagnostics is reportedly the leading coagulation vendor in Japan.

ARKAY

ARKRAY markets fully automated urine analyzers and sediment analysis systems, as well as dry-chemistry analyzers designed for small- to mid-sized laboratories and decentralized testing environments. The company has also strengthened its portfolio in HbA1c testing with both laboratory-based and point-of-care systems, supporting diabetes management across care settings.

GeneDx

GeneDx is a genomic diagnostics company focused on translating complex genetic data into clinically actionable insights, with a strong emphasis on rare and pediatric diseases. The company offers a broad portfolio spanning whole genome sequencing, whole exome sequencing, and targeted gene panels, supported by curated variant databases and advanced interpretation capabilities.

Fujirebio

Fujirebio has more than 50 years of accumulated experience in the IVD industry. The company operates offices in the United States, Europe, Latin America and Asia and markets through an international distribution network. Fujirebio has a strong presence in lab-based immunoassay markets.

Fulgent Genetics

Fulgent Genetics developed a proprietary technology platform that enables the company to offer a flexible, expandable test menu. The company combines NGS with its technology platform to perform full-genome sequencing.

Seegene

Seegene has developed a suite of proprietary PCR chemistries designed to enhance multiplexing capability, sensitivity, and specificity. These technologies enable simultaneous detection and quantification of multiple pathogens within a single reaction, supporting efficient and comprehensive molecular diagnostics

Horiba

The Horiba Group's Medical Diagnostic Instruments & Systems segment primarily focuses on hematology analyzers. The company's product line includes hematology analyzers, equipment for measuring immunological responses, clinical chemistry analyzers, and blood sugar measurement systems, but 80% of sales are generated from hematology reagents and instruments.

Randox

Randox is a privately owned diagnostic reagent and equipment manufacturer. Established in 1982, Randox has sales and distribution agreements in 130 countries and international offices with representation in the continents of Africa, Asia, Australia, Europe, North America and South America. The company's core products and services are Biochip Array Technology, clinical chemistry automation systems, external quality assurance schemes, Internet-driven QA systems, quality control materials, antibodies, recombinant proteins, clinical reagents, and environmental diagnostics.

Eiken Chemical Co

Eiken Chemical Co., LTD was established in 1939 and was the first Japanese company to successfully commercialize the manufacture of powdered culture media for microbiological

investigations. Eiken's businesses include clinical diagnostics, food and environment and animal testing. Although the Eiken company and its products are not widely known internationally, the company is a major player in Japan and across Asia/Pacific.

Nihon Kohden

Nihon Kohden is a multi-faceted company that is one of Japan's leading suppliers of medical technology Nihon Kohden's expertise is in hematology.

Meridian

Meridian Bioscience is a fully integrated life science company that manufactures, markets and distributes a broad range of diagnostic test kits, purified reagents and related products and offers biopharmaceutical enabling technologies. Meridian has strong market positions in the areas of gastrointestinal and upper respiratory infections, serology, parasitology and fungal disease diagnosis.

In addition, Meridian is a supplier of rare reagents, specialty biologicals and related technologies used by biopharmaceutical companies engaged in research for new drugs and vaccines. The company markets its products and technologies to hospitals, reference laboratories, research centers, veterinary testing centers, diagnostics manufacturers and biotech companies in more than 60 countries around the world.

Menarini Diagnostics

Menarini Diagnostics S.r.l focuses on cell pathology, diabetes, autoimmunity, hemoglobin analysis and other lab-based tests. Menarini Diagnostics has a worldwide network of subsidiaries in Austria, Belgium, France, Germany, Greece, Italy, the Netherlands, Portugal, Spain, and the United Kingdom. The product line includes: glucose self-testing and laboratory systems, clinical chemistry (dry, wet, and urinalysis), hematology (blood typing, ESR, cell counting), cell pathology, and autoimmune immunoassays.

Haemonetics

Haemonetics is a provider of blood and plasma supplies and services. It solutions include meeting the needs of critical care patients; full scope of plasma collection technologies and products to collect blood components.

IVD Companies Mergers & Acquisitions

Merger and acquisition activity in the IVD industry accelerated in 2025 and continues into the first half of 2026, reflecting a sustained effort to build broader technology portfolios, expand market access, and strengthen competitive positioning. The industry increasingly depends on integrating multiple technologies, including molecular diagnostics, immunoassays, sequencing, and digital tools, making partnerships and acquisitions essential. No single company possesses all of the capabilities required to support next-generation diagnostics, and companies continue to pursue acquisitions to access new technologies, enter adjacent markets, expand product portfolios, and improve operational scale and supply chain resilience.

Recent activity also reflects several structural shifts in the industry. There is a continued movement toward decentralized and point-of-care testing, increased investment in flow cytometry and cell-based analysis, and strong participation from private equity. Companies are actively streamlining portfolios to focus on higher-growth segments, while consolidation in areas such as digital PCR has reduced the number of independent platform providers. These trends are expected to persist over the next several years as diagnostics become more integrated, data-driven, and clinically focused.

Notable transactions include Werfen's acquisition of Immucor in 2023, strengthening its position in transfusion and transplant diagnostics, and Biosynex's acquisition of Chembio Diagnostics, expanding its presence in rapid and point-of-care testing. Randox acquired Cellix to enhance its capabilities in microfluidics and flow cytometry, while Bruker's acquisition of PhenomeX and later ELITech expanded its presence in cellular analysis and microbiology. Exact Sciences acquired Resolution Bioscience from Agilent to strengthen its oncology testing portfolio, and Roche acquired LumiraDx to expand its point-of-care diagnostics capabilities.

Activity continued through 2024 with acquisitions aimed at expanding molecular, genomic, and AI-driven diagnostics. Natera acquired select reproductive health assets from Invitae, while Illumina acquired Fluent BioSciences to advance single-cell analysis. Labcorp expanded its oncology and genetic testing capabilities through acquisitions of Invitae assets and other laboratory services businesses. OraSure acquired Sherlock Biosciences to strengthen its molecular testing portfolio, and Roche acquired Poseida Therapeutics to expand its presence in cell and gene therapy, reflecting increasing convergence between diagnostics and advanced therapeutics.

In 2025 and into 2026, consolidation continued with Bio-Rad's acquisition of Stilla Technologies, reinforcing its position in digital PCR, and QIAGEN's acquisition of Genoox, enhancing bioinformatics and sequencing data interpretation capabilities. One of the most significant recent developments is the completion in 2026 of the combination of BD's Biosciences and Diagnostic Solutions business with Waters Corporation, creating a large-scale life sciences and diagnostics entity with expanded capabilities across flow cytometry, analytical technologies, and clinical diagnostics.

Another major transaction reshaping the competitive landscape is Abbott's acquisition of Exact Sciences, completed in 2026. This deal significantly expands Abbott's presence in cancer screening and precision oncology, adding established products such as Cologuard and Oncotype DX, as well as a growing pipeline of liquid biopsy and early cancer detection technologies. The acquisition positions Abbott as a major competitor in oncology diagnostics and reflects the broader industry shift toward early detection, personalized treatment, and longitudinal disease monitoring.

Mergers and acquisitions remain a crucial growth strategy in the diagnostics industry, supporting the transition toward more automated, connected, and clinically integrated testing environments.

The table below details selected mergers and acquisitions from 2023 to 2026 (first half).

Table 2-5: Selected IVD Mergers and Acquisitions, 2023-2026 (first half)

Date	Acquiring Company	Company Acquired	Comments
Apr-26	Profusa	PanOmics	Adds to the core for precision medicine
Apr-26	Blackstone and TPG	Hologic	
Mar-26	Adidtxt	Ignite Proteomics	Expands targeted therapies in cancer
Mar-26	Axonia Medical	51% of Dipylon Medical	Expands Axonia position in molecular diagnostics and clinical microbiology market
Mar-26	CoaguSense	DOASENSE	Expands CoaguSense's portfolio to include rapid, POC testing
Mar-26	Agilent Technologies	Biocare Medical	IHC antibodies and reagents into Agilent existing pathology division
Mar-26	Abbott	Exact Sciences	Expand Abbott's oncology business
Mar-26	Thermo Fisher	Clario Holdings	Adds to clinical research offerings
Feb-26	Waters	BD Biosciences and Diagnostic Solution	Global expansion and expertise in chemistry, physics, and biology
Feb-26	Devyser	Cybergene AB	Strengthens customer offerings
Feb-26	Novacyte	Southern Cross Diagnostics	Allows access to the Australian diagnostic market
Jan-26	YD Bio	EG BioMed	Integration of advanced analytics and clinical execution
Jan-26	Genomate	Oncompass Medicine	Global expansion in Europe
Dec-25	Natera	Foresight Diagnostics	Reinforces Natera in precision oncology
Nov-25	QIAGEN	Parse Biosciences	Adds to growth in sample-to-answer and high-end molecular omics platform
Oct-25	Warburg Pincus	Sebia	Pinus will have a large minority stake
Oct-25	Tokuyama Corp	JSR IVD business	Expanded footprint of the new company
Oct-25	Blackstone Group	Hologic (diagnostics and women's health imaging)	Private equity interest and integration of imaging and assay businesses under one ownership

Date	Acquiring Company	Company Acquired	Comments
Sept-25	Labcorp	Certain assets from BioReference Health	Expands Labcorp's diagnostic and oncology portfolio
Aug-25	Sonic Healthcare USA	Cairo Diagnostics	Expands Sonic's footprint in oncology testing
Aug-25	Tempus AI	Paige	Advances Tempus AI's position in precision oncology
Aug-25	MDxHealth	Exosome Diagnostics	Enhances MDxHealth's precision diagnostics in urologic cancers
Jul-25	QuidelOrtho	LEX Diagnostics	Change in company direction – Savanna MDx system discontinuation
Jul-25	Waters	BD Biosciences DX business	Expand clinical footprint for Waters Pending
Jun-25	Fujirebio	Plasma Service Group	Strengthen IVD capabilities
Jun-25	bioMérieux	Day Zero Diagnostics	Facilitate growth in NGS infectious disease diagnostics
Jun-25	Bruker	Biocrates	Boost MS-based quantitative metabolomics
May-25	Mapmygenome	Microbiome Insights	Boosting global expansion
May-25	Castle Biosciences	Previse	GI expanded offerings
Apr-25	Eurofins	SYNLAB	Becomes the leading clinical diagnostic operator in Spain
Apr-25	QIAGEN	Genoox	Software analysis
Apr-25	GeneDx	Fabric Genomics	Additional screening opportunities
Apr-25	Source BioScience	Cambridge Clinical Labs	Increases the company's clinical diagnostics portfolio
Mar-25	Duomed Belgium NV	Launch Diagnostics (Avacta Therapeutics)	Expanding test unit
Mar-25	NeoGenomics	Pathline	Increase penetration rates in California, Florida, and Texas to support oncologists
Mar-25	Angsana Molecular & Diagnostics Laboratory	Pathonova Laboratories	Merged to form a new company – Archerfish
Feb-25	Bio-Rad	Stilla Technologies	Complement existing digital PCR portfolio

Date	Acquiring Company	Company Acquired	Comments
Jan-25	bioMérieux	SpinChip	POC expansion
Dec-24	Labcorp	Lenexa	Increase pathology assets
Dec-24	OraSure	Sherlock Biotechnologies	Expands diagnostic testing unit
Nov-24	Roche	Poseida	Increase footprint
Oct-24	Trinity Biotech	EpiCapture	Entrance to oncology space
Sept-24	Trinity Biotech	Metabolomics Diagnostics	Increase presence in maternal health
Sept-24	Labcorp	Balland Health Lab Services	Improvement of overall patient experience
Aug-24	Labcorp	Invitae assets	Add depth to Labcorp offerings in genetic testing for oncology
Jul-24	Roche	LumiraDx POC	Complement POC technology
Jul-24	Thermo Fisher	Olink	Proteonomic focus
Jul-24	Illumina	Fluent BioSciences	Single cell technology
Jul-24	Quest Diagnostics	LifeLabs (OMERS)	Enhance diagnostic services for Canadians
Jun-24	Quest Diagnostics	Allina Health	Lab assets
Jun-24	Quest Diagnostics	PathAI Diagnostics Lab	Accelerate adoption of AI and digital pathology
May-24	Bruker	NanoString	Adds to Bruker’s existing spatial biology portfolio
May-24	Bruker	ELITech	Complement to MALDI BioTyper platform
Apr-24	Maverix Medical	Cirrus Bio	Plans to develop lung cancer diagnostics
Jan-24	Hera Biotech	Scailyte	Tissue-based diagnostics for endometriosis
Jan-24	Myriad Genetics	Intermountain Precision Genomics	Acquired lab
Jan-24	Natera	Invitae	Reproductive assets
Dec-23	Biosynex	Theradiag	POC growth

Date	Acquiring Company	Company Acquired	Comments
Dec-23	PerkinElmer	Covaris	Increase life science offerings
Dec-23	Imaware	Binx Health	At-home consumer business
Dec-23	Bruker	Phasefocus	Optical cell analysis
Dec-23	Roche	LumiraDx	Acquire POC technology
Oct-23	Bruker	PhenomeX	Entry into single cell solutions
Sept-23	Abbott	Bigfoot Biomedical	Expands diabetes care for its FreeStyle Libre
Sep-23	LabGenomics USA	QSx Pathoogy	Strengthen diagnostic test offerings
Sep-23	Exact Sciences	Agilent's Resolution Bioscience	Advance Exact's precision oncology portfolio
Aug-23	Sunbird Bio	Glympse Bio	Development of protein-based diagnostic for neurological diseases and cancer
Jul-23	EDP Biotech	New Day Diagnostics	Companies to merge
Jul-23	Fortis Life Sciences	International Point of Care	Enables Fortis to provide customizable support for customers
Jun-23	Biosynex	ProciseDx!	Increases footprint in the United States
Jun-23	Avacta	Coris Bioconcept	Provides professional use rapid test produce portfolio
Jun-23	Bio-Techne	Spatial Biology	Access to Lunaphore technology
Jun-23	Quest Diagnostics	Haystack Oncology	Adds sensitive MRD liquid biopsy technology
Jun-23	Randox	Cellix Ltd	Broadens flow cytometry for Randox
May-23	MedGenome	Prognosis Laboratories	Expands market presence
May-23	Freenome	Oncimmune	Access to EarlyCDT Lung blood test
May-23	Nuclein	Minute Molecular Diagnostics	Merger
Apr-23	Pfizer	Lucira Health	At-home diagnostics
Apr-23	Quest	NY Presbyterian Lab	Enlarge footprint

Date	Acquiring Company	Company Acquired	Comments
Apr-23	Biosynex	Chembio Dx	Adds to complementary portfolio
Mar-23	Quest	Northern Light Lab	Access to advanced testing
Mar-23	Werfen	Immucor	Allows expansion of Werfen's specialized diagnostics
Feb-23	Sherlock BioSciences	Sense Bioscience	Provide attachments in forensic science
Feb-23	SD Biosensor	Meridian	Meridian will continue to operate independently under new ownership
Jan-23	QIAGEN	Verogen	Provide advancements in forensic science

Source: Kalorama Information

Collaboration, Partnership, Alliance Agreements

Almost daily, there is news of a new partnership or collaboration. Research indicated that there were several new collaborations, partnerships and alliances in 2024, 2025 and continuing into 2026. Examples of selected collaborations, partnerships and alliances from the companies include:

- In January 2024, Agilent signed an agreement with Incyte for the development of companion diagnostics for Incyte's hematology and oncology portfolio.
- In January 2024, Predicine entered into a collaboration with Janssen to develop a urine-based assay as a companion diagnostic to identify patients with bladder cancer that would benefit from targeted therapies.
- In February 2024, Becton Dickinson partnered with Camtech Health Partner to increase cervical cancer screening in Singapore.
- In February 2024, BioMark Diagnostics and Rubics LS signed a partnership to develop liquid biopsy cancer screening for underserved communities.
- In February 2024, Standard BioTools and Next Gen Diagnostics announced a partnership to provide complete automation of sample preparation for pathogen whole genome sequencing.
- In April 2024, Predicine partnered with Apollomics to develop a NSCLC liquid biopsy assay.
- In June 2024, Myriad Genetics entered into a collaboration with GSK for the development of an ovarian cancer testing program.
- In June 2024, Foundation Medicine partnered with Repare Therapeutics to develop CDx for lunresertib.
- In June 2024, DiaCarta entered into a collaboration with Capstone Health Alliance to provide precision diagnostics using liquid biopsy in cancer and infectious diseases.
- In July 2024, MGI Tech and Predica Diagnostics entered into a partnership to develop RNA-based cancer screening tests.
- In July 2024, Labcorp and Ultima Genomics are collaborating on a NGS cancer test.
- In July 2024, BD and Quest entered into a collaboration on development of flow cytometry-based companion diagnostics for cancer.

- In July 2024, MGI Tech and Predica Diagnostics entered into a partnership to develop RNA-based cancer screening tests.
- In July 2024, Labcorp and Ultima Genomics are collaborating on an NGS cancer test.
- In August 2024, Detect-Ion entered into a partnership with the Moffitt Cancer Center to develop a breath-based POC test for the early detection of lung cancer.
- In August 2024, Foundation Medicine entered into a collaboration with Merus N.V. to develop an RNA platform as a companion diagnostic for Merus's biospecific antibody zenocutuzumab (Zeno) to treat patients with neuregulin 1 fusion cancer.
- In September 2024, QIAGEN entered into a collaboration with Eli Lilly to develop an assay to detect genotypes that will indicate Alzheimer's disease risk.
- In September 2024, Roche entered into a collaboration with Stratipath to integrate the Stratipath Breast solution, an AI-based precision diagnostic solution, into Roche's Navify Digital Pathology.
- In September 2024, A. Menarini Diagnostics and Nucleix entered into a strategic partnership for the exclusive marketing of Bladder EpiCheck in Europe. This non-invasive CE-marked test detects primary or recurrent bladder and upper tract urinary cancers.
- In September 2024, Foundation Medicine entered into a partnership with Syndax Pharmaceuticals to develop a companion diagnostic based on the FoundationOne Heme platform for a leukemia drug that is under development by Syndax.
- In September 2024, QIAGEN and Bio-Manguinhos/Fiocruz agreed to collaborate on enhancing malaria and dengue detection in Brazil's national blood screening program. Bio-Manguinhos can now launch an advanced PCR-based molecular screening platform to detect malaria alongside HIV, hepatitis B, and C virus (HCV and HBV), a capability previously unavailable in Brazil's blood donation program.
- In October 2024, Trinity Biotech entered into a strategic investment with Novus Diagnostics to advance rapid sepsis testing. This investment will accelerate the development and commercialization of Novus' POC diagnostic solution.
- In November 2024, Agilent signed a co-marketing agreement with Tagomics. The two companies will give customers access to Tagomics and Agilent technologies. Tagomics has developed a multiomics platform called Interlace that unlocks disease-associated DNA biomarkers.

- In November 2024, Dexcom entered into a partnership with OURA to help individuals monitor activity and glucose data. The glucose data is collected by Oura Ring and will be combined with Dexcom's glucose data.
- In December 2024, GeneDx announced it had accepted new partners to its Patient Access Program for pediatric epilepsy, which provides access to whole exome sequencing.
- In December 2024, ESYA Labs partnered with Alamar Biosciences to collaborate on the detection and quantification of biomarkers for neurological and inflammatory diseases using Alamar's Nulisa platform and Argo HT System. ESYA Labs will be a certified service provider for Alamar.
- In January 2025, Scopio Labs extended its strategic alliance with Siemens Healthineers to include the global distribution of Scopio's Full-Field Bone Marrow Aspirate application. The Full-Field Bone Marrow Aspirate is the world's first digital bone marrow aspirate review solution.
- In January 2025, Revvity entered into a collaboration with Element Biosciences to advance DNA and multiomic sequencing solutions. The partnership involves a comprehensive IVD solution tailored for newborn sequencing. The new solution will be part of the next step in expanding Element's AVTI sequencing system and Revvity's newborn sequencing research workflow.
- In January 2025, the upstart AlterDiag, based in France, partnered with the Institut Pasteur to develop rapid diagnostics for infectious diseases. The companies plan to utilize single-domain antibodies in conjunction with immunochromatography to detect pathogens. Since its inception in July 2024, AlterDiag has raised over €2 million in seed funding for the project.
- In February 2025, Flatiron Health and Exact Sciences entered into a partnership to advance Exact Sciences' molecular residual disease test, Oncodetect.
- In February 2025, Siemens Healthineers signed an agreement with ABL that will allow ABL to manufacture and commercialize Siemens Healthineers' PCR testing product technologies. The agreement involves intellectual property from the defunct Fast Track Diagnostics, which Siemens acquired and closed in 2024.
- In February 2025, Foundation Medicine announced that it would launch hereditary germline tests in the United States in partnership with Fulgent Genetics. These tests,

offered through a partnership with Fulgent, are next-generation sequencing tests that analyze 50 genes associated with hereditary cancers.

- In February 2025, Foundation Medicine entered into a collaboration with Sumitomo Pharma America (SMPA) to develop a companion diagnostic to identify acute leukemia patients who may be eligible for treatment with SMPA's Menin inhibitor enzomenib (DSP-5336). The collaboration will utilize Foundation One's Heme platform to identify patients with JMT2A rearrangements or NPM1 mutations who may benefit from enzomenib.
- In February 2025, Renovaro Biosciences agreed to partner with BioSymetrics. The partnership is designed to enhance Renovaro's precision medicine solutions for cancer and other critical disease areas through BioSymetrics' proprietary Elion platform, an AI and machine-learning engine.
- In February 2025, DiaCarta and OncoAssure established a collaboration to launch OncoAssure's prostate test, designed to identify patients with a lower risk of prostate cancer recurrence.
- In February 2025, Imagene entered into a collaboration with Tempus AI to advance AI-driven diagnostics for NSCLC. The partnership is designed to advance cancer diagnostics by accelerating biomarker prediction and integrating AI-powered tools.
- In March 2025, Mainz Biomed entered into an agreement with Liquid Biosciences to access a portfolio of mRNA biomarkers for the detection of pancreatic cancer. Mainz Biomed will have the rights to develop a test using Liquid Biosciences' biomarkers. The companies plan to develop this blood-based test for potential future FDA applications. Liquid Biosciences developed the Emerge platform to identify a panel of clinically relevant mRNA biomarkers
- In March 2025, T-NeuroDx entered into a collaboration with Beckman Coulter to develop diagnostics for neurodegenerative diseases, including Alzheimer's disease. The companies will share knowledge on biomarker research for the detection of early Alzheimer's disease. The partnership combines T-Neuro-Dx's research in Alzheimer's disease with Beckman Coulter's expertise in flow cytometry.
- In April 2025, AccuStem Sciences announced that it was partnering with EmeritusDX to commercialize the MSC test for lung cancer screening. The collaboration will likely enhance the accuracy of lung nodule stratification. The MSC test analyzes 24 microRNAs to distinguish high-risk from low-risk cases, saving time and potentially

minimizing unnecessary procedures. The launch date for the MSC test is expected to be in 2026.

- In April 2025, Grifols entered into a partnership with IBL International to develop advanced biomarker panels for neurological and oncological conditions. Grifols' technology can detect disease signals in the early stages.
- In June 2025, QIAGEN entered into a collaboration with Incyte to develop companion diagnostics for patients with mutant CALR-expressing myeloproliferative neoplasms (MPN). QIAGEN will develop a multimodal panel using NGS technology and the Illumina NextSeq 550Dx platform.
- In June 2025, QIAGEN entered into a partnership with Gencurix for the development of oncology assays for use on the QIAcuityDx platform.
- In June 2025, QIAGEN entered into a partnership with two companies – Tracer Biotechnologies to develop blood-based MRD tests on the QIAcuity platform and Foresight Diagnostics to develop a kit version of its Clarity NGS assay for us in lymphoma.
- In July 2025, Viome and Scripps partnered to develop the first at-home RNA test designed to detect precancerous colon polyps.
- In July 2025, Personalis and Tempus AI expanded their collaboration, adding a new indication, colorectal cancer, to the existing agreement. Personalis and Tempus AI will collaborate to bring NeXT Personal, an ultra-sensitive, tumor-informed MRD test, to detect cancer recurrence across four areas: breast, lung, colorectal, and solid tumor immunotherapy monitoring.
- In August 2025, Exact Sciences and Humana expand their partnership for the Cologuard Plus Test. This partnership will provide Cologuard Plus for in-network Medicare Advantage members.
- Additionally, in August 2025, Exact Sciences entered into a collaboration with Freenome to develop certain blood-based screening and diagnostic products for colorectal cancer.
- In August 2025, Siemens Healthineers partnered with Carna Health to accelerate the adoption of Carna's AI-enabled chronic kidney disease platform. The agreement will improve early detection and CKD management for high-risk and underserved populations.

- In September 2025, AccuStem Sciences entered into a partnership with EmeritusDX to expand its blood-based testing capabilities. The two companies are building out their product portfolios to meet the demand for cancer diagnostics and treatment planning. This expansion will include installing AccuStem's Promega Maxwell RSC System at EmeritusDX, enabling consistent microRNA extraction from blood samples.
- In September 2025, Myriad Genetics entered into a collaboration with SOPHiA Genetics to develop a global liquid biopsy companion diagnostic test. The partnership will use Myriad's advanced laboratory capabilities to support global testing for clinical trials and SOPHIiA's decentralized network.
- In October 2025, Revvity announced that it had entered into a partnership with Sanofi to develop a T1D 4-plex IVD assay based on its 3-plex assay. Early detection of T1D enables options for patients and caregivers to improve outcomes through intervention to prevent diabetic ketoacidosis.
- In October 2025, Bluejay Diagnostics entered into an extended agreement with SanyoSeiko to expand its partnership in advancing the Symphony Platform, a near-patient testing system designed to provide rapid results for key biomarkers such as IL-6 in sepsis management.
- In October 2025, Bio-Rad extended its partnership with Gencurix. Gencurix will leverage Bio-Rad's established network and clinical diagnostics experience to expand its Droplex oncology testing kits, which are built on Bio-Rad's ddPCR technology and designed for use with Bio-Rad's QXDx ddPCR Systems.
- In October 2025, GRAIL and Samsung entered into a collaboration to provide GRAIL's multicancer early detection test to key Asian markets such as South Korea, Japan and Singapore.
- In October 2025, SOPHiA Genetics and A.D.A.M. Innovations entered into an agreement to collaborate on bringing liquid biopsy genomic testing to Japan. The partnership will focus on launching liquid biopsy – MSK-ACCESS powered with SOPHiA DDM. The test is designed to detect actionable genomic alterations and analyze ctDNA.
- In November 2025, SOPHiA Genetics entered into a collaboration with Element Biosciences to integrate SOPHiA's AI-powered analytics platform, SOPHiA DDM,

with Element's AVITI24 5D multi-omic and AVITI sequencing systems to provide an NGS workflow.

- In November 2025, Roche and Freenome cemented a $200 million licensing and commercialization deal for Freenome's cancer screening tests. Freenome will evaluate Roche's upcoming Sequencing by Expansion (SBX) technology for future development applications.
- In January 2026, Arima Genomics entered into a partnership with Fox Chase Cancer Center to advance 3D genome diagnostics for cancer care. The partnership will help physicians identify genomic changes that can affect the diagnosis and treatment of cancers.
- In January 2026, Daisy Genomics and New Day Diagnostics entered into a partnership to advance the development of CRC tests. This partnership will also include the University of Tennessee. The collaboration will utilize New Day's CRC liquid biopsy technology and Daisy Genomics sequencing platform.
- In January 2026, InterVenn Biosciences entered into a partnership with Aranscia to facilitate the commercialization of GlycoKnow, a proprietary blood-based liquid biopsy test that distinguishes ovarian cancer from a benign pelvic mass.
- In January 2026, Mirxes entered into a partnership with N Health to introduce Mirxes' advanced microRNA screening solutions to N Health's 60 hospitals across Thailand. This announcement comes on the heels of Mirxes' approval of FITRapid and HELICORapid tests for at-home testing.
- In January 2026, Guardant Health entered into a multi-year collaboration with Merck to develop companion diagnostics using Guardant's Infinity Smart platform.
- In February 2026, Targeted Genomics entered into a collaboration with Pathology Reference Laboratory to distribute the GlutenID test and celiac genetic testing services to Texas physicians. The testing service, CeliacDx, allows physicians to order a saliva-based GlutenID test for patients to rule out celiac disease. Additionally, consumers can purchase GlutenID
- In February 2026, Watchmaker Genomics and Visby Medical entered into a collaboration to develop next-generation diagnostic tests for respiratory pathogen detection in the at-home setting. This collaboration will combine Visby Medical's instrument-free PCR testing technology with Watchmaker's expertise in engineering enzymes to address performance gaps.

- In February 2026, PacBio entered into a collaboration with iHope to integrate PacBio's HiFi long-read whole-genome sequencing into iHope's network. iHope supports over 1,000 patients in its network and is the largest rare-disease genomic testing network. By adding PacBio's HiFi long-read whole-genome sequencing, the company will help to expand the range of genomic insights supporting iHope's network and strengthen its ability to interrogate challenging regions of the genome.
- In March 2026, C2N Diagnostics signed an agreement with BeauBrain Healthcare to provide PrecivityAD2, a breakthrough diagnostic test for Alzheimer's disease, to South Korea. The test, PrecivityAD 2, is an innovative blood test that helps detect amyloid plaques in the brain. The agreement will allow physicians in South Korea to provide access to C2N's blood test intended for use in patients with signs or symptoms of mild cognitive impairment or dementia, which is a pathological hallmark of Alzheimer's disease.
- In March 2026, MicrosensDx announced a partnership with ProteoGenix to advance novel biomarker tests for sepsis. MicrosensDx is developing a rapid, reliable diagnostic test for sepsis that will combine ProteoGenix's design solution, which combines high-throughput single B-cell screening, enabling identification of rare and highly specific binders, with a targeted approach designed to engage a defined region of the protein.
- In March 2026, Discovery Life Sciences entered into a partnership with Mindpeak, an AI-powered digital pathology. The partnership will aid in biopharma R&D and clinical research by improving biomarker quantification.
- In March 2026, Diasorin signed an agreement with McKesson Medical Surgical to expand the distribution of the LIAISON NES molecular POC platform. This agreement will support the commercialization of the LIAISON NES platform and its first FDA-cleared assay, the Flu A/B. RSV, and COVID-19 Panel.
- In April 2026, CellCarta and Pillar Biosciences entered into a partnership to expand rapid, decentralized tumor profiling for oncology. The collaboration will focus on producing relevant tumor profiling and combining Pillar's portfolio of oncoReveal NGS-based kitted panels with CellCarta's expertise.
- In April 2026, Leica Biosystems entered into a collaboration with CellCarta to combine their expertise, accelerating precision diagnostics in China. The collaboration will start in China and expand globally. Under this agreement, Leica

and CellCarta will combine their expertise to offer biopharmaceutical companies access to companion diagnostics.

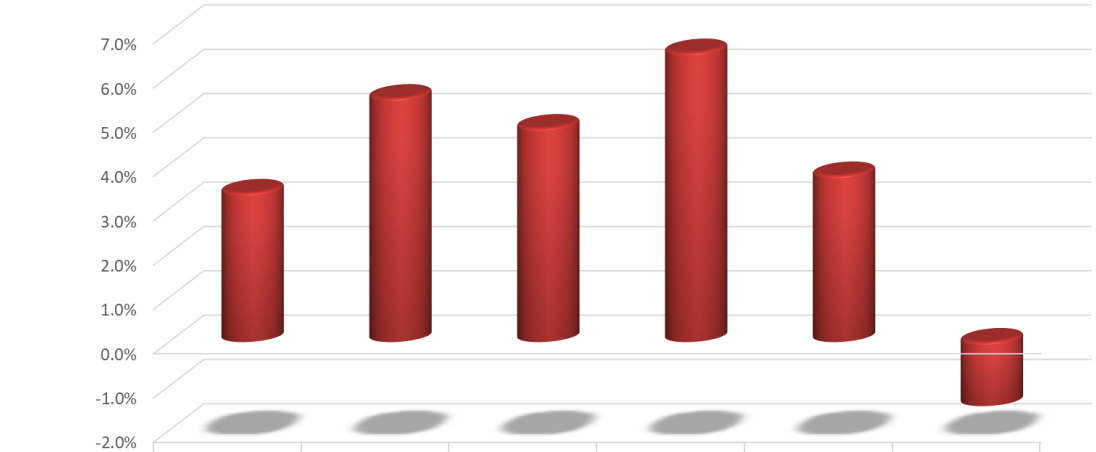
Test Services

The test service model has become a major route for highly sophisticated and specialized tests. The most successful company-owned test services involve anatomical pathology (histology/cytology) and molecular assays, primarily in situ hybridization (ISH) and PCR analysis of biopsied tissue for cancer analysis.

The company-owned test service business model is primarily a U.S. phenomenon, with a long history of commercializing highly specific assays as test services. U.S. reference labs were the first to introduce many groundbreaking tests in viral load testing, anatomical pathology, special analyses, and molecular assays. This sensitized the medical community to the value of these test services. The first generation of these tests targeted small markets where the financial investment for FDA market clearance – especially the PMA route that would have been required for these unique tests – would have been difficult to recuperate with a commercial test kit.

Test services remain one of the fastest-growing segments of the IVD market, far outpacing any other in the IVD industry.

Figure 2-2: Clinical Laboratory Test Service Market Forecasted Growth, by Segment, 2024-2029 (%)



	Clinical Chemistry - Routine & Essential Testing	Immunology & Microbiology Testing	Cytology & Histology Testing	Genetic Testing	Toxicology Testing	COVID-19 Testing
CAGR 2024-2029	3.4%	5.5%	4.8%	6.5%	3.8%	-1.4%

Source: Kalorama Information

For further test services information, please see Kalorama Information's *The Worldwide Market for Clinical Laboratory Services 10th Edition*

Hospital-based labs perform tests for hospitalized patients, patients seen in hospital emergency rooms and clinics, and sometimes serve as a reference lab for other hospitals. Independent (reference) labs are situated outside a hospital, and they perform tests on samples sent to them from physician offices, clinics and hospitals. The term POL is used in this report as a catch-all for tests performed in physician office labs, clinics, community health centers, retail clinic sites, and other settings.

The largest portion of the global market for clinical lab services is held by hospital-based labs. The global market for clinical laboratory services is estimated at $159.2 billion in 2024 and is projected to reach $197.1 billion in 2029. Market segmentation in 2024 is presented in the table below.

Table 2-6: Global Lab Market Segmentation, 2024 ($ billion)

[Hospital and Acute Care Labs, Independent Labs, Physician Office Labs]

Segment	Revenues	% Mkt
Hospital and Acute Care Labs	94.9	60%
Independent Labs	56.6	35%
Physician Office Labs	7.7	5%
Total	**159.2**	**100%**

Source: Kalorama Information

The clinical laboratory test services market in the United States was worth roughly $86.4 billion in 2024. Most major independent clinical laboratories have reported an annual increase in laboratory test volumes in both routine and specialty segments.

A trend toward preventive and risk-factor testing has been noted across several disciplines, particularly in oncology, endocrinology, and gynecology. Physicians in these areas are taking full advantage of testing for early detection and disease prevention.

New technologies in testing will likely continue to fuel growth, alongside an aging population, rising disease incidence and prevalence, a focus on prevention and early detection, and emerging trends in personalized medicine. Some key areas of growth include genomic and esoteric testing, anatomic pathology, and specialized testing in oncology and infectious disease. The market for COVID-19 is expected to continue to slow. It is likely to have a presence in the market, however.

Quest Diagnostics is a pioneer, innovator and leading provider of diagnostic testing services through its network of laboratories and patient service centers and provides interpretive consultation through its extensive medical and scientific staff. Quest's diagnostic testing services range from routine tests such as cholesterol panels, Pap testing and white blood cell counts to sophisticated cancer testing, gene-based and molecular testing.

Quest has developed a network of labs and collaborators worldwide. Quest's Nichols Institute performs specialized testing for hospitals and laboratories in the Americas, Europe, Asia and Australia. Quest also has operations in Brazil, India, Ireland, Mexico, Puerto Rico, and the United Kingdom.

Quest also provides a broad range of solutions for employers, including workplace drug testing for employers and government agencies; the Blueprint for Wellness employee wellness service; and risk assessment services for the life insurance industry

Quest Diagnostics Health Trends reports examine disease trends using the company's United States database. Quest Diagnostics Drug Testing Index reports examine trends in workplace drug testing and have been considered a benchmark for U.S. workforce drug positivity trends since 1988.

Quest offers a wide range of tests in the U.S. through a national network of 2,400 patient service centers. Most of Quest's services are provided in the U.S. The company provides services to approximately one-third of all U.S. adults, half of all U.S. hospitals and half of all physicians.

The core of Quest Diagnostics' business is rooted in routine and pathology tests. However, gene-based and esoteric testing services are helping to drive revenues. Along with its main competitor, Labcorp. Quest is a major supplier of cancer histology and pharmacodiagnostic tests to physicians and hospital labs.

Labcorp is the largest private laboratory worldwide, and a pioneer in commercializing new diagnostic technologies. It was the first in its industry to offer genomic testing. The company employed nearly 70,000 people and performed more than 700 million tests for patients globally in 2024. As one of the largest clinical laboratories, Labcorp operates nearly 2,200 PSCs. Additionally, the company offers services through a number of network branches and STAT laboratories.

Physicians using Labcorp's services for patient testing are among the main sources of the company's revenue. Revenues are paid directly by physicians, patients, insurance providers, and Medicare or Medicaid.

In March 2025, Labcorp acquired select assets of OPKO BioReference Health's oncology clinical testing services business. Through this acquisition, patients will gain greater access to Labcorp's oncology offerings.

Table 2-7: Total Revenues for Leading U.S.-based Reference Labs, 2023-2025 ($ million)

Company	2023	2024	2025
Labcorp	12,162	13,009	13,950
Quest Diagnostics	9,252	9,872	11,035
Bio-Reference Lab/OPKO	515	481	370

Source: Kalorama Information, company reports

POLs are primarily a U.S. phenomenon and are also common in Europe. Strict regulations on the quality control of tests performed have decreased the number of physician offices that perform tests, and most of these POLs can perform only a short list of CLIA-waived tests. According to CLIA statistics, there are approximately 133,062 in-office labs in the U.S. The tests most commonly performed in POLs are for disease screening, including diagnosis of common infectious diseases such as strep A, flu, mononucleosis, H. pylori, and RSV, as well as routine monitoring tests for patients with common chronic diseases such as diabetes and cardiovascular risk.

The most lucrative tests for labs are those that are unique and proprietary to the lab that developed them. These are generally known as lab-developed tests (LDTs). These tests are

usually low-volume and address very specific medical problems, such as viral load monitoring and cancer management. These tests are offered in CLIA, or CAP (College of American Pathologists) certified laboratories operated by independent laboratory services companies, hospital labs, or by the actual test manufacturer. The past few years have seen a literal explosion of these tests in the market.

The test service model is becoming a major route for highly sophisticated and specialized molecular and personalized medicine tests. The most successful company-owned test services involve anatomical pathology (histology/cytology), sequencing studies, and molecular assays, primarily in situ hybridization (ISH) and PCR analysis of biopsied tissue.

Historical IVD Market vs Today

The evolution of the IVD industry can be viewed through a traditional product development lens, moving from introduction to rapid growth and into maturity, although in reality the industry continues to cycle through new growth phases driven by technological innovation. Prior to the 1970s, laboratory medicine consisted of a relatively limited number of tests, largely performed manually using basic tools such as test tubes, microscopes, and early spectrophotometers. The 1970s marked a major technological shift with the introduction of radioimmunoassays, immunoelectrophoresis, and early clinical chromatography methods, laying the foundation for modern diagnostics. In the 1980s, the emergence of enzyme immunoassays and the first generation of automated chemistry and immunoassay analyzers significantly expanded laboratory capacity and efficiency. Around the same time, PCR was introduced, and although it did not replace immunoassay-based testing, it established the foundation for molecular diagnostics, which would later become a major growth driver in areas such as infectious disease, oncology, and genetic testing. Through the 1990s and 2000s, advances in molecular biology, proteomics, and genomics, including the sequencing of the human genome, further expanded the diagnostic test menu and clinical applications.

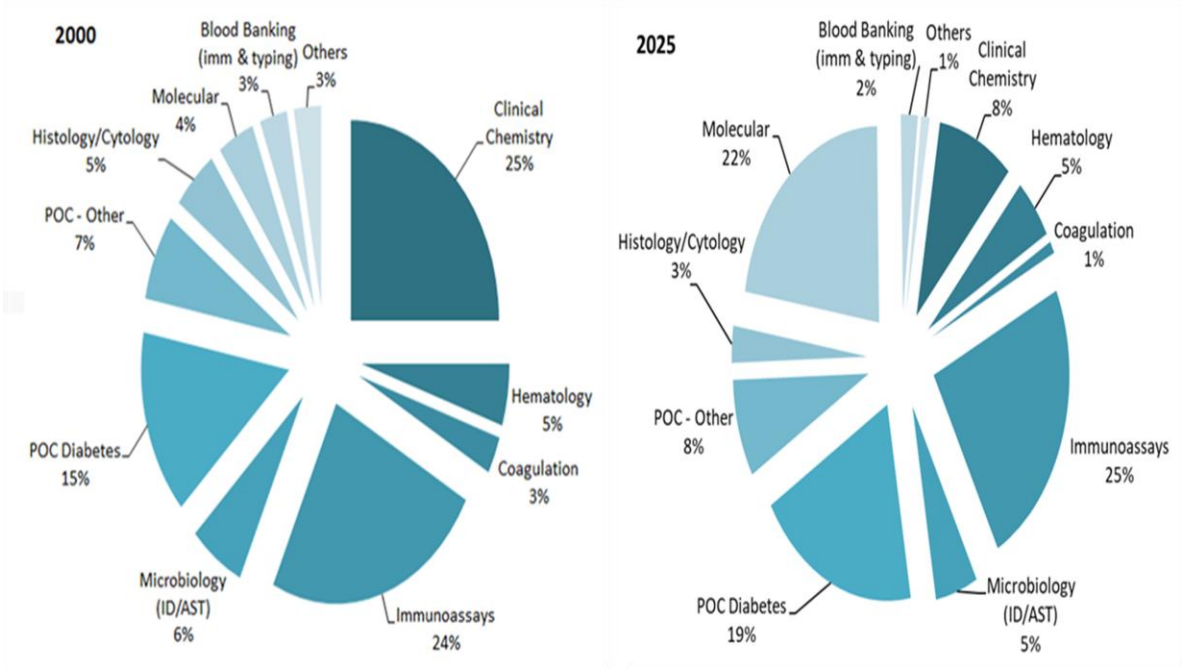
The IVD industry reflects both maturity and renewal. It continues to attract investment, consolidation, and participation from large global players, while also facing ongoing pressure from reimbursement constraints and the need to demonstrate positive clinical and economic value. Growth is increasingly tied to the development of medically actionable tests, integration with digital and informatics platforms, and the ability to offer value-based healthcare models. In addition, the industry is being reshaped by the continued shift toward decentralized testing across point-of-care and at-home settings, the expansion of multiplex and syndromic assays that improve clinical efficiency, deeper integration of informatics and connectivity solutions that link diagnostic results to clinical decision-making, and the growing role of companion diagnostics in precision medicine, particularly in oncology. Ongoing consolidation and strategic partnerships, combined with innovation from smaller and specialized companies in areas such as liquid biopsy, sequencing, and AI-enabled diagnostics, are further accelerating this transformation and reinforcing the expanding role of clinical diagnostics in healthcare.

In the Beginning to Now

Over the past two decades, Kalorama has closely monitored the evolution of the IVD industry, witnessing significant shifts in technology and market composition. In the 1990s, the IVD market was largely dominated by routine chemistries and immunoassays, which together accounted for approximately 58% of total market sales. By 2000, this share had declined to around 50%, and as of 2025, these core segments represent only about 32% of the market. This decline reflects the industry's transition toward more advanced diagnostic modalities, particularly molecular diagnostics and POC testing. Molecular diagnostics, once nearly absent in clinical settings two decades ago, now constitute approximately 22% of the market, with growth significantly accelerated by the COVID-19 pandemic and the associated demand for rapid POC molecular testing. The industry has also embraced smaller-footprint testing systems and genomic data to enable more precise disease detection and management. This chart shows the percentage change in each category over time from 2000 to today.

Figure 2-3: Share of Global IVD Market, by Segment, 2000 and 2025 Compared (%)

[Blood Banking (imm & typing); Clinical Chemistry; Coagulation; Hematology; Immunoassays; Microbiology [ID/AST]; Molecular; POC – Other; Histology/Cytology; POC Diabetes; Others]



Source: Kalorama Information

Future

As indicated in prior editions, the future of the IVD industry remains both promising and somewhat unpredictable. The COVID-19 pandemic introduced significant disruption across healthcare, including diagnostics, but it also accelerated innovation and the adoption of new technologies. The rapid implementation of molecular diagnostic platforms during the pandemic expanded the installed base and helped integrate molecular testing into routine clinical workflows, particularly in decentralized and point-of-care settings. While pandemic-driven testing volumes have declined, the broader use of molecular systems continues to support market growth as test menus expand into infectious disease, oncology, and other applications.

Prior to COVID-19, limited system penetration constrained growth, but this barrier has largely been reduced, enabling further technological advancement. Key developments shaping the future of IVD include the growing convergence of diagnostics with information technology, where artificial intelligence and data-driven tools are increasingly used to enhance workflow efficiency, result interpretation, and clinical decision-making. Molecular testing in physician office laboratories and near-patient settings continues to expand, particularly for respiratory and syndromic testing, although adoption is influenced by cost and reimbursement considerations. The direct-to-consumer and at-home testing segments have established a lasting presence, with continued growth driven by consumer demand for convenience and increased comfort with self-testing. Wearable glucose monitoring devices with real-time connectivity have become standard in many developed markets and are expanding into broader patient populations and geographies. In addition, home-based sample collection, including HPV testing, is gaining traction as regulatory acceptance increases, further supporting the shift toward more decentralized models of care.

Next-Generation Sequencing

Next-generation sequencing represents a powerful platform that enables the parallel sequencing of millions to billions of DNA fragments, supporting comprehensive analysis of genetic variation across the genome. It has become a key driver of advances in personalized medicine, genetic disease testing, and clinical diagnostics. Compared to earlier sequencing methods, NGS offers improved scalability, higher throughput, and lower cost per base, making it a foundational technology in modern molecular testing, although costs and turnaround times can still vary by application and setting.

The most widely adopted clinical NGS technologies are provided by Illumina and Thermo Fisher Scientific, with additional competition emerging from newer platform developers. Thermo Fisher continues to advance its Ion Torrent–based semiconductor sequencing technology, centered on platforms such as the Ion GeneStudio S5 series, which are designed for targeted sequencing applications in clinical and translational settings. These systems detect nucleotide incorporation through pH changes generated during DNA synthesis, eliminating the need for optical detection. Illumina remains the leading provider of sequencing-by-synthesis technology, which uses reversible terminator nucleotides and optical imaging to generate highly accurate sequence data. Its portfolio spans benchtop systems such as MiSeq, MiniSeq, and iSeq 100, as well as mid- to high-throughput platforms such as the NextSeq and NovaSeq families, with continued enhancements focused on speed, cost efficiency, and broader accessibility.

Innovation in sequencing platforms has accelerated with the introduction of new systems designed to improve performance and reduce cost barriers. Emerging competitors are advancing both short-read and long-read sequencing technologies, with long-read platforms improving the resolution of structural variation and complex genomic regions. New sequencing approaches and chemistries are being developed to enhance accuracy, simplify workflows, and expand multiomic applications. Additionally, there is increasing emphasis on automation, integrated sample-to-answer workflows, and improved bioinformatics to address ongoing challenges in data analysis and interpretation.

NGS continues to play a critical role in clinical decision-making, particularly in oncology, rare disease diagnostics, and infectious disease testing. While North America and Europe remain the largest markets, adoption in Asia Pacific has expanded significantly, supported by national genomics initiatives, investment in precision medicine, and growing laboratory infrastructure. The COVID-19 pandemic accelerated the use of sequencing for pathogen surveillance, and NGS remains an essential tool for monitoring viral and emerging infectious diseases, with ongoing integration into public health.

In addition to sequencing platforms, companies such as QIAGEN market supporting technologies for NGS workflows, including library preparation, sample processing, and bioinformatics solutions. These tools help streamline laboratory operations and improve efficiency, supporting broader adoption in both research and clinical environments.

Cancer Testing (Liquid Biopsy)

Liquid biopsy is an important component of clinical oncology, enabling noninvasive assessment of tumor biology through analysis of circulating tumor DNA, circulating tumor cells, and other tumor-derived biomarkers such as extracellular vesicles. The technology continues to progress and is now used in advanced cancer care for genomic profiling, therapy selection, and disease monitoring, with growing application in minimal residual disease detection and early recurrence assessment. Clinical adoption has expanded significantly; this is supported by broader reimbursement and guideline inclusion, with comprehensive genomic profiling assays such as Guardant360 achieving widespread coverage across multiple advanced solid tumors.

Product development has focused on expanding the clinical utility of liquid biopsy across several segments of IVD. Multi-cancer early-detection assays, such as new blood-based screening tests that can identify multiple tumor types from a single sample, represent a rapidly emerging segment. At the same time, minimal residual disease testing has become one of the fastest-growing areas, with highly sensitive personalized assays, including NeoGenomics' RaDaR, designed to detect recurrence at very low levels of circulating tumor DNA. Companies such as Guardant Health have expanded their portfolios with blood-based screening tests and enhanced monitoring assays, while Exact Sciences has introduced multi-cancer detection platforms to complement its existing cancer diagnostics portfolio.

Strategic acquisitions and partnerships continue to strengthen liquid biopsy capabilities across the industry. Labcorp expanded its genomic profiling and liquid biopsy offerings through the acquisition of Personal Genome Diagnostics, while Myriad Genetics has incorporated liquid biopsy into precision medicine workflows through collaborations with clinical partners. Technology development continues at the platform level, with Bio-Rad offering circulating tumor cell workflows through tools such as Celselect Slides, and companies such as OraSure enabling more flexible sample collection through saliva-based systems that support certain molecular applications. Additionally, emerging multi-omic approaches combine genomic, epigenomic, and protein biomarkers to improve detection sensitivity and clinical performance.

Companion Diagnostics

Companion diagnostics (CDx) have become an essential part of personalized medicine, particularly in oncology, where they are used to identify patients most likely to benefit from targeted therapies. While the concept of linking diagnostics to treatment decisions has existed for decades, the modern CDx market began to take shape in the late 1990s and 2000s with the emergence of targeted therapies. Early examples such as trastuzumab and imatinib helped establish the clinical and commercial value of aligning diagnostics with therapy selection. Since then, the field has expanded significantly beyond oncology into other therapeutic areas, although cancer remains the primary driver of CDx development.

A wide range of technologies is used in companion diagnostics and personalized medicine. Traditional PCR-based assays continue to play an important role in detecting specific mutations, while more advanced methods such as next-generation sequencing are increasingly used for broader genomic profiling. In hereditary cancer testing, single-gene analysis has largely been replaced by multigene panels that assess mutations across a wide range of clinically relevant genes, reflecting the complexity of cancer risk and tumor biology. Tumor characterization also incorporates phenotypic and molecular features; for example, microsatellite instability can be assessed using PCR or NGS-based approaches, while classifications such as triple-negative breast cancer are determined by protein expression and then further evaluated with genomic testing to guide treatment decisions.

The complexity of hereditary and somatic cancer diagnostics continues to drive the adoption of more comprehensive technologies. Multigene panels and NGS-based assays allow simultaneous analysis of numerous cancer-associated genes, improving the ability to identify actionable mutations. Techniques such as digital PCR and NGS have largely replaced older sequencing approaches in many settings, particularly where sensitivity and scalability are required. Broad genomic profiling assays, including FoundationOne CDx, have further advanced the field by enabling simultaneous assessment of multiple biomarkers across solid tumors, supporting more personalized treatment strategies.

Companion diagnostics continue to evolve alongside targeted therapies, with increasing collaboration between diagnostic companies and pharmaceutical developers. Tests such as BRACAnalysis CDx are used to identify patients with specific genetic alterations who may benefit from targeted treatments, including PARP inhibitors in cancers such as ovarian, breast, and prostate. Many more companion diagnostics are listed throughout the report.

Chapter 3: The Global Picture for In Vitro Diagnostic Markets

Scope

This section focuses on global events related to the sale of clinical diagnostics and provides several country IVD market profiles to establish the global market context. The report uses this information to discuss opportunities and threats for IVD manufacturers and marketers in specific geographic markets. While this report concentrates on developments at work in the mature markets of North America, the European Union and Japan, it also provides some insight to opportunities in emerging nations, primarily Saudi Arabia, China, Turkey, Southeast Asia, South Korea and Latin America. Finally, this chapter details 'next wave' countries, while not fully developed or commonly targeted IVD markets, that should be on the IVD marketer's watch list.

Overview

IVD are growing in all parts of the world. Some areas are growing faster than others. Social and economic events in selected countries will continue to influence the IVD market but overall, the IVD market plays an important role in the evolution of the healthcare industry worldwide.

Simultaneous Threats: Chronic and Acute

Two major trends continue to shape the global healthcare landscape. As populations age, demographic shifts are driving a steady increase in the prevalence of chronic diseases such as arthritis, autoimmune disorders, asthma, diabetes, cancer, and cardiovascular disease. Longer life expectancy, combined with lifestyle factors, is contributing to a growing burden of noncommunicable diseases worldwide.

At the same time, infectious diseases are a persistent and evolving challenge. Globalization, urbanization, climate change, and increased human mobility have contributed to the continued spread and re-emergence of infectious diseases, including dengue, Chagas disease, Lyme disease, West Nile virus, and periodic outbreaks of emerging pathogens such as SARS-related viruses and mpox. In addition, long-standing global health challenges such as hepatitis, tuberculosis, HIV, and sexually transmitted infections continue to place a significant strain on healthcare systems.

This combination of rising chronic disease burden alongside ongoing infectious disease threats reflects a dual challenge for healthcare systems, particularly in regions with aging populations and limited resources.

Expected World IVD Market Developments

The next five to ten years are expected to bring steady but meaningful evolution in IVD product markets. Key trends likely to shape the industry include:

- Continued expansion of rapid and POC testing, particularly in molecular diagnostics, as platforms become faster, more portable, and easier to use in decentralized settings.
- Increased automation across laboratory workflows driven by staffing shortages, rising labor costs, and the need for greater efficiency and standardization.

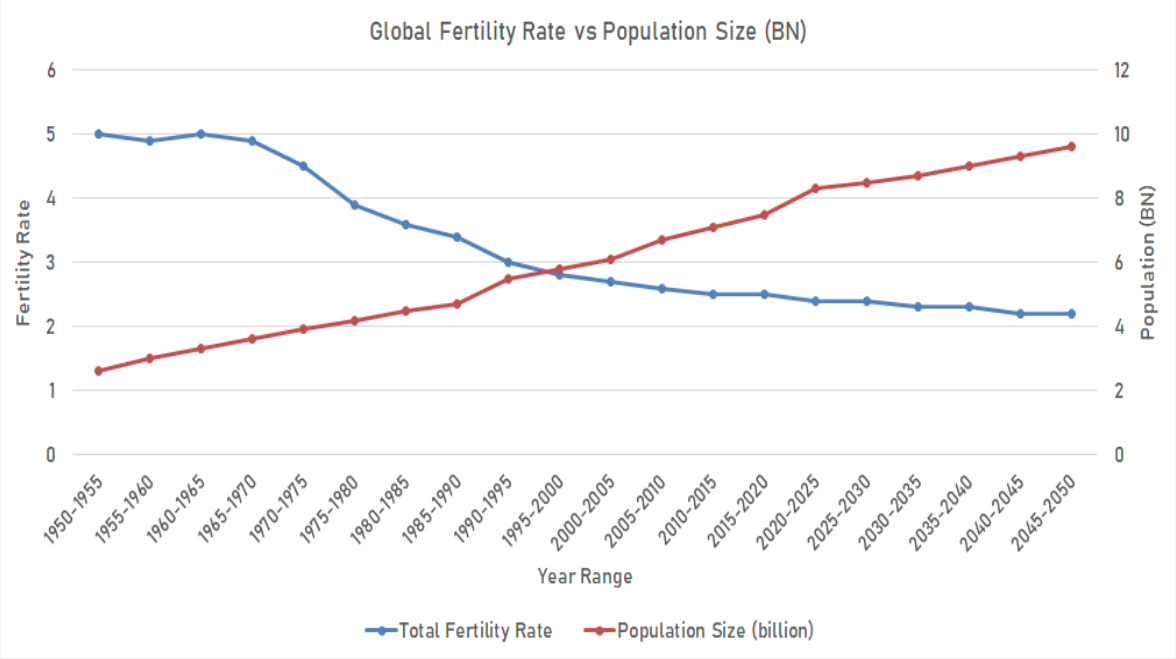
- Growth in partnerships, collaborations, and strategic alliances as manufacturers combine technologies, expand test menus, and support integrated solutions such as companion diagnostics and precision medicine.
- An aging global population that will drive higher testing volumes, particularly for chronic disease management, while also increasing pressure from governments and payers to control costs and reimbursement.
- Moderate growth in developed markets, with stronger volume growth in emerging regions, although pricing pressures and reimbursement limitations may constrain revenue expansion.
- Expanding healthcare access and insurance coverage in key emerging markets, including China, India, Brazil, Mexico, Saudi Arabia, and other Gulf states, creating new opportunities for diagnostic testing adoption.
- Continued growth in Southeast Asia, parts of Latin America, and the Middle East, which are becoming increasingly important markets for IVD companies seeking geographic expansion.
- Ongoing development of diagnostic systems designed for decentralized and resource-limited settings, including portable, lower-cost, and easy-to-use platforms.
- Increased adoption of multiplex and syndromic testing, particularly in infectious disease diagnostics, enabling simultaneous detection of multiple targets from a single sample.
- Greater integration of digital tools, artificial intelligence, and connectivity solutions to provide workflow optimization, remote diagnostics, and population health management.
- Continued shift toward decentralized and near-patient testing, including use in clinics, pharmacies, and home settings, supported by telehealth and digital health platforms.
- Growing use of multi-omics approaches that combine genomic, proteomic, and other data to provide more comprehensive diagnostic insights, particularly in oncology and complex disease management.
- Increased focus on supply chain resilience and regional manufacturing capacity, driven by lessons learned from recent global disruptions.

- Ongoing regulatory complexity and changing compliance requirements, alongside continued reimbursement pressure, which will influence product development, market access, and pricing strategies

Global Population and Aging

The world's population exceeds 8.2 billion. Average growth currently stands at about 1% with a projected population of 9.7 billion for 2050. Despite slowing population growth, it is still growing. This has led to renewed concerns about whether the Earth's land and resources can support a population that continues to swell. While many countries in the developed world face low birth rates and aging populations, growth in developing countries, particularly in sub-Saharan Africa, continues largely unabated.

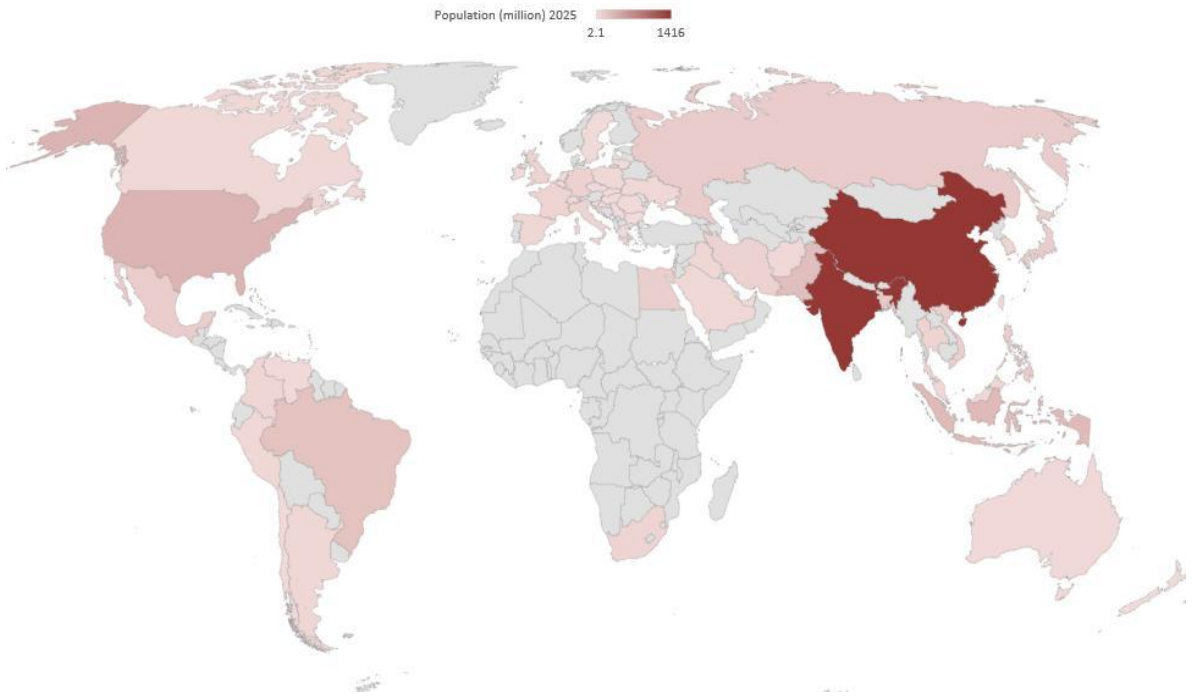
Figure 3-1: Global Fertility Rate vs. Population Size, 1950-2050 (billion)



Source: Compiled from data retrieved from United Nations Population Fund

In terms of population, the Asia Pacific region hosts the most individuals with 4.1 billion people; the European region has the second most individuals with 748 million, followed by Latin America with 656 million and North America (excluding Latin American countries) with 371 million.

Figure 3-2: Global Population Distribution, 2025



Source: Compiled from data retrieved from United Nations Population Fund

Even when the aging process is slower, there are challenges. Africa, for instance, is projected to still have a young population in 2050; the number of older Africans is expected to almost quadruple, with 150 million older Africans joining the global population.

According to the U.S. Census Bureau, about 13.5% of the population is currently over the age of 60. By 2050, about 21.4% of the population is projected to be over the age of 60. This supports a growing need for health services and more specifically, services which are personalized to patients, age groups and disease profiles.

Demographic aging puts pressure on a nation's ability to support its elderly citizens. A commonly used indicator of this pressure is the elderly support ratio, calculated as the number of working-age people aged 15 to 64 divided by the number of people aged 65 or older. This ratio serves as a rough indicator of the number of potential providers of support (including healthcare costs) per potential elderly dependent. In 1950, there were 12 working-age people for every elderly person in the world. By 2010, this ratio declined to 9, with the largest decline

occurring in more developed countries. However, China and other BRIC economies are expected to feature elderly support ratios in 2050 near or below those of developed countries such as France and the United States, where stable fertility rates and immigration will stabilize ratios that otherwise declined in past decades.

Table 3-1: Elderly Support Ratio in Various Countries, 2010 and 2050

[Australia; Brazil; Canada; China; China, Hong Kong SAR; France; Germany; India; Italy; Japan; Mexico; Saudi Arabia; Singapore; South Africa; Spain; Turkey; United Kingdom; United States; World]

Region/Country	2010	2050
Australia	5	3
Brazil	10	3
Canada	5	2
China	9	2
China, Hong Kong SAR	6	2
France	4	2
Germany	3	2
India	13	5
Italy	3	2
Japan	3	1
Mexico	11	3
Saudi Arabia	23	4
Singapore	8	2
South Africa	14	6
Spain	4	1
Turkey	9	3
United Kingdom	4	2
United States	5	3
World	9	4

Source: Kalorama Information

Workforce Reduction

Aging populations mean fewer workers on the job. This is evidenced in a milestone reached in 2016, the year the world's advanced economies reached a critical milestone. For the first time since 1950, their combined working-age population declined per UN data. By 2050, that population will shrink 5%. Among advanced countries, the working-age population will shrink 26% in South Korea, 28% in Japan, and 23% in both Germany and Italy, according to the U.N. For middle-income countries, it will rise 23%, led by India at 33%. But Brazil's will edge up just 3% while Russia's and China's will contract 21%.

Along with age comes the timing of retirement, which is changing. Over the past 50 years, labor force participation among persons aged 65 or over has declined by more than 40 percent globally. And more aging means healthcare costs rise both as the number of patients grows and as the complexity of their treatment (illness tends to be more expensive for the old than for the young) increases.

WHO Essential IVD List

WHO released the First WHO Model List of Essential In Vitro Diagnostics (EDL). The list, similar to the ongoing publication of Essential Medicines List, the WHO Model List of Essential Medicines contains the medications considered to be the most effective and safe to meet the most important needs in a health system, thus advancing these strategic priorities. Access to high-quality, affordable IVDs that enable healthcare providers to make timely diagnoses and provide the most appropriate treatment is also essential to achieving these goals.

A second WHO model list of essential IVD products was released in 2019. A third edition was released in January 2021, and selected categories are listed. The fourth edition was released in mid-2023. It provides evidence-based recommendations on the accessibility of essential products, helping countries make decisions about which diagnostic products to use. An updated release of the WHO Essential Medicines List was released in September 2025.

Table 3-2: WHO Model List of Essential In Vitro Diagnostics (EDL)

Category	Diagnostic Test
For Primary Health Care	**Includes IVDs for health posts, community health centers, doctors' offices, outreach clinics and ambulatory care.**
Hematology	Hemoglobin (Hb)
Clinical chemistry and immunoassays	Albumin
	Bilirubin
	Glucose
	Hemoglobin A1c (HbA1c)
Blood transfusion	Blood typing
Serology	Human chorionic gonadotropin (hCG)
Microbiology, mycology and parasitology	Urine dipstick and urine microscopy
	Microscopy
Hepatitis B	Hepatitis B surface antigen (BHsAg)
	Hepatitis B e antigen (HBeAg)
Hepatitis C	Hepatitis C virus antibody (anti-HCV Ab)
Hepatitis E	IgM antibodies to hepatitis E virus RDT
HIV infection	HIV 1/2 antibody (anti-HIV Ab)
	Combined HIV antibody/p24 antigen (anti-HIV/p24 Ag)
Malaria	Plasmodium spp. Antigens; species specific (e.g., HRP2) and/or pan-species-specific (e.g., pan-pLDH)
	Plasmodium spp.
Tuberculosis	Mycobacterium tuberculosis
	Immune response
Syphilis	Antibodies to Treponema pallidum
	Combined antibodies to T. pallidum and to HIV 1/2

Category	Diagnostic Test
Chagas disease	Trypanosoma cruzi IgG antibody
Cholera	Vibrio cholerae antigen
Coronavirus	SARS-CoV-2 benchtop or handheld
For Health Care Facilities with Clinical Laboratories	**District, regional, provincial or specialized hospitals or laboratories and national reference laboratories.**
Clinical chemistry and immunoassays	Alanine amino-transferase (ALT)
	Albumin
	Alkaline phosphatase
	Aspartate amino-transferase (AST)
	Bilirubin
	Blood pH and gases
	Blood urea nitrogen (BUN)
	Creatinine
	D-dimer
	Electrolytes
	Glucose
	Hemoglobin A1c (HbA1c)
	C-reactive protein (CRP)
	Lipid profile
	Basic metabolic panel (BMP)
	Comprehensive metabolic panel
	Amylase and lipase
	Troponin T/I
	Urinalysis
Blood transfusion	Blood cross-matching

Category	Diagnostic Test
	Transfusion-transmitted infections
Serology	Human chorionic gonadotropin (hCG)
Microbiology, mycology and parasitology	Urine dipstick and urine microscopy
	Microscopy
	Culture
	Blood culture
	Antimicrobial susceptibility testing
Hematology	Hematocrit (Hct)
	Prothrombin time test and international normalized ratio (PT/INR)
	Platelet count
	Complete blood count (CBC), automated, differential
Hepatitis B	Hepatitis B surface antigen (HBsAg)
	Virological (HBV DNA – quantitative)
	Hepatitis B e antigen (HBeAg)
	IgM-specific antibodies to hepatitis B core antigen (IgM anti-HBc)
	Antibodies to hepatitis B surface antigen (anti-HBs)
Hepatitis C	Antibodies to HCV (anti-HCV)
	Antibodies to HCV (anti-HCV) and HCV core antigen (HCV cAg)
	HCV core antigen (HCV cAg)
	HCV RNA (qualitative or quantitative)
HIV infection	Antibodies to HIV 1/2 (anti-HIV) test
	Combined HIV antibody/p24 antigen (anti-HIV/p24 Ag test)
	Qualitative or quantitative virological test
	Quantitative virological test
	CD4 cell enumeration (quantitative)

Category	Diagnostic Test
	Cryptococcal antigen test
Malaria	Plasmodium spp. Antigens: species-specific (e.g., HRP2) and/or pan-species-specific (e.g., pan-pLDH)
	Plasmodium spp.
	Glucose-6-phosphate dehydrogenase activity (G6PD)
Tuberculosis	Mycobacterium tuberculosis bacteria
	M. tuberculosis DNA
	M. tuberculosis DNA mutations associated with resistance
	Drug susceptibility testing in M. tuberculosis culture
	Lipoarabinomannan (LAM) antigen
	Immune response
HPV infection	Human papillomavirus (HPV) nucleic acid
Syphilis	Antibodies to Treponema pallidum
	Combined antibodies to T. pallidum and to HIV 1/2 (anti=HIV)

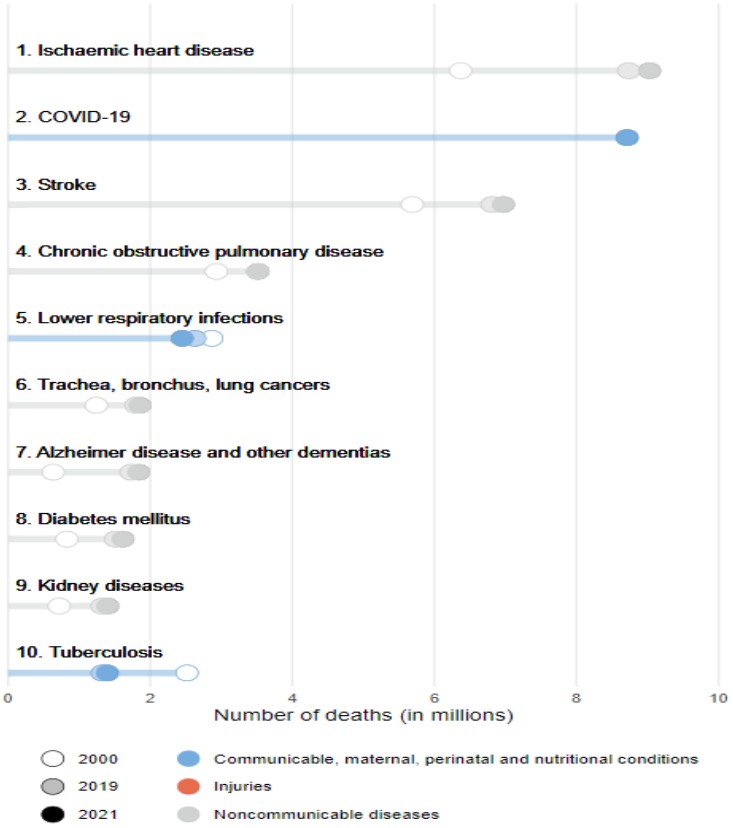
Source: WHO

Increase in Chronic Diseases

The prevalence of chronic medical conditions significantly impacts the growth and development of the IVD market. Conditions such as hypertension, cancer, HPV, and hormone imbalances have a high incidence and require continuous evaluation. IVD tests are necessary for diagnosis and monitoring disease progression, treatment, and overall patient health.

Around the world, millions of people lose their battle with a chronic disease each year. Chronic diseases account for about 44 million deaths annually. Ischemic heart disease is the leading cause of death worldwide, with around 9 million deaths annually.

Figure 3-3: Leading Causes of Death Globally, 2021* (number of deaths in millions)



Notes: The world's biggest killer is ischaemic heart disease, responsible for 13% of the world's total deaths. Since 2000, the largest increase in deaths has been for this disease, rising by 2.7 million to 9.1 million deaths in 2021. As a newly emerged cause of deaths, COVID-19 was directly responsible for 8.8 million deaths in 2021, and consequently, largely pushed down other leading causes of death by one place. Instead of being the second and third leading causes of death as in 2019, stroke and chronic obstructive pulmonary disease became the third and fourth in 2021, responsible for approximately 10% and 5% of total deaths, respectively.

Lower respiratory infections remained the world's most deadly communicable disease other than COVID-19, ranked as the fifth leading cause of death. However, the number of deaths has gone down substantially: in 2021 it claimed 2.5 million lives, 370 000 fewer than in 2000.

Deaths from other noncommunicable diseases were also on the rise. Trachea, bronchus and lung cancers deaths have risen from 1.2 million in 2000 to 1.9 million in 2021 and are now ranked sixth among leading causes of death.

In 2021, Alzheimer's disease and other forms of dementia ranked as the seventh leading cause of death, killing 1.8 million lives. Women are disproportionately affected. Globally, 68% of deaths from Alzheimer's and other forms of dementia are women.

Diabetes was also among the top 10 causes of death, following a significant percentage increase of 95% since 2000.

Other diseases which were among the top 10 causes of death in 2000 are no longer on the list. HIV and AIDS are among them. Deaths from HIV and AIDS have fallen by 61%, moving from the world's seventh leading cause of death in 2000 to the twenty-first in 2021. Similarly, deaths due to diarrhoeal diseases have dropped by 45%, from sixth leading cause of death in 2000 to thirteenth in 2021.

In contrast, kidney diseases have risen from the world's nineteenth leading cause of death to the ninth, with number of deaths increasing by 95% between 2000 and 2021

* Note: 2021 is the most recent data available

Source: WHO Global Health Estimates.

By 2030, there will likely be 67.2 million deaths reported, with chronic diseases accounting for 77% of total deaths, or 52 million. The rate of growth in chronic disease mortality from 2016 to 2030 is estimated at 1.3% compounded annually, compared with 0.6% for acute disease mortality over the same period.

In the United States, nearly 8 in 10 seniors are living with at least one chronic health condition; 50% have two or more. About 25% of older Americans are obese; 20% have been diagnosed with diabetes; more than 70% have heart disease; nearly 60% have arthritis, a leading cause of disability. Adults 65 and older spend nearly twice as much on health care each year as those aged 45 to 64; they spend three to five times as much as all adults younger than 65.

These statistics demonstrate the enormous pressures on healthcare systems around the world and emphasize the need for highly efficient tests and systems for chronic diseases of aging, at a time when emerging viruses and infectious diseases remain an ongoing concern.

COVID-19

Coronavirus (COVID-19) is a virus that is identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China and has resulted in an ongoing pandemic worldwide. The pandemic has turned the spotlight on the IVD industry. The industry stepped up with rapid development of diagnostics, fast-tracked regulatory clearance and ramped up distribution.

This table includes information about authorized SARS-CoV-2 molecular diagnostic tests in 2024 and 2025. The EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories.

Table 3-3: Selected Molecular EUA Tests for COVID-19, 2024-July 2025

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]
7/25/2025	BioFire Defense	BioFire COVID-19 Test	RT, Nested multiplex PCR, Pooling, Saliva, Multiple targets	H.M
4/3/2025	Visby Medical	Visby Medical Respiratory Health Test	RT-PCR, Multi-analyte, multiple targets	H, M,W
2/21/2025	Aptitude Medical Systems	Metrix COVID/Flu Test	RT, LAMP, Over the Counter (OTC) Home Testing, Multi-analyte, Multiple Targets	Home, H,M,W
1/17/2025	Pfizer	Lucira by Pfizer COVID-19 & Flu Home Test	RT, LAMP, Over the Counter (OTC) Home Testing, Multi-analyte, Multiple Targets	Home, H,M,W
10/31/2024	DNA Genotek	ORAcollect RNA OR-100 and ORAcollect RNA ORE-100 saliva collection device	Saliva collection device	N/A
10/3/2024	Luminex	NxTAG Respiratory Pathogen Panel + SARS-CoV-2	RT-PCR Multiple targets, Multianalyte	H
8/20/2024	CDC	Influenza SARS-CoV-2, Multiplex Assay	RT-PCR single target, Multianalyte	H
8/9/2024	Roche Molecular	cobas liat SARS-CoV-2 influenza A/B & RSV nucleic acid test	RT-PCR Multiple targets, Multianalyte	H,M,W
7/1/2024	SalivaDirect	SalivaDirect for use with DTC Kits	DTC Home collection kit, RT-PCR saliva, screening, pooling single target	H
7/1/2024	SalivaDirect	SalivaDirect	DTC Home collection kit, saliva, screening	N/A
7/1/2024	SalivaDirect	SalivaDirect	real-time RT-PCR pooling saliva multiple targets	H
6/7/2024	Roche Molecular	cobas liat SARS-CoV-2 Influenza A/B & RSV nucleic acid test	real-time RT-PCR multiple targets, multi-analyte	H,M,W
5/14/2024	3EO Health	3EO Health COVID-19 Test	RT, LAMP, OTC home testing multiple targets	Home, H,M,W

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]
4/16/2024	ADL Diagnostics dba Anavasi Diagnostics	The AscencioDx COVID-19 and the AscencioDx Molecular Detector	RT-LAMP multiple targets	H,M,W
4/12/2024	Aptitude Medical	Metrix COVID-19 Test	RT, LAMP, OTC home testing multi-analyte, multiple targets	Home, H,M,W
4/4/2024	GenMark	ePlex Respiratory Pathogen Panel 2	RT-PCR and electrochemical detection, multi-analyte multiple targets	H,M
4/1/2024	LMSI dba Lighthouse Lab	SalivaNow SARS-CoV-2 Assay	real-time RT-PCR single target	H
3/26/2024	Nanobiosym Precision Testing	The Nano Test for COVID-19	real-time RT-PCR pooling saliva multiple targets	H
3/19/2024	Tetracore	EZ-SARS-CoV-2 Real-Time RT-PCR	real-time RT-PCR multiple targets	H
1/31/2024	Revvity	New Coronavirus Nucleic Acid Detection Kit	real-time RT-PCR pooling saliva multiple targets	H
1/26/2024`	Revvity	Respiratory SARS-CoV-2 RT-PCR Panel 1	real-time RT-PCR multiple targets, multi-analytes	H
1/25/2024	Uh-Oh Labs	UOL COVISD-19 Test	RT-LAMP single target	H,M,W

[1] Authorized settings include the following:

H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.

W - Patient care settings operating under a CLIA Certificate of Waiver.

Source: FDA

Antigen tests are rapid tests that produce results in about 15 minutes. Antigen tests detect structural features on the surface of the virus that cause a color change. These tests proliferated during the pandemic, both in the professional arena and the POC/self-tests. There are a significant number of SARS-CoV-2 antigen immunoassay tests that have been granted emergency use authorization (EUA) by the FDA.

Table 3-4: Selected Antigen Immunoassay Tests for SARS-CoV-2, 2024-2025

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]
10/7/2025	CorDx	CorDx TyFast Flu A/B & COVID-19 At Home Multiplex Rapid Test	Lateral Flow, Visual Read, OTC Home Testing, Multi-analyte, Single Target	Home, H,M,W
7/25/2025	Wondfo USA	WELLlife COVID-19/ Influenza A/B Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Multi-analyte, Single Target	Home, H,M,W
7/1/2025	Sekisui	OSOM Flu SARS-CoV-2 Combo Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Multi-analyte, Single Target	Home, H,M,W
7/1/2025	ACON	Flowflex Plus COVID-19 and Flu A/B Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Multi-analyte, Single Target	Home, H,M,W
6/17/2025	iHealth Labs	iHealth COVID-19/Flu A&B Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Multi-analyte, Single Target	Home, H,M,W
6/10/2025	LumiraDx (Roche)	LumiraDx SARS-CoV-2 Ag Test	Microfluidic Immunofluorescence Assay, Instrument Read, Serial Screening, Single Target	H,M,W
3/27/2025	Healgen	Healgen COVID-19/Flu A&B Ag Combo Rapid Test Cassette	Lateral Flow, Visual Read, Multi-analyte, Single Target	H,M,W
3/20/2025	iHealth	IHealth COVID-19/Flu A&B Rapid Test Pro	Lateral Flow, Visual Read, Multi-analyte, Single Target	H,M,W
2/3/2025	Wondfo USA	WELLife COVID-19Influenza A&B Test	Lateral Flow, Visual Read, Multi-analyte, Single Target	H,M,W
1/14/2025	CorDx	CorDx TyFast Flu A/B & COVID-19 AT home Multiplex Rapid Test	Lateral Flow, Visual Read, Multi-analyte, OTC, Single Target	Home, H,M,W
11/18/2024	NanoDitech	Nano-Check Influenza + COVID-19 Dual Test	Lateral Flow, Visual Read, Multi-analyte, Single Target	H,M,W
10/23/2024	Princeton BioMeditech	VirDA SARS-CoV-2/Flu A/B Rapid Antigen Test	Lateral flow, visual read, serial screening, single target	H,M,W
10/18/2024	OSANG	QuickFinder COVID-19/Flu Antigen Self Test	Lateral flow, visual read, OTC, serial screening, single target	Home, H,M,W

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s)[1]
10/9/2024	iHealth	IHealth COVID-19/Flu A&B Rapid Test	Lateral flow, visual read, OTC, serial screening, single target	Home, H,M,W
9/12/2024	SD Biosensor	STANDARD Q COVID-19 Ag Test 2.0	Lateral flow, visual read, serial screening, single target	H,M,W
9/12/2024	OraSure	InteliSwab COVID-19 Rapid Test	Lateral flow, visual read, OTC, serial screening, single target	Home, H,M,W
9/4/2024	SKEISUI	OSOM Flu SARS-CoV-2 Combo Home Test	Lateral flow, visual read, OTC, serial screening, single target	Home, H,M,W
7/10/2024	Genabio Dx	Genabio COVID-19 Rapid Self-Test Kit	Lateral flow, visual read, OTC, serial screening, single target	Home, H,M,W
7/8/2024	Maxim Biomedical	MaximBio ClearDetect COVIDS-19 Antigen Home Test	Lateral flow, visual read, OTC, serial screening, single target	Home, H,M,W
7/1/2024	Advin Biotech	Advin COVID-19 Antigen Test @Home	Lateral flow, visual read, OTC, serial screening, single target	Home. H,M,W
5/8/2024	Watmind USA	Speedy Swab Rapid Covid-19 + Flu A&B Antigen Self-Test	Lateral flow, visual read, OTC, serial screening, single target	Home, H,M,W
4/30/2024	CTK Biotech	ImmuView COVID-19 Antigen Home Test	Lateral flow, visual read, OTC, serial screening, single target	Home, H,M,W
2/1/2024	iHealth	iHealth COVID-19 Antigen Rapid Test Pro	Lateral flow, visual read, serial screening, single target	H,M,W
1/23/2024	Xiamen Boson Biotech	Rapid SARS-CoV-2 Antigen Test Card	Lateral flow, visual read, OTC, serial screening, single target	Home, H,M,W

[1] Authorized settings include the following:

H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.

W - Patient care settings operating under a CLIA Certificate of Waiver.

Source: FDA

Emerging and Emerged Markets

The maturation of IVD markets in developed countries has IVD companies continuing to cast their nets in developing countries, where rising incomes and standards of living are anticipated to spark a new health-conscious population with growing demands for quality medical care. While once the focus was on the BRIC countries, Kalorama Information has identified 12 top emerging markets of interest, including:

- Brazil
- China
- India
- Indonesia
- Malaysia
- Mexico
- Saudi Arabia
- South Africa
- South Korea
- Thailand
- Turkey
- Vietnam

Developed and developing markets are classified using the United Nations economic framework. The following table highlights global developed and developing economies by region. Despite growth in developing regions, developed markets for IVD command the largest share of revenues, 78.6%. Much of this hefty market share is due to major companies' presence in developed markets, consumer demand in those regions, and reduced pricing sensitivity. These factors will likely influence the forecast period to maintain, and slightly grow, the developed market at a faster pace than the developing regions.

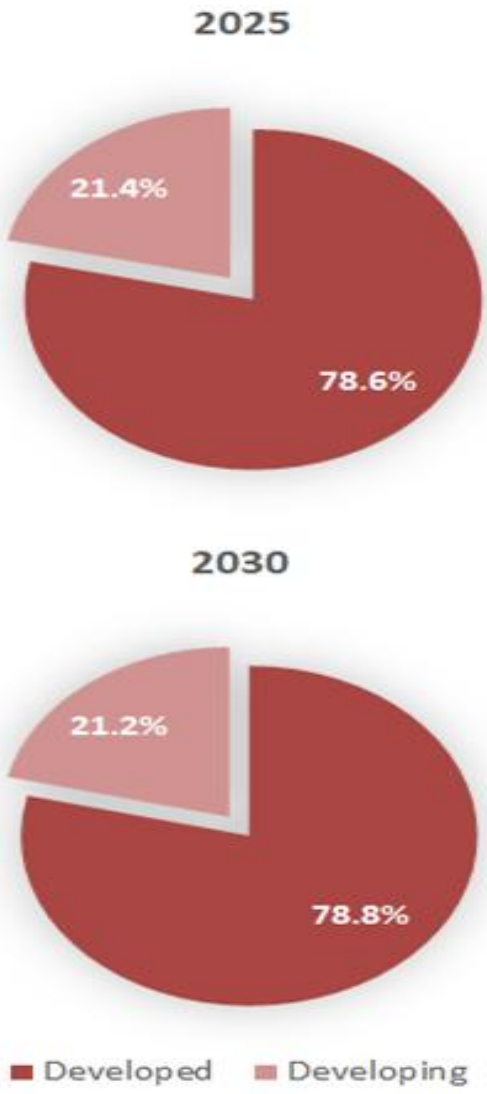
Table 3-5: Developed/Developing Economies, UN Classification* Table, 2025

Developed Economies	Developing Economies
U.S.	Eastern Europe: Poland, Czech Republic, Romania, Slovakia, Hungary, Croatia, Slovenia, Bulgaria, Russia, Estonia, Latvia, Lithuania, Albania, Belarus, Bosnia, Herzegovina, Kosovo, Macedonia, Moldova, Montenegro, Serbia, Ukraine
Canada	Asia & Pacific: China, India, Vietnam, Indonesia, Thailand, Malaysia, Philippines
Europe: Germany, Italy, France, Spain, UK, Belgium, Netherlands, Portugal, Greece, Sweden, Austria, Denmark, Finland, Ireland, Luxembourg, Switzerland, Norway	Latin America: Brazil, Mexico, Colombia, Argentina, Ecuador, Chile, Peru, Venezuela, Bolivia, Costa Rica, Cuba, Dominican Republic, El Salvador, Guatemala, Guyana, Haiti, Honduras, Nicaragua, Panama, Paraguay, Uruguay
Asia Pacific: Japan, South Korea, Australia, New Zealand, Singapore	Middle East: Egypt, Iran, Turkey, Iraq, Saudi Arabia, United Arab Emirates, Jordan
Middle East: Israel	Africa: South Africa

Note: *Status according to the United Nations system (UN M49/UNDP), which uses the developed economies / developing economies / LDC framework.

Source: Kalorama Information

Figure 3-4: Developed vs. Developing IVD Market Shares, 2025 and Projected 2030 (%)



Source: Kalorama Information

Where are the best markets? As a starting point, one major aspect of commercial potential is examining the available market. For this report, the percentage of the population that is urban can be used, since urban populations usually have greater access to healthcare, including physicians, hospitals, clinics, etc. As governments in developing countries expand healthcare infrastructure in rural communities, the diagnostics market is expected to grow

significantly. These diagnostics would cover many primary care segments, including diabetes, anemia, hypertension, infectious diseases, sexually transmitted diseases, and cancer screening.

The following table demonstrates how increases in urbanization provide a large available market. Among the countries listed, China has made the greatest effort to bring healthcare to its rural population; however, recent changes to healthcare infrastructure, aimed at controlling spending, are expected to limit overall growth in the country. Despite changes and potential slowing of growth, China remains an important market opportunity with an aging population.

Table 3-6: Countries To Watch for IVD Opportunities, by Total Population and Percent Urban, 2025

[Australia; Brazil; China; France; Germany; Hungary; India; Mexico; Netherlands; Poland; Romania; Saudi Arabia; South Africa; South Korea; Sweden; Switzerland, Turkey; United Kingdom; United States]

Country	Pop (M)	% Urban
China	1,416	65%
India	1,409	36%
United States	342	83%
Brazil	220	88%
Mexico	131	82%
Turkey	84	78%
Germany	84	78%
United Kingdom	69	85%
France	68	82%
South Africa	60	69%
South Korea	52	82%
Poland	39	60%
Saudi Arabia	37	85%
Australia	27	87%
Netherlands	18	93%
Romania	18	55%
Sweden	11	89%
Hungary	10	73%
Switzerland	9	74%

Source: Kalorama Information

There is an expectation that, with economic growth, the growing middle class will invest and spend dollars on Western-style healthcare. It is Kalorama Information's experience that members of the middle and more affluent classes in developing countries are clients of private healthcare providers.

The United Nations (UN) describes it as a historic shift not seen for 150 years. Throughout history, the vast majority of people in the now most affluent emerging markets (India and Brazil) lived in desperate poverty, living on a dollar a day or less. Yet, these countries are undergoing a remarkable transformation, one that is unfortunately not shared by most of the population. UN statistics indicate that 1.8 billion people made up the worldwide middle class in 2009, 3.5 billion in 2020, and 4.8 billion in 2030. By 2030, Asia will be the home of 3.49 billion middle-class people. It would be 10 times more than in North America and 5 times more than in Europe. By 2050, they are forecast to account for nearly half of world output, far surpassing the G7.

Indonesia is experiencing rising per capita incomes among working professionals and the middle class, which is prompting a shift from self-medication to clinical and hospital treatment, supported by subsidized healthcare services. Maternal and child healthcare has improved in recent years, reducing the child mortality rate.

There is also substantial growth in the rest of the emerging world. The middle class in Latin America is expected to grow from 181 million to 313 million by 2030, with Brazil leading the growth. In Africa and the Middle East, it is projected to more than double, from 137 million to 341 million.

According to the United Nations and the Organization for Economic Co-operation and Development (OECD), members of the middle class vary widely, from people who earn $10 per day to those who earn $100 per day or more. This gives them enough disposable income to invest in consumer goods such as household electronics and cars, but it also allows them to buy healthcare insurance or to become members of healthcare clubs.

While several developing countries will make significant progress in improving prosperity, most will not generate sufficient GDP growth to upgrade their medical delivery systems to developed-world standards. Moreover, ongoing political strife and corruption will preclude many Asian, African, Central and South American, Middle Eastern, and Eastern European nations from realizing needed economic and healthcare gains. Although remaining prosperous, the United States and the vast majority of Western European and other developed

countries (e.g., Australia, Canada, Israel, Japan, New Zealand, Singapore, South Korea, Taiwan, and the United Arab Emirates) will continue to encounter an increasing healthcare cost burden, forcing the adoption of more stringent cost containment initiatives. This was particularly evident in China's growing economic status in recent years and in the 2025 shift in government health structures to control rapid health spending in the country.

Currently, the IVD market in emerging countries and especially the top seven is dominated by established players such as Abbott Diagnostics, Roche Diagnostics, Danaher, Siemens Healthineers, QuidelOrtho and Becton Dickinson. However, literally 100s of domestic players, such as Transasia, SRL, JMitra, Horiba, Kehua, Mindray, Wama, and others, have expanded the distribution of IVD products from urban to rural areas in their respective markets.

In many emerging markets, these domestic players are not only improving distribution in rural and underserved areas but also strengthening their competitive position through localized manufacturing, lower-cost platforms, and greater technological capability. In some segments, particularly in rapid testing and routine diagnostics, and in mid-tier instruments, regional companies are gaining share and competing more directly with multinational suppliers.

Size and Forecast for the Global IVD Market

The global market for traditional in vitro diagnostics is estimated at $116 billion in 2025 and is expected to reach $150 billion by 2030.

These figures represent the traditional IVD market; however, additional revenues of $12.7 billion can be found in the combined segments of flow cytometry, clinical sequencing, prenatal test services, direct-to-consumer genetic testing, digital imaging and other specialized market segments. Major markets, North America, Western Europe, and Japan, with shares of 42%, 27%, and 5%, respectively, make up 74% of the total IVD market in 2025. By 2030, major markets (North America, Western Europe, and Japan) will continue to dominate, accounting for 75% of sales. Overall, developing markets will experience 5% annual growth, while the developed world will see approximately 4.8% annual growth.

Table 3-7: Global In Vitro Diagnostic Market, Major Country/Region Markets, 2025 and 2030 ($ million)

[Australia; Brazil; Canada; China; Eastern Europe; EU 15/W. Europe; India; Japan; Mexico; Peru; Russia; Saudi Arabia; South Africa; South Korea; Turkey; UAE; United States; Vietnam; Rest of World]

Country/Region	2025	% Mkt	2030	% Mkt	CAGR 2025-2030
United States	48,349	42%	64,131	43%	6%
EU 15/W. Europe	31,491	27%	41,236	27%	6%
China	5,997	5%	7,361	5%	4%
Japan	5,726	5%	6,810	5%	4%
Canada	3,429	3%	4,233	3%	4%
Eastern Europe	2,712	2%	3,363	2%	4%
Australia	1,976	2%	2,508	2%	5%
Brazil	1,885	2%	2,581	2%	6%
India	1,390	1%	1,803	1%	5%
Russia	1,307	1%	1,509	1%	3%
Turkey	1,093	1%	1,473	1%	6%
Mexico	839	1%	1,077	1%	5%
Saudi Arabia	676	1%	898	1%	6%
South Korea	521	0%	728	0%	7%
South Africa	377	0%	463	0%	4%
UAE	259	0%	318	0%	4%
Peru	175	0%	214	0%	4%
Vietnam	137	0%	172	0%	5%
ROW	7,220	6%	9,568	6%	6%
Total	**115,559**	**100%**	**150,446**	**100%**	**5%**

Source: Kalorama Information

Table 3-8: Global In Vitro Diagnostic Market, Regional Markets, 2025 and 2030 ($ million)

[Africa, Asia Pacific, Europe, Latin America, Middle East, North America]

Regional Markets	2025	% Mkt	2030	% Mkt	CAGR
North America (United States/Canada)	51,778	45%	68,364	46%	5.7%
Europe (Western/Eastern)	36,176	31%	46,931	31%	5.3%
Asia Pacific	18,249	16%	23,203	15%	4.9%
Latin America	4,333	4%	5,652	4%	5.5%
Middle East	3,969	3%	5,032	3%	4.8%
Africa	1,054	1%	1,264	1%	3.7%
Total	**115,559**	**100%**	**150,446**	**100%**	**5.4%**

Source: Kalorama Information

The following tables show the 2024-2025 year-over-year growth for specific segments as calculated by Kalorama Information.

Table 3-9: Global In Vitro Diagnostic Market, YOY Growth, by Segment, 2024-2025 (%)

[Blood Bank Molecular; Blood Bank Screening – Immunoassays; Blood Grouping/Typing; Clinical Chemistry; Coagulation (PT/INR, Molecular); D-dimer; Diabetes HbA1c, Lab; Drugs of Abuse; Hematology - Core Lab; Histology/Cytology; Immunoassays - Infectious Disease; Immunoassays - Other Immunos; Mass Spectrometry (Micro/Non-Micro); Microbiology (ID/AST); Microbiology (Molecular); NAAT – Oncology; NAAT – Genetic/Inherited; POC, OTC Glucose OTC; POC Continuous Glucose; POC, OTC Other; POC, Professional/Hospital]

Segment	2024-2025 (YOY %)
POC continuous glucose	16.1%
HPV, molecular	12.3%
Hematology - core lab	7.3%
Mass spectrometry (micro/non-micro)	6.3%
NAAT - oncology	5.7%
Non-infectious – immunoassays	5.3%
Coagulation - (PT/INR, molecular)	5.2%
Histology/cytology	5.0%
Diabetes HbA1c, lab	4.4%
POC, professional/hospital	4.4%
Clinical chemistry	4.0%
Microbiology (ID/AST)	3.2%
Blood grouping/typing	3.0%
Blood bank screening – molecular	2.6%
NAAT - Genetic/Inherited	2.4%
Drugs of abuse – immunoassays	1.8%
D-dimer	1.4%
POC, OTC other	1.1%

Segment	2024-2025 (YOY %)
Infectious disease – Immunoassays	0.8%
POC Glucose OTC	0.7%
Microbiology (molecular)	-1.5%
Blood bank screening – immunoassays	-3.5%
Other (circulating tumor cells, transplant testing, other, etc.)	14.7%

Source: Kalorama Information

Table 3-10: Global In Vitro Diagnostic Market, Regional Markets, 2024-2025 YOY Change (%)

[Africa, Asia Pacific, Europe, Latin America, Middle East, North America]

Region	2024-2025 (YOY %)
Latin America	5.5%
Middle East	5.3%
North America (United States/Canada)	5.2%
Asia Pacific	4.1%
Europe (Western/Eastern)	3.5%
Africa	2.9%

Source: Kalorama Information

The IVD Market in the United States

The U.S. market dominates the IVD industry. In 2025, IVD systems and related consumables accounted for $48,349 million ($48.3 billion), representing 41% of the global IVD market. The U.S. major IVD market is in a state of flux, trying to manage a myriad of issues, all of which collide with a huge system that costs more than any other in the world.

Table 3-11: United States IVD Market Share, by Segment, 2025 (%)

[Blood Grouping; Clinical Chemistry; Coagulation; Hematology; Histology; Immunoassay Infectious Disease; Immunoassay Other; Microbiology ID/AST; Microbiology Molecular; Nucleic Acid Assays; POC Diabetes; POC Other; Others]

Segment	Share (%)
POC Diabetes	20.4%
POC Other	13.5%
Immunoassay Infectious Disease	13.2%
Immunoassay Other	10.9%
Microbiology Molecular	9.2%
Clinical Chemistry	8.3%
Nucleic Acid Assays	6.5%
Histology	4.7%
Hematology	4.7%
Microbiology ID/AST	3.8%
Coagulation	2.3%
Blood Grouping	1.1%
Others	1.4%
Total	**100%**
Total Market ($ million)	**$48,349**
Clinical Sequencing ($ million)	$3,203

Source: Kalorama Information

Healthcare in the United States is in a continuous cycle of change through various administrative policies. In the U.S., the American Hospital Association estimates that at least 70% of hospitals are members of a hospital system or participate in a group purchasing organization. Thus, the majority of labs located in the largest single market for IVD products,

the U.S., acquire their instruments, reagents, and supplies for routine tests at negotiated and large discounted prices.

CMS released a report highlighting expenditures. The major findings for national health expenditures 2023-2032 were:

- National health spending is projected to grow at an average annual rate of 5.6 percent for 2023-2032.
- Because national health expenditures are projected to grow 4.3 percentage points faster than gross domestic product per year on average over 2023–2032, the health share of the economy is projected to rise from 17.3 percent in 2022 to 19.7 percent in 2032.
- Among major payers, Medicare is expected to experience the fastest spending growth (7.4 percent per year over 2023-2032), largely as a result of having the highest projected enrollment growth.
- Medicaid projected spending is projected to be 5.2% - stabilizing after 2024.
- Private health insurance spending over 2023-2032 is projected to be 5.6%
- Out-of-pocket spending is projected to average 4.7% during 2023-2032.
- Average annual retail prescription drug spending is expected to be 6% over 2023-2032.

PAMA and Reimbursement Changes

For the foreseeable future, healthcare payers will continue to wrestle with escalating healthcare costs. Each year, CMS releases new payment rates for medical products and procedures. The "Protecting Access to Medicare Act of 2014" (PAMA) marked the first substantial change to the clinical laboratory fee schedule since it was created nearly 30 years ago. These PAMA regulations reflect changes based on usage and other factors; they are designed to incorporate economies of scale and reduce excess expense, but significant year-over-year changes for some products can create major problems for manufacturers.

After decades of program cuts, reconfigurations and substitutions, momentum is increasing around a new model: value-based care and its corollary, value-based reimbursement. This initiative is part of the Merit-based Incentive Payment System (MIPS), which combines

elements of the Physician Quality Reporting System (PQRS), the Value-based Payment Modifier (VBM), and the Medicare Electronic Health Record Incentive Program into a single program under the Medicare Access and CHIP Reauthorization Act (MACRA).

PAMA was designed to introduce a more market-based approach to Medicare reimbursement for laboratory testing by aligning Clinical Laboratory Fee Schedule rates with private payer pricing, replacing earlier broad-based reductions with a data-driven methodology. In practice, the law has exerted downward pressure on reimbursement for many routine, high-volume tests, although the pace and magnitude of cuts have been moderated by ongoing legislative delays and adjustments. The pricing environment has contributed to continued consolidation within the clinical laboratory market and has increased focus across the IVD industry on developing higher-value, more specialized, and clinically actionable assays. Smaller and independent laboratories have faced greater challenges adapting to these changes due to limited scale and pricing flexibility, reinforcing competitive advantages for larger, more diversified companies.

Impact of CARES Act on PAMA

As a response to the Coronavirus at the start of 2020, the US Congress passed an amendment to the PAMA reductions scheduled for 2021. This amendment includes a suspension of the reimbursement rate reductions. On February 3, 2026, requirements were passed for CDLTs that are not ADLTs. The next reporting period will be from May 1, 2026, to July 31, 2026, and, based on the updated data, the collection period is set for January 1, 2025, through June 30, 2025. There is no phase-in reduction in 2026.

Table 3-12: Proposed Clinical Diagnostic Laboratory Test (CDLT) Rates, 2020-2027

CDLT Rates	Based on Reporting Period	Reduction Cap
2020	January 1, 2017 - May 30, 2017	10%
2021	January 1, 2017 - May 30, 2017	0%
2022	January 1, 2017 – May 30, 2017	0%
2023	January 1, 2017 – May 30, 2017	0%
2024	January 1, 2017 – May 30, 2017	0%
2025	January 1, 2017 – May 30, 2017	0%
2026	January 1,2017 – May 30, 2017	0%
2027	May 1, 2026 -July 31, 2026	15%

Source: Centers for Medicare and Medicaid.

Saving Access to Laboratory Service Act (SALSA)

Legislation known as the Saving Access to Laboratory Services Act (SALSA) has been proposed to make significant, more permanent modifications to PAMA requirements governing how Medicare Clinical Laboratory Fee Schedule rates are determined. The legislation is intended to address ongoing concerns around data reporting methodology and the magnitude of reimbursement reductions for routine laboratory testing. Industry groups, including the American Clinical Laboratory Association, have continued to advocate for reform through initiatives such as the Stop Lab Cuts campaign, emphasizing the impact of sustained reimbursement pressure on patient access, laboratory sustainability, and investment in innovation. While there has been bipartisan interest in addressing these issues, SALSA has faced repeated delays and has not yet been enacted as a permanent solution, leaving reimbursement uncertainty as an ongoing challenge for the clinical laboratory and IVD sectors.

LDT Update

The laboratory-developed test (LDT) market can be viewed as a subset of the broader IVD industry. The FDA defines an LDT as an in vitro diagnostic test that is designed, manufactured, and used within a single laboratory operating under a CLIA certificate. LDTs, often referred to as in-house or "home brew" tests, are considered medical devices under the Federal Food, Drug, and Cosmetic Act. Historically, however, the FDA has exercised enforcement discretion, choosing not to actively regulate most LDTs through premarket review, while CMS maintains oversight of laboratory operations and test performance under CLIA.

LDTs were originally developed to address unmet clinical needs where no commercial tests were available, but advances in technology have significantly increased their complexity. Many LDTs now resemble commercially distributed IVD tests in terms of sophistication, clinical application, and risk profile. This evolution has driven ongoing debate over the appropriate level of regulatory oversight. For decades, the FDA has maintained that it has authority to regulate LDTs but has taken a limited approach, while laboratories have continued to develop and offer these tests under CLIA, provided they are not distributed as kits to other laboratories.

Efforts to formalize FDA oversight, including proposals such as the VALID Act, have been discussed for several years but have not been enacted, leaving the regulatory framework unsettled. In April 2024, the FDA issued a final rule intended to bring LDTs more fully under its medical device regulatory framework. However, in March 2025, a federal court vacated the rule, determining that the FDA's approach exceeded its statutory authority under existing law. Following this decision, the FDA declined to appeal and in late 2025 formally reverted to its prior enforcement discretion framework, restoring the long-standing regulatory approach under CLIA.

As a result, LDTs are offered without FDA clearance under the traditional enforcement discretion model, while debate over future oversight continues among regulators, industry stakeholders, and policymakers. The court decision has shifted the path forward toward potential legislative action rather than agency rulemaking, leaving the long-term regulatory framework unresolved. As advances in molecular diagnostics, precision medicine, and point-of-care testing continue to expand the scope and clinical impact of LDTs, laboratories and developers will need to remain adaptable, ensuring robust analytical and clinical validation while preparing for potential future changes in regulatory requirements.

Bundled Insurance Payments for ESRD Patients

Under updated Medicare payment policies, certain patient populations are subject to bundled reimbursement models, most notably patients receiving dialysis for end-stage renal disease (ESRD). In January 2011, CMS implemented the ESRD Prospective Payment System (PPS), which introduced a comprehensive dialysis payment bundle. This system combined previously separate payments for dialysis services, including many routine laboratory tests associated with dialysis treatment, into a single per-treatment payment. Over time, the bundle has been refined and expanded, reinforcing the shift toward consolidated reimbursement for dialysis-related care. The bundled approach primarily applies to laboratory tests directly related to ESRD management, while unrelated tests may still be billed separately. Although oral medications were initially excluded and covered under Medicare Part D, CMS has continued to evaluate and phase in certain ESRD-related oral drugs into the bundled payment structure, with implementation timelines extending into the later part of the decade.

Table 3-13: Laboratory Tests Subject to ESRD Consolidated Billing

Test Code	Description	Test Code	Description
80047	Basic Metabolic Panel (ionized)	84157	Assay of protein by other source
80048	Basic Metabolic Panel (total)	84295	Assay of serum sodium
80051	Electrolyte Panel	84466	Assay of transferrin
80053	Comprehensive Metabolic Panel	84520	Assay of urea nitrogen
80069	Renal Function Panel	84540	Assay of urine/urea-N
80076	Hepatic Function Panel	84545	Urea-N clearance test
82040	Assay of serum albumin	85014	Hematocrit
82108	Assay of aluminum	85018	Hemoglobin
82306	Vitamin D, 25 hydroxy	85025	Complete CBC, automated (HgB, HCT, RBC, WBC, and Platelet Count) and automated differential WBC
82310	Assay of calcium	85027	Complete CBC, automated (HgB, HCT, RBC, WBC, and Platelet count)
82330	Assay of calcium, iodized	85041	Automated RBC count
82374	Assay, blood carbon dioxide	85044	Manual reticulocyte count
82379	Assay of carnitine	85045	Automated reticulocyte count
82435	Assay of blood chloride	85046	Reticyte/HgB concentrate
82565	Assay of creatinine	85048	Automated leukocyte count
82570	Assay of urine creatinine	86704	Hepatitis B core antibody, total
82575	Creatinine clearance test	86705	Hepatitis B core antibody, IGM
82607	Vitamin B12	86706	Hepatitis B surface antibody
82652	Vitamin D1, 25 dihydroxy	87040	Blood culture for bacteria
82668	Assay of erythropoietin	87070	Culture, bacteria, other
82728	Assay of ferritin	87071	Culture, bacteria aerobic other
82746	Blood folic acid serum	87073	Culture, bacteria anaerobic

Test Code	Description	Test Code	Description
83540	Assay of iron	87075	Culture, bacteria, except blood
83550	Iron binding test	87076	Culture, anaerobic identify, each
83735	Assay of magnesium	87077	Culture, aerobic identify
83970	Assay of parathormone	87081	Culture screen only
84075	Assay alkaline phosphatase	87340	Hepatitis B surface AG, EIA
84100	Assay of phosphorus	87341	Hepatitis B surface AG, EIA
84132	Assay of serum potassium	G0499	HepB screen high risk indiv
84134	Assay of prealbumin	G0306	CBC/diff WBC w/o Platelet
84155	Assay of protein, serum	G0307	CBC w/o Platelet
84157	Assay of protein by other source	-	Protein composition of CSF
84295	Assay of serum sodium	-	Sodium concentration in serum, plasma or whole blood

Source: CMS ESRD PPS Consolidated Billing List

Under the previous reimbursement structure, a composite rate system was used to pay dialysis facilities, with rates set at a fixed amount per treatment and adjusted through Congressional action. While this system covered certain core dialysis services, many items, such as drugs and laboratory tests, were reimbursed separately. Medicare generally serves as the primary payer for ESRD patients who are not covered by employer-sponsored insurance, typically after an initial coordination period, and is available to individuals age 65 and older as well as to younger patients with qualifying disabilities or ESRD. Patients who do not qualify for Medicare may access state assistance programs, while certain populations, such as veterans, may receive care through other federal systems.

Under the Medicare ESRD program, Medicare typically covers 80% of the approved reimbursement amount, with patients responsible for the remaining 20%, although this portion is often supplemented by secondary insurance or Medicaid. While bad debt levels in the dialysis industry are relatively low, they are largely associated with uncollected patient co-insurance obligations.

Since the implementation of the ESRD Prospective Payment System (PPS) in 2011, reimbursement has shifted to a bundled payment model that includes dialysis-related services, drugs, and many laboratory tests. CMS continues to update the ESRD PPS annually. For calendar years 2024 and 2025, CMS finalized modest payment increases along with ongoing policy refinements. For calendar year 2026, CMS continued this trend, increasing the base rate to approximately $281.71 and projecting a modest overall payment increase of just over 2%. The bundled reimbursement structure remains unchanged, with ongoing refinements to wage index adjustments, outlier payment thresholds, and add-on payments for drugs, equipment, and training. However, providers continue to face cost pressures from labor, staffing, and operating expenses, underscoring the importance of efficiency within the bundled payment framework.

Advanced Laboratory Tests (ADLT)

Advanced laboratory tests are evaluated separately for payment structures. To qualify as an ADLT, the test must meet one of the following criteria:

Criterion (A): The test:

- Is an analysis of multiple biomarkers of DNA, RNA, or proteins.

- When combined with an empirically derived algorithm, it yields a result that predicts the probability a specific individual patient will develop a certain condition or conditions, or respond to a particular therapy or therapies;
- Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
- May include other assays.
- Criterion (B): The test is cleared or approved by the FDA.
- Laboratories requesting ADLT status under Criterion (B) are required to submit documentation of premarket approval or premarket notification from the FDA.

Table 3-14: List of Approved ADLTs, March 2026

Test Code	Company	Test Name	Test Descriptor	Approval Date	New ADLT Initial Period	Payment Amount for Dates of Service Before Initial Period	Payment Amount for Dates of Service During New ADLT Initial Period
0537 U	Guardant Health	Shield	Oncology analysis of cell-free DNA for epigenomic patterns, NGS >2500 differentially methylated regions, plasma, algorithm, reported as positive or negative	09/10/2025	4/1/2025-12/31/2025	Contractor Priced	$1,495
0473 U	Tempus AI	xT CDx	ONC SLD Tum BLD/SLV 648 GENE	06/26/2024	7/1/2024-3/31/2025	Contractor Priced	$4,500
0356U	Naveris	NavDx	Oncology eval of 17 DNA biomarkers using ddPCR, cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence	03/18/2024	4/1/2024-12/31/2024	Contractor Priced	$1,800
0315U	Castle Biosciences	DecisionDx-SCC	Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result (i.e., Class 1, Class 2A, Class 2B)	06/30/2023	7/1/2023-3/31/2024	Contractor Priced	$8,500
0360U	Biodesix	Nodify CDT	Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy	06/30/2023	n/a	n/a	n/a

Test Code	Company	Test Name	Test Descriptor	Approval Date	New ADLT Initial Period	Payment Amount for Dates of Service Before Initial Period	Payment Amount for Dates of Service During New ADLT Initial Period
0295U	PreludeDx	DCISionRT	Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, SIAH2), with 4 clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a recurrence risk score	03/23/2023	4/1/2023-12/31/2023	Contractor Priced	$2.350
01080	Castle Biosciences	TissueCypher Barrett's Esophagus Assay	Gastroenterology (Barrett's esophagus), whole slide–digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer	03/24/22	4/1/22-12/31/22	Contractor Priced	$2,350
TBD	Natera	Signatera	TBD	6/17/21	7/1/21-3/31/22	Contractor Priced	$3,500
0242U	Guardant Health, Inc.	Guardant360 CDx	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements	3/18/2021	4/1/21 – 12/31/21	Contractor Priced	$5,000

Test Code	Company	Test Name	Test Descriptor	Approval Date	New ADLT Initial Period	Payment Amount for Dates of Service Before Initial Period	Payment Amount for Dates of Service During New ADLT Initial Period
0239U	Foundation Medicine, Inc.	FoundationOne Liquid CDx	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations	1/25/2021	4/1/21 – 12/31/21	Contractor Priced	$3,500
81554 (eff. 7/1/2020)	Veracyte	Envisa Genomic Classifier	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])	9/17/2020	10/1/20-6/30/21	Contractor Priced	$5,500
0172U (eff. 7/1/2020)	Myriad	myChoice CDx	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	12/11/2019	1/1/20-9/30/20	Contractor Priced	$4,040.00
0090U	Myriad	myPath Melanoma	Oncology (cutaneous melanoma), mRNA gene expression profiling by RTPCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (i.e., benign, indeterminate, malignant)	9/6/2019	10/1/19-6/30/20	Contractor Priced	$1,950.00

Test Code	Company	Test Name	Test Descriptor	Approval Date	New ADLT Initial Period	Payment Amount for Dates of Service Before Initial Period	Payment Amount for Dates of Service During New ADLT Initial Period
0080U	Biodesix	BDX-XL2	Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy	5/17/2019	7/1/19-3/31/20	Contractor Priced	$3,520.00
81529 (eff. 1/1/2021)	Castle Biosciences, Inc.	DecisionDx-Melanoma	Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis	5/17/2019	7/1/19-3/31/20	Contractor Priced	$7,193.00
81552* (eff. 1/1/2020) (Previously 0081U)	Castle Biosciences, Inc.	DecisionDx-UM	Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis	5/17/2019	N/A	N/A	N/A
81538*	Biodesix	Veristrat	Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival (VeriStrat, Biodesix, Inc.)	12/21/2018	N/A	N/A	N/A

Test Code	Company	Test Name	Test Descriptor	Approval Date	New ADLT Initial Period	Payment Amount for Dates of Service Before Initial Period	Payment Amount for Dates of Service During New ADLT Initial Period
0037U	Foundation Medicine, Inc.	FoundationOne CDx	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	5/18/2018	7/1/18 - 3/31/19	Contractor Priced	$3,500.00

*Existing ADLT. An existing ADLT is a laboratory test for which ADLT status has been granted by CMS and payment for the test has been made under the Medicare CLFS prior to January 1, 2018.

See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/Guidance-for-Laboratories-on-ADLTs.pdf for more information.

Source: CMS

Precision Medicine and NGS

Precision medicine refers to the tailoring of disease prevention, diagnosis, and treatment to the individual characteristics of each patient. While traditional medical approaches have historically followed a one-size-fits-all model, it is now well understood that patients can respond very differently to the same therapy. Advances in precision medicine have led to the development of targeted therapies and diagnostic tools based on genetic, molecular, and phenotypic characteristics, particularly in oncology, where molecular testing is now routinely used to guide treatment decisions, improve clinical outcomes, and reduce unnecessary toxicity.

The success of precision medicine is closely tied to the quality and depth of diagnostic testing. Next-generation sequencing has become a cornerstone technology, enabling rapid and comprehensive analysis of large portions of the genome. These tests allow clinicians and researchers to identify genetic variants that inform diagnosis, guide therapy selection, and improve understanding of disease biology. As a result, NGS has moved from a specialized research tool to a core component of clinical care in areas such as cancer, rare disease, and infectious disease.

The FDA continues to play a role in ensuring that NGS-based tests are accurate, reliable, and clinically meaningful. The large volume and complexity of data generated by sequencing technologies present regulatory challenges compared to traditional single-analyte tests. In response, the FDA has worked with stakeholders across industry, academia, and healthcare to support more flexible regulatory approaches that incorporate evolving standards, curated genomic databases, and advanced bioinformatics methods. Earlier guidance helped establish pathways for demonstrating analytical and clinical validity.

In recent years, NGS-based companion diagnostics have become increasingly common, supporting the use of targeted therapies across a range of cancers. Assays such as Oncomine Dx Target Test and FoundationOne CDx reflect the growing integration of genomic profiling into routine oncology care. More recently, precision medicine has continued to evolve toward highly individualized approaches, with growing interest in therapies designed for very small patient populations or even single patients, particularly in rare diseases. Advances in artificial intelligence, gene editing technologies, and bioinformatics are expanding the ability to identify actionable targets, optimize treatment selection, and support clinical decision-making. In addition, sequencing technologies are increasingly used not only for diagnosis but also to support therapy development, safety assessment, and clinical trial design

IVD Market in Europe

The IVD industry in Europe is undergoing significant regulatory change under the In Vitro Diagnostic Regulation (IVDR 2017/746), which replaced the previous IVDD framework. Although the regulation formally took effect on May 26, 2022, full implementation has been phased in through extended transition timelines that now run into 2027–2028 for many devices. The IVDR introduces stricter compliance requirements, expanded expectations for clinical evidence, and a risk-based classification system designed to enhance patient safety, improve product performance, and increase market transparency.

Key developments include:

- Notified Bodies are now designated to assess IVD devices under IVDR; however, capacity constraints remain, contributing to longer certification timelines and ongoing bottlenecks.
- IVDs are classified into risk categories (Classes A–D), with higher-risk devices subject to more rigorous conformity assessment and oversight.

- Many manufacturers have experienced delays in transitioning to IVDR due to increased regulatory complexity, higher data requirements, and limited Notified Body availability.
- Transitional provisions have been extended to avoid supply disruptions, allowing legacy devices to remain on the market while manufacturers work toward compliance.

The impact of IVDR is increasingly evident across the European IVD market. Many manufacturers are rationalizing their product portfolios, prioritizing higher-volume, higher-margin assays while discontinuing lower-volume or niche tests due to increased compliance costs and complexity. This has raised concerns about potential gaps in test availability, particularly for specialized or rare disease diagnostics.

Notified Body capacity, while improved compared to earlier years, remains constrained relative to demand, requiring manufacturers to plan submissions well in advance. At the same time, regulatory scrutiny of laboratory-developed tests has increased, prompting hospital and reference laboratories to reassess their test menus and documentation processes to ensure compliance, potentially shifting some testing toward commercially available IVD kits.

The cost of compliance has risen significantly, driven by requirements for clinical evidence, performance evaluation, post-market surveillance, and quality system upgrades. Smaller companies in particular face challenges in meeting these requirements, contributing to ongoing market consolidation. Despite these challenges, IVDR is expected to improve overall quality, transparency, and standardization in the European IVD market, while strengthening alignment between diagnostics, clinical evidence, and precision medicine applications.

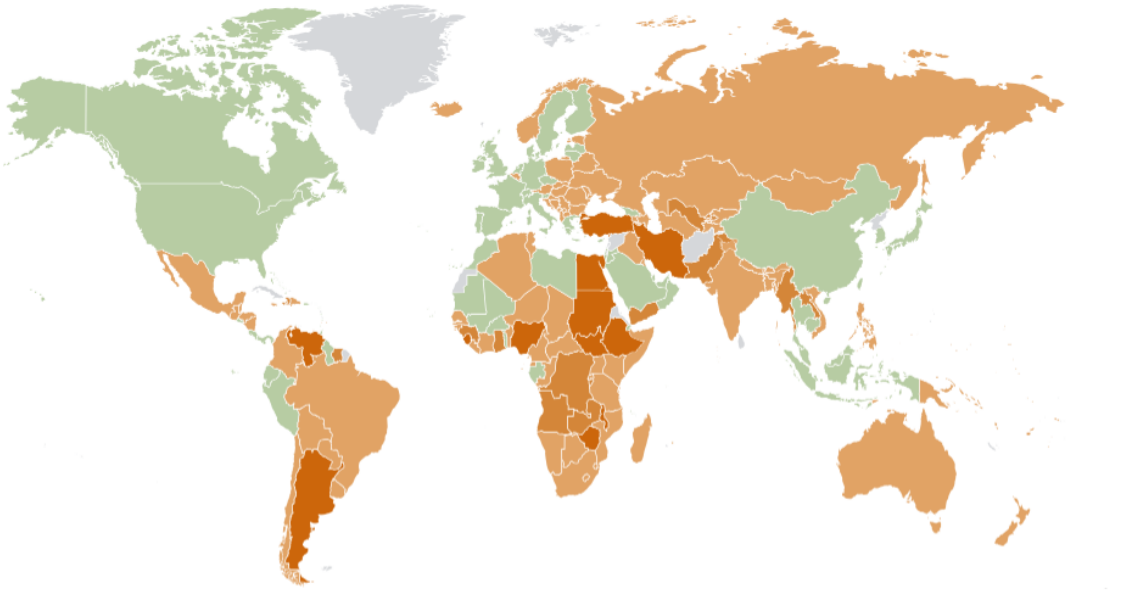
The European IVD market has stabilized following pandemic-related disruption, although economic growth remains modest. Ongoing geopolitical tensions and elevated energy and commodity costs continue to influence the broader economic environment. Growth in the region has been relatively slow but stable, with gradual improvement expected as regulatory clarity increases and healthcare systems adapt to new requirements. In the IVD sector, the market continues to show gains across all segments in 2025.

Glucose testing is roughly 18% of the European IVD markets. Despite the increasing number of type 2 diabetic patients, there remains a significant barrier to adoption due to cost. Prior to COVID-19, European markets were experiencing improved economic stability and rising

GDP. There is still a great deal of uncertainty about economic stability due to the lingering Russia-Ukraine conflict. The following information from the European Commission describes economic indicators from 2020 through 2024 for select European countries.

Kalorama Information's research indicates that the UK has increased demand for precision medicine; France has seen technological advancements that are driving growth; and Germany has increased demand for early disease detection.

Figure 3-5: International Monetary Fund Inflation Map, Global 2024



Region	Value	Region	Value
Africa (Region)	18.4	Middle East (Region)	10.7
Asia and Pacific	5	North Africa	19.7
Australia and New Zealand	3.5	North America	3
Caribbean	6.8	Pacific Islands	4.2
Central America	3	South America	no data
Central Asia and the Caucasus	41.4	South Asia	6.7
East Asia	1.3	Southeast Asia	3
Eastern Europe	5.7	Sub-Saharan Africa (Region)	17.6
Europe	3.4	Western Europe	2.4

Source: International Monetary Fund

In 2025, the countries in Western Europe account for 27% of the global IVD market. Country market estimates are detailed below.

Table 3-15: Western European IVD Market, by Country, 2025 ($ million, estimated)

[Austria; Belgium; Denmark; Finland; France; Germany; Greece; Ireland; Italy; Luxembourg; Netherlands; Norway; Portugal; Spain; Sweden; Switzerland; UK]

Country	Sales
Germany	9,244
France	4,958
UK	4,160
Italy	3,465
Spain	2,667
Netherlands	1,301
Switzerland	1,256
Sweden	741
Belgium	737
Austria	692
Denmark	437
Portugal	407
Greece	363
Ireland	356
Finland	321
Norway	216
Luxembourg	170
Total	**31,491**

Source: Kalorama Information

EU Regulation

The European Directive 98/79/EC on in vitro diagnostic medical devices provides Europe with one single regulation for in vitro diagnostics (IVD). Devices receiving the CE mark after a successful conformity assessment procedure can be introduced into 32 European member countries and those that have signed agreements.

The IVDR introduces a new risk-rule classification system based on the Global Harmonization Task Force (GHTF) classification rules, which, for the first time, takes patient impact into account. This change to the classification system will affect all IVD manufacturers. The majority of IVDs are currently self-declaring devices, but under the new regulation, about 80% of IVDs require some form of conformity assessment by a Notified Body.

Under the IVD Directive, approximately 80% of IVDs on the EU market are self-declared devices, in which the manufacturer has sole responsibility for meeting the directive's requirements. Under the new regulation, 80% of IVDs will require some form of conformity assessment by a Notified Body. The new in vitro diagnostic medical device regulations contain a series of important improvements to modernize the current system. These include:

- Classification and Conformity Assessment - In the new classification system, IVD devices will be divided into four classes of risk: A (lowest risk), B, C and D (highest risk). Using the seven classification rules, devices will be divided into one of four classes that dictate notified body involvement. The conformity assessment procedure for the lowest-risk Class A devices will be the manufacturer's sole responsibility. Class B, C, and D devices are characterized by increasing risk levels and will all require involvement of a notified body.
- Clinical Evidence - A performance evaluation report that includes the scientific validity report, the analytical performance report, the clinical performance report, and an assessment of these reports will be required; the reinforcement of clinical evidence, including an EU-wide coordinated procedure for authorization of multi-center clinical investigations.
- Identification and Traceability - Manufacturers must have a UDI (unique device identification) on the device label. Additionally, manufacturers of high-risk Class C and D devices are to make publicly available a summary of safety and performance.

- Notified Bodies - The position of notified bodies in relation to manufacturers will be significantly strengthened. They have a right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on devices. The regulation also requires rotation of the notified body's personnel involved in IVD assessments at appropriate intervals to strike a reasonable balance with the knowledge and experience required to carry out thorough assessments.
- Vigilance and Market Surveillance - An electronic portal will be introduced, where manufacturers can report serious incidents, safety corrective actions, field safety notices and periodic summary reports. There is also a reduction for reporting a serious incident to the national competent authority within 15 days of the manufacturer becoming aware of the incident.
- Companion Diagnostics - Companion diagnostics will be classified in Class C and will require notified body involvement.

Concerns about the capacity of the European Union's notified body system to support timely certification under the Medical Device Regulation and In Vitro Diagnostic Regulation remain an issue in the regulatory landscape in 2026, although conditions have improved compared to the early implementation period. The approval pathway was slower than expected, creating significant bottlenecks for manufacturers seeking conformity assessment. While the number of designated notified bodies has increased substantially since then, capacity remains uneven across product categories and risk classes, particularly for complex and higher-risk devices and IVDs. As a result, manufacturers continue to face extended timelines and must engage early with notified bodies to secure review slots.

The MDR became applicable in May 2021 following a one-year pandemic-related delay, and the IVDR became applicable in May 2022. Since that time, additional legislative measures have extended transition periods, in some cases into the latter part of the decade, allowing for a more gradual implementation and helping to reduce the risk of product shortages and certification backlogs. Guidance from European regulatory authorities has expanded significantly, providing greater clarity, although the interpretation of requirements, particularly in areas such as clinical evidence, performance evaluation, and post-market surveillance, continues to evolve, placing ongoing demands on manufacturers.

The regulatory framework is now firmly established but remains under operational pressure. The notified body network has expanded, yet access to capacity and specialized expertise continues to limit the pace of certification and recertification, especially for higher-risk IVDs. At the same time, the gradual rollout of systems such as EUDAMED, along with continued regulatory refinements, reflects a transition toward stabilization rather than disruption. The system is functioning, but it remains resource-constrained, and manufacturers are increasingly taking a more strategic approach to portfolio management and regulatory planning. Early engagement with notified bodies and proactive compliance strategies remains essential for maintaining market access in Europe.

Table 3-16: IVD Market Per Capita, Europe, 2025 Estimates

[Bulgaria; Croatia; Czech Republic; France; Germany; Greece; Hungary; Italy; Lithuania; Netherlands; Poland; Romania; Russia; Serbia; Slovakia; Slovenia; Spain; Sweden; Switzerland; Ukraine; UK]

Country	USD ($)
Bulgaria	13.97
Croatia	33.33
Czech Republic	24.91
France	70.16
Germany	107.69
Greece	32.38
Hungary	29.29
Italy	55.70
Lithuania	35.38
Netherlands	71.80
Poland	26.85
Romania	22.98
Russia	9.08
Serbia	34.18
Slovakia	26.96
Slovenia	46.67
Spain	54.59
Sweden	68.87
Switzerland	163.03
Ukraine	6.89
United Kingdom	59.37

Source: Kalorama Information

Precision Medicine in Europe

Precision medicine is an important component of European healthcare strategies as governments balance cost pressures with the need to improve clinical outcomes. While Europe was initially slower than the United States to implement precision medicine, adoption has accelerated significantly, particularly in oncology and rare diseases, where biomarker-driven testing is now part of routine clinical practice in many markets. Reimbursement systems across Europe remain fragmented and continue to adapt to the complexity of advanced diagnostics, but they are no longer uniformly constrained. Germany, the UK, and France continue to lead with more structured reimbursement pathways, due to established national genomics programs, health technology assessment frameworks, and targeted investment in precision medicine infrastructure. The UK stands out for its coordinated national approach to genomics and testing, while other countries, including the Netherlands and the Nordic region, have made meaningful progress in integrating precision diagnostics into clinical care, although funding levels and access continue to vary.

Despite this progress, there is still no fully harmonized EU-wide system for reimbursement of precision medicine diagnostics, as coverage and pricing decisions remain at the national level. However, coordination across Europe in evaluating clinical evidence is increasing, supported by emerging EU-level health technology assessment frameworks and greater alignment among regulatory and HTA bodies. This has begun to reduce duplication and improve consistency in clinical review, although it has not eliminated differences in reimbursement outcomes. As a result, precision medicine in Europe is no longer confined to pilot programs, but it is also not yet uniformly accessible, with ongoing disparities in reimbursement, infrastructure, and clinical implementation across the region.

Brexit

In June 2022, new regulations were published by the UK's Medicines and Healthcare products Regulatory Agency (MHRA). The new regulations improve the safety of medical devices. At present, these regulations only apply to Great Britain. The MHRA will allow products that have CE marking to remain on the market until July 2028.

Japan

Japan remains a strong IVD participant. It is highly structured, and it has a strong regulatory architecture. Japan's regulatory process remains rigid. Japan's IVD sector is well organized and it provides long-range opportunities. There has been an uptick in demand for CDx tests.

Japan's IVD sector emphasizes domestic manufacturing, which concentrates in hematology, immunochemistry, companion diagnostics, molecular diagnostics, and point-of-care testing. Japan's IVD sector encourages AI-enhanced platforms, rapid immunoassays and at-home testing.

In 2025, the Japanese market for IVDs is estimated at nearly $5,726 million, growing at an average annual rate of 3.5%. The market will reach roughly $6,810 million in 2030. Japan is the second-largest single-country market after the U.S. and thus holds an important place in the IVD market. While the market for IVDs in Japan remains stable, the Japanese government battles significant challenges in containing overall healthcare costs as its population ages and the national budget deficit continues to expand.

Healthcare spending represents about 10.8% of GDP in Japan. Exacerbating the issue is the "2025 problem", in which all baby boomers in Japan will have at least reached the age of 75, which will increase healthcare costs even further, as the government foots a greater portion of the bill for citizens who reach that age. The Japanese government will continue to evaluate budget requests to address growing demands for health services.

Overall, this is a large market but not a growth opportunity for new IVD vendors. Global leaders have a strong grip on the market, and significant local competition is also a factor. Entry into the Japanese IVD market is hard, with many regulatory hoops to navigate and a strong domestic market.

General influences affecting the level and mix of clinical chemistry product demand in Japan include a prosperous but slow-growing economy; a steadily aging, gradually shrinking population; and an advanced, well-distributed medical delivery system. More direct influences include hospitalization, surgical, and outpatient consultation rates that are well above global averages, as well as tight government controls on healthcare benefits and costs.

Healthcare coverage in Japan is provided through a broad-based social insurance system operated by the Ministry of Health and Welfare (MHW). The system incorporates two major

types of health plans, occupational and regional. Occupational plans, managed either by health insurance societies or government agencies, cover private employees, government workers, merchant seamen, teachers, and their dependents. Specific benefits include up to 80 percent reimbursement for hospital care, outpatient care, nursing care services, and ambulance transportation. In addition, the plans pay for up to 70 percent of prescription drugs and medical supplies. Dependent coverage is set at 80 percent for inpatient services and 70 percent for outpatient care and medical products.

Funding for occupational health plans is obtained from payroll taxes and employer contributions, with the MHW absorbing all or part of the administrative expenses. In addition to primary healthcare, these plans provide varying levels of benefits for lost wages, maternity leave, and funeral costs. About two-thirds of the population is eligible for occupational health insurance. Residents who are not enrolled in occupational health plans (including retirees, agricultural workers, self-employed individuals, unemployed persons, and their dependents) are covered by regional health insurance plans. Administered by municipalities and trade associations, these schemes pay for between 70 and 80 percent of primary healthcare services. In addition to regional plans, elderly residents are eligible for supplemental health insurance through the Health and Medical Services System for the Elderly. This program provides partial reimbursement for most home healthcare procedures, nursing home care, and various other services.

Because of the extensive nature of public coverage, private health insurance plays a very limited role in the Japanese medical delivery system. Most private plans provide upgraded inpatient accommodations and cover selected outpatient services and medications that are not eligible for public reimbursement. Due to a potentially adverse effect on cost containment, private health insurance, by law, is not permitted to absorb patient copayments required by the national health insurance system.

The rapid aging of the population will expand the need for clinical chemistry testing in Japan. Moreover, the country's advanced medical delivery system will strive to keep current with advances in reagent and instrument technologies. This trend will have a favorable impact on demand posted by most clinical chemistry product groups. On the downside, hospital, clinical laboratory and point-of-care markets will become increasingly price-sensitive as the national health insurance imposes tighter constraints, and often reductions, on reimbursement rates for patient tests. Other diagnostic tests will be purchased as Japan faces new disease threats.

Table 3-17: Japan IVD Market, Share by Segment, 2025 (%)

[Clinical Chemistry; Coagulation; Hematology; Histology; Immunoassay Infectious Disease; Immunoassay Other; Microbiology ID/AST; Microbiology Molecular; POC Diabetes; POC Other; Others]

Segment	Share
POC Other	15%
POC Diabetes	14%
Immunoassay Other	13%
Histology	12%
Microbiology ID/AST	9%
Clinical Chemistry	8%
Microbiology Molecular	8%
Hematology	7%
Immunoassay Infectious Disease	5%
Coagulation	4%
Others	6%
Total	**100%**
Market in $ million = $5,726	

Source: Kalorama Information

Eastern Europe: Growth Region

The Eastern European IVD market is making steady gains, mainly due to rising rates of chronic diseases and growing demand for rapid, non-invasive diagnostic tests. The market, with government support, has encouraged the adoption of advanced technologies such as liquid biopsies, NGS, immunoassays and point-of-care testing. Many companies are seeking out Eastern Europe as a place to make gains.

Table 3-18: Eastern European IVD Market, by Country, 2025 ($ million)

[Bulgaria; Croatia; Czech Republic; Hungary; Poland; Romania; Slovakia; Slovenia; Ukraine; Other]

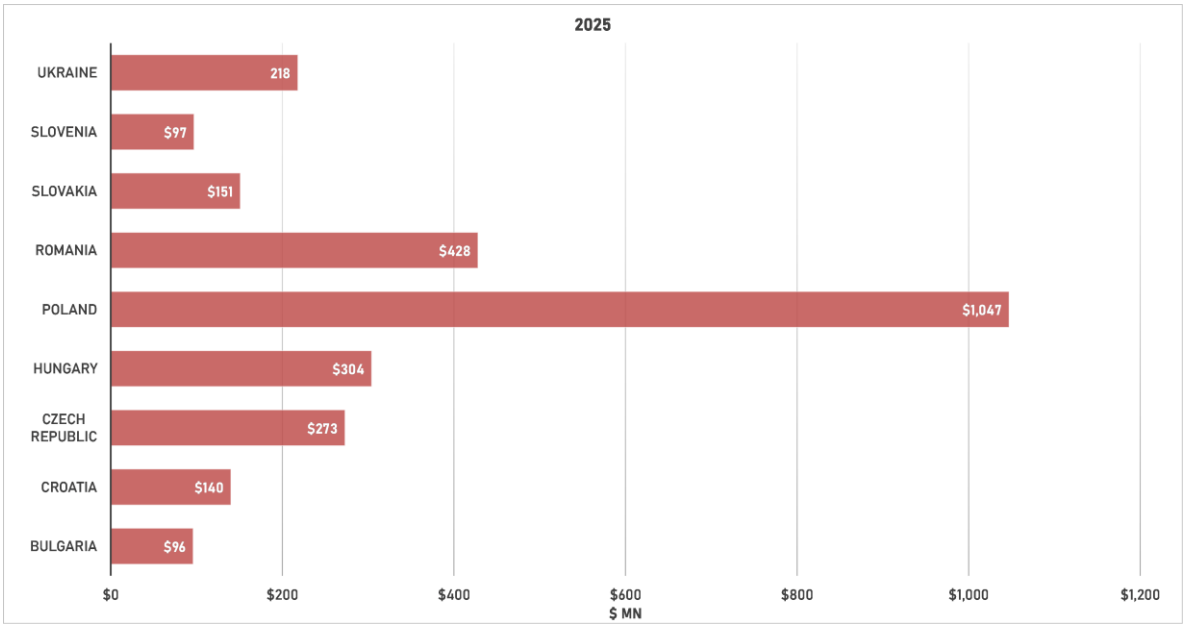
Country	Sales
Poland	1,047
Romania	428
Hungary	304
Czech Republic	273
Ukraine	218
Slovakia	151
Croatia	140
Slovenia	97
Bulgaria	96
Other Eastern Europe*	624
Total	**3,378**

Note: *Albania, Belarus, Bosnia, Estonia, Herzegovina, Kosovo, Latvia, Lithuania, Macedonia, Moldova, Montenegro, Serbia

Source: Kalorama Information

Figure 3-6: Eastern Europe IVD Market, by Country, 2025 ($ million)

[Bulgaria; Croatia; Czech Republic; Hungary; Poland; Romania; Slovakia; Slovenia; Ukraine; Other]



Source: Kalorama Information

China: Current IVD Market

During 2025, several diagnostics and medical device companies reported slower sales growth in China, reflecting changes in reimbursement, pricing, and public procurement policies that reduced demand for higher-priced IVD products. At the same time, China and Malaysia launched a mutual regulatory reliance pathway for medical devices and in vitro diagnostics, aimed at streamlining reviews and accelerating market access. The pilot program, implemented by China's National Medical Products Administration and Malaysia's Medical Device Authority, went into effect on July 30, 2025.

In 2025, the Chinese market for IVDs is estimated at nearly $5,997 million and is expected to grow at an annual rate of 2.1% to reach $7,361 million in 2030. Glucose monitoring is a major focus area in the Chinese IVD market, accounting for roughly 21% of the market value.

China is one of the largest IVD markets globally and a key region in the Asia Pacific; however, growth has slowed relative to earlier revenue expectations. The market has experienced pricing pressure and slower expansion due to healthcare reforms and centralized and volume-based procurement programs. The country has implemented increased cost controls, particularly affecting reagent pricing and routine testing. While the number of domestic IVD companies has continued to grow, consolidation is beginning to emerge as smaller players face margin pressure and increased regulatory requirements. The decline in testing volumes following the COVID-19 pandemic has also contributed to slower growth, particularly in molecular diagnostics.

Table 3-19: China IVD Market, Share by Segment, 2025 (%)

[Blood Bank Screening; Clinical Chemistry; Coagulation; Hematology; Histology; Immunoassay Infectious Disease; Immunoassay Other; Microbiology ID/AST; Microbiology Molecular; POC Diabetes; POC Other; Others]

Segment	Share
POC Diabetes	21%
POC Other	13%
Clinical Chemistry	12%
Immunoassay Other	9%
Microbiology ID/AST	8%
Immunoassay Infectious Disease	8%
Hematology	8%
Microbiology Molecular	5%
Histology	5%
Coagulation	3%
Blood Bank Screening Molecular	2%
Others	6%
Total	**100%**
Market in $ million = $5,997	

Source: Kalorama Information

Along with India, the People's Republic of China is one of the world's most populous countries, with more than 1.4 billion people. Of these, more than 1.39 billion live in mainland China and about 7 million live in Hong Kong. At present, the Chinese population is growing at an annual rate of 0.5%. The government's goal is to stabilize the population and population growth early in the 21st century.

The population distribution is expected to shift toward the 65-and-over group, which is projected to account for 27% of the total Chinese population by 2050, up from less than 3%

in 2010. Both the 15-64 and 0-14 population groups are declining considerably, accounting for 60% and 13% of the population in 2050, respectively; this is down from 73% and 18% in 2010. The two most impactful reasons for changing demographics are a lower birth rate and increasing life expectancy.

Table 3-20: Total Midyear Population, by Broad Age Group: China, 2010-2050 (million persons)

Age Group	2010	2020	2030	2040	2050	CAGR 2010-2050	% of Total China Population (2010)	% of Total China Population (2050)
0-14	240.2	241.1	221.1	178.8	170.8	-0.8%	18%	13%
15-64	981.5	980.9	944.1	859.4	782.7	-0.6%	73%	60%
65+	115.0	172.0	238.7	326.5	348.1	2.8%	9%	27%
Total	**1,336.7**	**1,394.0**	**1,403.9**	**1,364.7**	**1,301.6**	**-0.1%**	**100%**	**100%**

Source: Kalorama Information

China spends only about $4.19 per person per year on IVD products, indicating a significantly underserved market. To address the growing demand for health services, recent improvements to the medical insurance system were announced, and these changes may boost opportunities in the diagnostic market. In September 2021, the State Council announced a Five-Year Plan for National Medical Security and outlined improvements to the medical insurance system to better address the growing needs of the Chinese population, including access to medical services and drugs. This piggybacks on the 13th Five-Year Plan, which wrapped up in 2020 and led to increased medical coverage for the population.

In a geographical sense, the IVD market distribution in China is fragmented, with the invigoration of rural healthcare and the rising profile of second-tier cities outside the already highly competitive first-tier cities of Hong Kong, Shanghai, Beijing, Guangzhou, Tianjin, and Shenzhen. However, distribution to these urbanized provinces and emerging cities involves new regulatory authorities, including those outside of first-tier markets with slight oversight by central authorities. China is a highly price-sensitive market as a middle-income, developing country. The healthcare market trait is reinforced by highly decentralized pricing and reimbursement schemes and diversified purchasing strategies. There are 33 provinces,

each of which operates a Provincial Pricing Bureau. All products must be assigned a price before distribution and sales. Pricing of routine reagents and semi-automated instruments has been fairly straightforward with established precedents in the healthcare sector.

China's hospital density per 100,000 population is estimated at about 0.9, again showing a significant disproportion when compared with other Asian countries, such as Japan, which exceeds 7/100,000, and Korea, with 3.42/100,000.

Most hospitals in China are evaluated as three major levels (I, II, and III). Each of these levels is further divided into A, B and C. With this classification, class III A is the best. Most testing is done in hospital laboratories. There is virtually no physician office laboratory testing in China, and commercial laboratories account for only 2% of the IVD market value.

China is changing its reimbursement policy, which will no longer allow differentiation based on testing methodology. This could hurt CLIA testing and other automatic immunoassay systems. There are thousands of domestic IVD manufacturers, who are becoming major suppliers of ELISA and point-of-care tests, but CLIA systems, which are the prevailing hospital laboratory immunoassay technology in Europe and the U.S., are still behind.

The majority of the population cannot benefit from immunoassay technology for the time being due to poor cold-chain transportation, high costs, and a lack of reliable electricity and trained laboratory technicians. Rapid testing is the first technology that can reach remote yet major potential users, while manual ELISAs and an open system are ideal for this market.

China faces cancer as a mounting health challenge, as cancer is believed to be the leading cause of death in China. The burden of several forms of cancer, such as lung, stomach, liver, colorectal, and esophageal, proportional to the population, is significantly above global averages. Among urban Chinese, cancer is the leading killer, with lung cancer as the most dominant contributor.

This reflects a rising public health threat from cancer throughout both developed and developing nations. According to the American Cancer Society, 1 in 8 deaths worldwide are due to cancer, and globally, cancer causes more deaths than HIV/AIDS, tuberculosis, and malaria combined. It is the leading cause of death in economically developed countries and the second leading cause of death in developing countries, and imposes a substantial burden on the world economy.

Tobacco is one of the main culprits for much of the increase in cancer in developing countries, especially in the Asia Pacific, where one-third of the world's smokers live. China alone is home to 350 million smokers. According to a report from the International Agency for Research on Cancer (IARC), about 15% of cancers in low- and middle-income countries are linked to tobacco use, and that figure is expected to climb sharply. People in developing countries are also adopting other Western habits, such as overeating and exercising too little. Meanwhile, they have less access to resources for prevention and treatment. In China, the country with the world's highest population of smokers, annual lung cancer mortality rates have risen by 500% over the past 25 years, representing about 626,000 lung cancer deaths annually.

The prevalence of non-communicable chronic diseases associated with risk factors such as inactivity, smoking, diet and urban air quality has risen across the Chinese population in the past several decades due to modernization and income mobility. The scourge of diabetes has already been noted in this chapter. Cardiovascular disease has also seen significant movement in the past decade or has remained elevated in the Chinese population relative to global averages. Hypertension is another condition that has resulted in an increasing morbidity rate for Chinese urban populations in recent years.

China is seeing a rise in chronic lifestyle diseases overall. Roche offers the cobas pro integrated solutions for the core laboratory. The product is a scalable, modular serum work area analyzer for mid- to high-volume clinical chemistry and immunochemistry testing.

Clinical Laboratory Market in China

The clinical laboratory testing market in China is valued at $3.4 for 2024. The China National Accreditation Service (CNAS) database contains records of over 500 accredited laboratories across the country. Of these, the majority are hospital-based laboratories (73%), followed by university laboratories (21%) and independent or reference laboratories (6%).

China has begun encouraging the private sector to invest in hospitals to help ease the burden placed on the public health-care system, which is grappling with surging rates of chronic conditions such as diabetes and heart disease. Chinese patients are often reluctant to choose private hospitals because they rarely receive government reimbursement for medical treatment.

Globally, about 20,000 independent clinical laboratories are currently operational, and China represents a major market opportunity due to its favorable demographics. Demand for service from the growing urban middle class has spurred the development of private labs. There are about 110 independent clinical laboratories in China, but most are small and lack China National Accreditation Service (CNAS) accreditation—roughly 1/3 of facilities are accredited.

China is home to an estimated 10% of all laboratories worldwide providing clinical genetic testing services; 15% of all NGS systems used in research or applied testing; and nearly 10% of global revenue from cancer testing services. Outside of North America, Europe and Japan, China is primed to emerge as the leading market for clinical NGS and molecular cancer testing.

Volume-Based Procurement in China

Chinese healthcare has undergone significant reform in recent years as the government seeks to control costs amid an aging population and rising rates of chronic disease. Historically, procurement of drugs and in vitro diagnostics was decentralized, but this approach proved insufficient to manage growing healthcare expenditures. In response, the government introduced a more centralized and structured system through volume-based procurement (VBP), overseen by the National Healthcare Security Administration in coordination with regional and national procurement bodies. This system centralizes operations to negotiate lower prices, fundamentally reshaping purchasing dynamics across the healthcare sector.

The impact on the IVD industry has been significant, with substantial pricing pressure and margin compression across many product categories. While the degree of price reduction varies, the overall effect has been a shift toward lower-cost procurement, creating challenges for both domestic and multinational companies. Rather than exiting the market, most companies have adjusted their strategies by focusing on innovative and differentiated products that are less exposed to VBP pricing, while also increasing collaboration with local partners and strengthening their presence within China's domestic system.

China's healthcare system remains highly diverse, requiring a multifaceted commercial approach. Demand is driven primarily by hospital and public laboratory networks, but also includes private hospitals, reference laboratories, rural healthcare systems, and research institutions. The country's tiered hospital system remains a central focus of reform, with efforts to strengthen primary care and expand access to higher-quality services at larger

medical centers. At the same time, China has continued to promote domestic manufacturing and local innovation, increasing competition across the IVD market.

Reimbursement reform is also ongoing, with broader adoption of case-based payment systems such as Diagnosis-Related Groups and Diagnosis-Intervention Packet models. These approaches are being implemented across many regions to standardize payments and improve cost control, although adoption and execution vary geographically. Policies aimed at modernizing healthcare infrastructure and expanding access to medical equipment are creating selective growth opportunities, even as pricing pressure remains a defining feature of the market.

Kalorama Information believes that the outlook for business in China remains challenging for the short term. However, the long-term outlook is favorable by focusing on differentiated, high-value products, which are not subject to VBP impact.

India: Population and Opportunity

Along with China, India is one of the most populous countries in the world, with 1.4 billion people residing in the country in 2025. It is the seventh-largest country in Asia, behind China. Despite a declining birth rate, India's population will continue to increase, reaching 1.46 billion by 2030. An increase in life expectancy will more than offset the lower births in the country over the next decade. Considering the health consequences of aging, the over-65-year-old group will likely require additional health care, which is also likely to be more comprehensive. Through 2060, the aging population is expected to grow by 3.2% annually, reaching 317.7 million, up from 95.2 million in 2020.

The IVD market in India is considered complex in its regulatory process and has a fragmented system for device registration and geographical market penetration. Despite the challenges, the IVD market is growing at a 5% CAGR and attracting steady foreign investment. India is highly dependent on medical imports and continues to grow despite the increasing number of domestic medical equipment suppliers.

India is high in its utilization of public health care but there is a growing demand for private services. This is driving demand in areas such as molecular testing and advanced testing technologies. The burden of obesity, diabetes, and cardiovascular disease is among the major drivers for the market, which has increased demand for POC testing, in particular, at the consumer level.

India's new classification and adverse event systems will provide consistency to harmonize regulatory control

The IVD market in India is valued at $1,390 million in 2025. The market is expected to grow at a 5% CAGR through 2025-2030, reaching $1,803 million in sales.

Table 3-21: India IVD Market, Share by Segment, 2025 (%)

[Clinical Chemistry, Hematology, Coagulation; Histology/Cytology; Immunoassays; Microbiology/Virology; POC Glucose; POC Other; Others]

Segment	Share
Point-of-Care - Other	39%
Chemistry, Hematology, Coagulation	24%
Immunoassays	16%
Microbiology/Virology	11%
Point-of-Care - Glucose	3%
Histology/Cytology	4%
Other segments	3%
Total	**100%**
Market in $ million = $1,390	

Source: Kalorama Information

India is home to over 100 cities with populations large enough to generate demand for diagnostic centers that cater to a wide range of requirements. Large metropolitan cities with more than one million people include Mumbai, Delhi, Madras, Calcutta, Hyderabad, and Bangalore. Cities with people of around one million include Ahmadabad, Kanpur, Chandigarh, Patna, Dehradun, Pondicherry, Pune, etc. have a population of around one million.

In terms of population, the country is vast; however, the IVD market remains limited in value despite high demand. The country is classified as a very high degree of risk for infectious disease and struggles to diagnose and treat conditions which overwhelm the health infrastructure, including:

- Food- water-borne diseases: bacterial diarrhea, hepatitis A and E, typhoid fever
- Vector-borne diseases: dengue fever, Crimean-Congo hemorrhagic fever, Japanese encephalitis, malaria, and, more recently, COVID-19

- HIV: more than 2.3 million people in India are living with HIV, which is the second highest ranking country in the world, second to South Africa.
- Tuberculosis affects between 2.5 and 3 million people each year in India, accounting for more than one-fourth of the world's TB cases. The high rate of TB in the country prompted Honorable Prime Minister Shri Narendra Modi to announce an aggressive and ambitious plan to end TB by 2025 with increased notifications of cases and better patient-provider support. This initiative has been renewed with an end date of 2030.

In addition to infectious disease, India is struggling to control its growing rate of obesity, where a total of 5% of the population is classified. In contrast, the country is also facing a high rate of underweight and malnutrition in children under the age of 5 years (35% underweight).

Lifestyle and communicable diseases are no longer restricted to urban centers and are spreading to rural areas as well. As a large portion of rural areas lack even basic healthcare facilities, several cases remain undiagnosed. Both the government and private sector provide healthcare in India, but patients increasingly turn to private hospitals and clinics for quality treatment and better facilities. According to estimates from industry sources, India has about 100,000 listed labs, with the majority in tier I cities, and more than double that number of unlisted and unregulated labs in tier II and tier III cities. This includes specialized laboratories, laboratory facilities in hospitals and nursing homes, and small testing centers with basic facilities.

Leading IVD companies have established themselves in India and are seeking long-term growth in the country, with significant investments needed to gain market share and develop products for the domestic market and international distribution.

Although private healthcare expenditures continue to outpace public expenditures by a factor of 3 to 1, and out-of-pocket spending accounts for 90% of private expenditures, health insurance coverage in India is rising. The growth of private insurance is fast. In addition to private insurance, government-provided insurance is available, although it is limited both in terms of recipients (typically those who otherwise cannot afford care) and in the amount of coverage. Most of these policies have an upward limit of about $3,000 for an entire family, and this often suffices for simple conditions and routine care.

As in other technology sectors, India’s rapidly expanding healthcare industry offers many opportunities for globally trained scientists to transfer knowledge and expertise gained

abroad into growing companies. Demand is particularly strong in segments requiring a high degree of technical know-how, which is often not available within India's domestic industry, such as pre-clinical contract research and biotechnology. Even more than in the pharmaceutical sector, India's biotech companies offer many opportunities for globally trained scientists to transfer the knowledge and expertise they have gained.

Clinical Laboratory Market in India

India is a fragmented market; the nation boasts approximately 100,000 laboratories, including specialized laboratories, hospital and nursing home laboratories, and small testing centers with only basic capacity. Test volumes range from 50 to 100 samples per day at a laboratory in a small town to several thousand samples per day at a major laboratory. The clinical laboratory service market in India is estimated at roughly $1.1 billion for 2025.

The quality of services provided by these laboratories also varies widely. The National Accreditation Board for Testing and Calibration Laboratories (NABL) was established to accredit the laboratories; however, the number of accredited laboratories has remained low since its establishment.

This emerging trend of corporate players establishing diagnostic centers in small towns and rural areas will provide opportunities for the import of automated systems and imported reagents.

Government laboratories procure equipment and supplies through tenders where price plays a major role in the decision-making process. Private hospitals and laboratories, however, make their own purchase decisions and consider both quality and price. The Government of India does not require a license to import equipment and reagents. In fact, imports provide approximately 60% of the diagnostic medical equipment and supplies market.

Several Indian and foreign companies are active in the equipment and reagent market: Transasia Bio Medical, Roche Diagnostics, Accurex, Siemens Healthineers, Becton and Dickinson, bioMérieux India, Nicholas Piramal, Wipro Biomed, Johnson and Johnson, Olympus Diagnostics/Beckman Coulter/Danaher, SigmaAldrich, Hitachi, QuidelOrtho, Ranbaxy Diagnostics, and Bio-Rad Laboratories.

The Indian medical diagnostics laboratory sector is market-driven and poised to grow rapidly to meet rising demand from a growing middle class that supports the private healthcare

sector. Existing hospitals are upgrading their medical laboratory facilities, and new hospital projects and stand-alone medical laboratories are being incorporated in the country. These developments continue to contribute to the growth of the medical laboratory reagents.

IVD Regulation

The Medical Device Regulation Act of 2020 is the regulatory framework for medical devices. Medical devices and IVDs are controlled by the Drug Controller General of India.

According to a recent notification, from April 1, 2020, medical devices that meet the following definition will be regulated as drugs under the "DCA and MDR": "All devices, including an instrument, apparatus, appliance, implant, material, or other article, whether used alone or in combination, including software or an accessory, intended by their manufacturer to be used specially for human beings or animals, which does not achieve the primary intended action in or on the human body or animals by any pharmacological, immunological, or metabolic means, but which may assist in its intended function by such means for one or more of the aforementioned-

- Diagnosis, prevention, monitoring, treatment, alleviation, or assistance for any disease or disorder;
- Diagnosis, monitoring, treatment, alleviation or assistance for any injury or disability;
- Investigation, replacement or modification or support of the anatomy or of a physiological process;
- Supporting or sustaining life;
- Disinfection of medical devices; and
- Control of conception

The new regulations will ensure that all medical equipment undergoes quality control before being released in the Indian market.

India's Mukt Bharat Campaign

The Indian Ministry of Health launched the 100-day TB Mukt Bharat campaign. The campaign will focus on vulnerable populations, tribal communities and the nation's poor. This will help bring attention to the issue and enhance early detection and access to TB

services. Previously, India had committed to eliminating TB by 2025. However, due to unforeseen circumstances, the goal was not met, but it did achieve a 21% reduction in TB incidence and a 25% decline in TB mortality over the past decade.

The Mukt Bharat, also known as "Yes! We Can End TB," emphasizes a whole-community approach and the strengthening of technology-driven interventions. These include rapid, accurate diagnostics to improve early detection and increased access to testing.

Co-Diagnostics, along with its partner, CoSara Diagnostics is committed to helping the Mukt Bharat campaign. Co-Diagnostics has begun shipping its PCR Pro instruments, PCR Mycobacterium tuberculosis (MTB) and NPOC TB test kits for TB to support clinical performance studies of the TB tests. The Co-Diagnostic platform aligns with the WHO guidance for TB protocols. The test uses sputum or tongue swabs to obtain the sample.

The Co-Diagnostics platform is under regulatory review and not yet available on the market.

Rest of Asia

Outside of China, India and Japan, IVD manufacturers have found markets in Asia and the rest of the region will be a source of revenues for IVD manufacturers for the coming years. In December 2020, the World Economic Forum (WEF) released its 2020 Global Competitiveness Index. In the prior year, the Index was based on the policies, institutions, and other factors that influence a nation's productivity and relative level of prosperity, which led to a ranking system. The World Economic Forum looks at indicators such as labor market efficiency, market size, education level, and technological readiness. In 2025, the IMD World Competitiveness Report showed that:

- Malaysia ranked 23 up three positions from 2023. It is the highest-ranked out of developing Asian countries.
- Thailand moved to 30
- China was in the 16th position. Low levels of innovation and inefficient bureaucracy continue to drag down China's competitiveness level.
- Other Asian notables include Taiwan (6), South Korea (27), Hong Kong (3), and Singapore (2).
- India continues to move to 41.

However, despite encouraging economic and infrastructure statistics, IVD growth in Asian countries is largely constrained by shortages of skilled healthcare workers and laboratory facilities. Government reimbursement for medical technologies is also expanding around the region, making the therapies more affordable. Western medical product companies should find increasing opportunities in the Asian medical markets.

A growing number of nations in Southeast Asia, including Malaysia, Thailand, Cambodia, and Indonesia, offer basic medical coverage to their citizens. This trend is driving rapid growth in demand for medical devices, drugs, and diagnostic test kits and reagents, benefiting Western companies marketing their products in the region.

South Korea is increasing government healthcare funding, which has boosted sales in the country. Product registration in South Korea is more difficult; however, the newly introduced Immediate Market Entry is available for cutting-edge technologies. The country is also developing the first guideline for generative AI device reviews.

Table 3-22: Asia Pacific Region IVD Market, by Country, 2025 ($ million)

[Australia; China; India; Indonesia; Japan; Malaysia; Philippines; Singapore; South Korea; Thailand; Vietnam]

Country	2025 Revenues
China	5,997
Japan	5,726
Australia	1,976
India	1,390
South Korea	521
Indonesia	307
Thailand	199
Philippines	152
Vietnam	137
Malaysia	132
Singapore	113
Rest of AP	1,599
Total	**18,249**

Source: Kalorama Information

Brazil

Brazil has implemented significant regulatory changes, such as ensuring compatibility with international markets and raising product manufacturing standards, that are helping to drive the IVD market forward. Brazil is the largest health market in Latin America and only second to the U.S. in the entire Americas. The largest country in Latin America and the sixth most populous in the world, Brazil's 218 million people have long been a target for major IVD vendors. Growth is evident; Brazil's population will likely reach 232 million by 2050, representing an average annual increase of 0.7% between 2010 and 2050. That population growth is also an aging growth. The 65+ population in the consideration segment is forecast to grow at an average annual rate of 4%, reaching 50 million by 2050. This is more significant given that it is up from just 13.1 million in 2010.

The majority of the Brazilian population is concentrated in the southeast region and consists of the cities of Sao Paolo, Brasilia and Rio de Janeiro. There is a growing trend of urbanization. Approximately 86% of the population is urban: Sao Paulo boasts almost 10% of the nation's population; Rio de Janeiro has over 13 million; and Belo Horizonte, Brasilia, Fortaleza and Recife also have large populations.

The Brazilian government has been largely involved in providing healthcare to its people. The constitution of 1988 and the Organic Health Law of 1990 structured the country's universal healthcare system.

This system provides access to healthcare for all citizens of Brazil through designated public and private hospitals. Healthcare is government-reimbursed, but funding for the healthcare system comes from both the public and private sectors.

There are nearly 6,200 hospitals operating throughout Brazil, with additional outpatient service centers, home care facilities, and other medical facilities, further increasing the total number of facilities in the country. The distribution to public versus private is about 40:60 and more than two-thirds are for-profit entities. In Brazil, there are about 2.2 hospital beds for every 1,000 people. The number of available beds has not kept pace with the growing population and need. In 1975, there were about 4.5 beds per 1,000 population, but over the years, the number of beds has declined and may not adequately accommodate the population if the demand increases.

The market for IVDs in Brazil is estimated at $1,885 million in 2025 and, with 5.5% annual growth, will reach $2,581 million in 2030. The diagnostics market is divided between 42% in the public sector and 58% in the private sector. There are significant variations by market segment. For example, allergy, cancer, and hormones are predominantly a private market, while the public sector is stronger in flow cytometry.

Advancements in molecular techniques, increasing awareness and acceptance of precision medicine, the rising prevalence of chronic diseases, and the need to diagnose these diseases at early stages are key factors driving growth in the molecular diagnostics market. On the other hand, the development of a wide variety of reagents and analytical techniques, along with inexpensive, automated POC testing, is a key driver of growth in the reagents market.

Table 3-23: Brazil IVD Market, by Broad Segment, 2025 (%)

[Core Lab; Histology; Immunoassays; Microbiology/Virology; Point-of-Care - glucose; Point-of-Care - other]

Segment	Share
Immunoassays	38%
Core Lab	23%
Microbiology/Virology	17%
Point-of-Care - glucose	10%
Histology	4%
Point-of-Care - other	3%
Others	5%
Total	**100%**
Market in $ million = $1,885	

Source: Kalorama Information

Disease Trends

Infectious and parasitic diseases are common in Brazil; government bulletins cite Brazil as having a very high risk of contracting an infectious disease and list the most common food- and waterborne diseases as bacterial diarrhea and hepatitis A; vector-borne diseases as

dengue fever and malaria; and water-contact diseases as schistosomiasis. There is also an increasing number of people diagnosed with cancer, diabetes, and respiratory diseases. This provides a foundation for diagnostic testing markets and advanced technologies.

Diabetes affects more than 20 million people in Brazil, or 10% of the population. The market for diabetes treatments in Brazil has grown at nearly 12% annually, with more than $100 million spent each year. A contributing factor to the growing diabetes prevalence is the increase in adult and pediatric obesity. The population is facing unprecedented obesity rates in adults of more than 22% of the population.

There are more than 440,000 new cases of cancer affecting Brazilians each year, with 225,000 deaths reported. Today, cancer is the second leading cause of death in Brazil. Cancer in Brazilian men accounts for just over 51% of cases, with roughly 225,000 reported versus 215,000 for women. The risk of getting cancer before the age of 75 is approximately 21% for the total Brazilian population.

Brazil has one of the highest rates of HIV infection in the Americas with more than 827,000 people currently living with the disease, nearly 0.4% of the population. More than 35% of these cases are women. Additionally, 15,000-16,000 Brazilians die each year from the disease. For these reasons, Brazil is a highly attractive region for HIV testing skills and technologies, with strong government support. Brazil has an active HIV prevention strategy and offers a wide range of treatment options through the public healthcare system at little or no cost.

Malaria continues to be a widespread problem in Brazil, with 42% of all malaria cases in Latin America distributed in Brazil. Malaria affects about 150,000 people each year and results in about 35 deaths. Although the country has been proactive in reducing case numbers, it still struggles to control the disease.

Dengue is classified as an ongoing public health problem in Brazil by PAHO and WHO, despite efforts to control the disease. Dengue is an infectious disease caused by the dengue virus and primarily transmitted by the Aedes aegypti female mosquito. The definitive diagnosis of dengue infection requires the detection of specific antibodies in a patient's blood sample. The recommended testing method is serological methods with viral isolation and identification for a complete detection profile. The last two years have seen an uptick in dengue cases due to El Niño, which has raised temperatures and increased rainfall from the Pacific. Brazil has already had about 194,000 dengue cases in 2025.

The outbreak of the Zika virus in 2015 prompted the Brazilian medical delivery system to focus increased attention on controlling the spread of potentially life-threatening infectious diseases. In addition to the Zika virus, the country has sought to reduce the incidence of several other widespread infectious diseases, including bacterial diarrhea, dengue fever, hepatitis A, and schistosomiasis.

It is expected that the high rate of infectious disease will continue to present growth opportunities for infectious disease IVD products, although constraints on healthcare spending will hold down overall demand gains.

Clinical Laboratory Market in Brazil

Currently, there are more than 12,500 diagnostic laboratories operating throughout the country with an additional 45,700 collection sites. The distribution of hospital vs. commercial laboratories is estimated at 46%-54%.

There is a growing trend among medical facilities in Brazil to align with U.S. and European standards. The growing private health system is becoming well known for its exceptional standard of care that, in some instances, exceeds that of developed nations. There are roughly 8,200 hospitals operating throughout Brazil, with additional outpatient service centers, home care facilities, and other medical facilities, bringing the total to more than 8,200. There are currently 63 organizations accredited by the Joint Commission International, which is considered the 'gold standard' in global health care.

There are three large diagnostic laboratory service groups operating throughout Brazil: Diagnosticos da America, Grupo Fleury, and AFIP Diagnostic Medicine

These four operators account for about 60% of the volume of laboratory services. Diagnosticos da America (DASA). Diagnosticos da America (DASA) is the largest clinical laboratory group in Latin America and is credited with being the fifth-largest in the world. The group is the result of a merger of Club DA, Delboni Auriemo and Lavoisier in São Paulo. The DASA lab chain operates more than 500 collection centers and 12 central laboratories that serve as a reference lab for hospitals. The group also provides complementary services and support to an additional 5,000 laboratories throughout Brazil, offering products under its Alvaro brand. DASA reports generating R10 billion in annual revenue, with about one-third attributed to its clinical laboratory services. The company initially responded to the COVID-19 pandemic in 2020 by forming a partnership with the Brazilian Ministry of Health to donate

human resources and infrastructure, expanding processing capacity to up to 3 million RT-PCR samples for virus detection.

Grupo Fleury is the largest provider of clinical laboratory services in Brazil, performing 90 million tests annually, or more than 7 million each month. The group operates more than 250 care centers and generates more than R7.8 billion in revenue in 2024. Grupo Fleury acquired Hermes Pardini, the third-largest clinical laboratory service provider in Brazil.

AFIP Diagnostic Medicine (AFIP Medicina Diagnostica) offers laboratory diagnostic tests for medical and scientific research purposes. Its specialties include serology, immunology, hematology, radioimmunology, parasite, urinalysis, pathology, anatomy, cytology, molecular biology, and validation for procedures and inputs. It prides itself on operating only with the most advanced, state-of-the-art technology. The lab processes 5 million tests per month.

IVD Regulation

ANVISA is the regulating authority overseeing pharmaceuticals, medical devices, cosmetics and any medical product or service produced or consumed in Brazil. ANVISA is regulated by Brazil's Ministry of Health, which periodically restructures and assigns duties to the agency.

The agency is tasked with protecting and promoting public health throughout Brazil and, in doing so, monitors the performance and risks of products and services, including processes, ingredients, and technologies that pose health risks to the population. ANVISA continues to be one of the more heavily regulated regulatory bodies for medical devices, largely due to concerns about domestic medical device manufacturers who are slow to adopt Good Manufacturing Practices for Medical Devices and to manufacture to high standards. The country continues to depend heavily on imports from the U.S., Canada, and European markets to meet the demand for high-tech medical devices. Despite its requirement for imported devices, the import system is complex and costly, contributing to barriers to entry for smaller device manufacturers.

Classification of medical devices in Brazil includes Classes I, II, III, and IV, which are determined by the level of risk they pose to the health of consumers, patients, operators, or third parties involved.

After approval is granted in Brazil, this opens opportunities within other select South American countries, including Argentina, Paraguay, and Uruguay. Brazil and these countries are member states of Mercosur, which allows for improved opportunities for market participation among member states once approval is granted.

Mexico

Mexico's IVD market is worth about $839 million in 2025 and expected to reach nearly $1,077 million by 2030, representing a CAGR 6.5%. Growth is supported by continued acceptance of advanced equipment and growing distribution channels. Immunoassay, Histology, Others)

Table 3-24: Mexico IVD Market, by Broad Segment, 2025 (%)

[Clinical Chemistry, Hematology, Coagulation; Histology; Immunoassays; Microbiology; Point-of-Care; Others]

Segment	Share
Immunoassays	30%
Clinical Chemistry, Hematology, Coagulation	25%
Point-of-Care	22%
Microbiology	14%
Histology	6%
Others	3%
Total	**100%**
Market in $ million = $839	

Source: Kalorama Information

The second largest country in Latin America, behind Brazil, is Mexico. In terms of population, Mexico accounts for 20% of the region's total. Mexico is the twelfth most populous country in the world, with 130 million people residing in the country. Following current population growth trends, Mexico's population will likely reach 155 million by 2050, with an average annual increase of 0.7% between 2010 and 2050.

The distribution of the population is expected to shift toward the 65-and-over population, which is projected to account for 18% of the total population in the country by 2050, up from 6% in 2010. The 15-64 population group is expected to remain relatively stable; while the 0-14 population is declining considerably, accounting for 18% of the population in 2050,

down from 30% in 2010. Mexico's healthy life expectancy at birth is estimated by the World Health Organization to be 69 years, which is 8 years less than the country's total life expectancy at birth. Despite the increase in life expectancy and a slight increase in healthy life expectancy, the population is expected to face increasing chronic disease, disability, and morbidity due to lifestyle trends resulting in obesity and diabetes.

The majority of Mexico's population is concentrated in the middle to middle-upper regions of the country, in the cities of Mexico City, Guadalajara, and Monterrey; these cities combined account for about 25% of the total population. There is a growing trend of urbanization with a 1.57% annual increase since 2010. Approximately 80.7% of the population is urban; 17% of the population resides in the capital, Mexico City.

Mexico currently spends an average of 5.4% of GDP on healthcare and has the second-largest health market in Latin America behind Brazil. Roughly 52% of health spending is funded by public and government sources, while the remaining 48% is funded by private payors. Out-of-pocket spending on health care is a major barrier to health utilization and is reflected in several economic and health indicators. The Mexican government offers publicly subsidized health insurance to its population through the Seguro Popular de Salud (The People's Insurance), or SPS. The system can be classified as a mixed health plan, combining both public and private resources.

Despite the challenges, Mexico’s economy and health system are expected to show gradual improvement and expand through various changes and enhancements to the country’s economic and health structures. In the past few years, Mexico has become an attractive target for foreign investments and with new trade deals and partnerships between major export and import countries, it demands a watchful eye.

The H1N1 flu epidemic in 2009 exposed deficiencies and imbalances in the availability and accessibility of patient testing services in Mexico. As a result, government health authorities planned to expand the number of clinical laboratory and point-of-care testing sites throughout the country. These efforts were designed to boost demand for infectious disease IVD products. However, due to ongoing constraints on the national healthcare budget, reagents and instruments for basic procedures continue to account for the majority of sales.

The Russian Federation

The Russian health system is facing significant challenges due to the ongoing conflict in Ukraine. Since the collapse of the Soviet Union and the birth of the Russian Federation (Russia) in 1991, the health status of the Russian population has declined dramatically. Rates of tuberculosis, cancer, and heart disease are the highest rates of any industrialized country. Spending on healthcare, which was approximately 7% of GNP in the 1960's, was reduced to approximately 3% in 1991. Since then, the country has slowly worked to increase this to some 5-6% of GNP by the mid-2000s. Healthcare spending is somewhat stuck at this rate due to a lack of resources to support the huge, lumbering system.

Russia's first major economic meltdown in the late 1990s had a significant effect on the IVD industry there. The lack of government funds meant that hospitals and labs could not afford to purchase foreign-made products, primarily reagents. The result was that some of Russia's high-tech manufacturers shifted from defense production to basic, routine reagents for chemistry, hematology, and immunoassays. These companies still hold a major share of the routine test segments.

Domestic production accounts for only 15%-25% of the market, depending on the diagnostic product type. These products include a limited variety of semi-automated analyzers and spectrophotometers, laboratory furniture and glassware, laboratory scales, sterilizers, incubators, thermostats, microscopes, and a wide range of reagents for testing blood, hormones, viruses, and urine.

A few elite Russian hospitals and clinics, predominantly in Moscow and St. Petersburg, can afford to use the latest advanced diagnostics, including immunoassays and molecular tests. However, most hospitals and clinics, especially in Russian regions, can only perform simple clinical and selected biochemical tests.

Yet, despite the barriers and apparent downfalls, it is a compelling IVD market because of a large population and a vast healthcare infrastructure with more hospitals, doctors, etc. (per capita), than many other countries in the world. Russia is also the ninth most populous nation in the world, with about 142 million inhabitants, but its population is declining, and it will fall in population rank by 2050. There are other issues as well; Russia is unable to take care of its population. Life expectancy is on the decrease, TB and sexually transmitted diseases are on a rampage, and non-communicable diseases, especially heart problems and hypertension, are a major source of suffering and death.

The rise in the incidence of infectious diseases in Russia over the past several years has led to a significant increase in demand for high-quality laboratory diagnostic equipment and reagents. The official statistics show substantial increases in tuberculosis (130,000 people or 86.1 per 100,000 of the population), HIV (1.5 million infected), and sexually transmitted diseases (1 million). The number of drug addicts in Russia is some 3 million and more than 2.5 million people have diabetes.

The Russian Federation's strategy for healthcare in 2025 includes hepatitis C prevention, early diabetes screening, and expanding access to high-tech and specialized services.

During 2022, the Russian invasion of Ukraine and the ongoing war in Ukraine from 2023 to 2026 have impacted the IVD market through the retraction of some foreign businesses. The market for IVDs is estimated at $1,307 million in 2025, with a CAGR of 2.9%, reaching $1,509 million in 2030. This shows slower-than-average growth in the region due to the lasting effects of the invasion of Ukraine.

Canada

Demographics and healthcare spending fuel Canada's relatively large IVD market. The population of Canada will retain a slightly younger age distribution than that of its U.S. neighbor but will grow in line with U.S. trends. A moderately high birth rate and a comparatively low death rate will account for overall demographic changes. Due to the low death rate and increasing longevity, Canada's 65-and-older segment will grow much faster than the total population, reaching approximately 8 million in 2025. Growth in elderly age groups will intensify the country's healthcare cost burden. This trend will prompt the provincial health plans to impose tighter controls on the coverage and cost of medical services, including IVD procedures.

The publicly funded Medicare universal health insurance program covers all Canadian residents for hospital care, physicians' consultations, mental health counseling, laboratory testing, and nursing home care. In addition, elderly and low-income residents are eligible for varying prescription drug benefits. Medicare is funded through federal and provincial income taxes. The administration and payment of benefits are delegated to the 10 provincial governments, each operating a separate plan that complies with general guidelines set by federal law. Most government funding (94%) comes from the provincial level.

Hospital care and lab testing are delivered by publicly funded hospitals in Canada. Most public hospitals, each of which is an independent institution incorporated under provincial Corporations Acts, are required by law to operate within their budgets. The amalgamation of hospitals and labs in the 1990s has reduced competition between hospitals. As the cost of patient care has increased, hospitals have been forced to cut costs or reduce services. Growth will reflect the testing activities of 1,500 hospitals, nearly 100,000 physicians, and 3,500 clinical laboratories.

Under the Canada Health Act, public funding is required to cover medically necessary care, but only if it is delivered in hospitals or by physicians. There is considerable variation across the provinces and territories in the extent to which costs for out-of-hospital prescription medications, laboratory tests, physical therapy, long-term care, dental care, and ambulance services are covered.

There is no service fee for lab tests in Canada. The majority of testing is performed in hospital labs that operate under a fixed annual budget. Therefore, doing more with less is a fact of life for most lab professionals. As in other developed countries, resources to support

medical laboratory testing are dwindling, even as physicians order more tests and labs must spend it on acquiring new diagnostic technologies. Therefore, Canada's network of private laboratories has undergone significant consolidation.

The IVD market is strongly represented within Canadian manufacturing companies and is complemented by the strength of the strong research community. Similar to the U.S., the Canadian IVD market is dominated by the top IVD companies. However, the Canadian IVD market is highly fragmented, with numerous SMEs, both Canadian and international manufacturers, competing for market share. Canada's IVD market is estimated at approximately $3,429 million in 2025.

Emerging Markets

The countries covered in the previous section are known markets of opportunity. The following section examines several markets identified by IVD vendors as the next growth areas. The countries range from relatively well-known countries such as Turkey, South Africa, Vietnam, and South Korea to riskier but potentially high-growth areas such as the Philippines, Malaysia, and Thailand.

Saudi Arabia IVD Market

Saudi Arabia is the home to some 33.7 million people, 79% of whom live in cities. It is a young country, with only 3% of the population aged 65 or over; however, the country's aging population is increasing, as shown in the population pyramid comparison below. Immigrants make up nearly 40% of the total population, according to data released by the United Nations.

Saudi Arabia is an oil-rich nation that occupies the majority of the Arabian Peninsula. It wields considerable military and political power in Middle Eastern affairs and is the sole Arab nation to be part of the G-20. Over the past decade, Saudi Arabia benefited from increased crude oil production. Health and living standards in Saudi Arabia are very good. About 85% of the population has ready access to medical providers. All residents are covered for basic and essential healthcare services through a national health insurance scheme coordinated by the Ministry of Health.

Expansion of overall healthcare services and laboratory facilities is required to meet the increasing demands on Saudi Arabia's healthcare system due to the mix of infectious diseases and chronic conditions. Unlike elsewhere, in Saudi Arabia, publicly funded hospitals are perceived to provide higher-quality healthcare than private-sector hospitals.

The Ministry of Health (MOH) and other government-affiliated hospitals account for 77% of Saudi Arabia's healthcare infrastructure, with private healthcare comprising the remaining 23%. However, private facilities serve some 65% of the population, including expatriates (30% of the population) and private-sector employees (35% of the population) and their families, who do not have access to public institutions.

The prevalence of diabetes is expected to continue to increase from its current 24.3%, and other lifestyle diseases, such as cardiovascular diseases, are expected to grow and add pressure to the current healthcare infrastructure.

IVDs play an essential role in the government's healthcare plans. Currently, only 1.5% of the overall healthcare expenditure in Saudi Arabia is spent on IVD, reflecting a comparatively lower rate than the global average of 2%.

The IVD market in Saudi Arabia is largely generated through imports from diagnostic companies outside the country; there is a nearly nonexistent domestic manufacturing market for diagnostics in Saudi Arabia. In 2025, the diagnostics market in Saudi Arabia is estimated to reach $676 million.

South Africa IVD Market

South Africa's population, regional dominance, and healthcare expenditure levels make the most attractive Sub-Saharan IVD market a notable entry on the list. South Africa operates one of the most prosperous economies in sub-Saharan Africa but is adversely affected by imbalances in healthcare resources and significant epidemic problems. Only two-thirds of the population has access to medical services. Moreover, nearly 20% of adult residents are afflicted with HIV/AIDS. Other widespread infectious diseases include bacterial diarrhea, hepatitis A, schistosomiasis, and typhoid fever.

South Africa has a two-tier healthcare system- a public system and a private system. Approximately 84% of South Africans use public healthcare

Diagnostic firms keen to leverage opportunities in South Africa will have to account for a highly heterogeneous landscape. Discrepancies at the state level highlight the depth of healthcare inequality between South Africa's urban and rural landscapes. pricing strategies and an assessment of province-level variations.

Like other countries around the world, South Africa is reporting strong growth in its over-65 population relative to its total population. This will likely create stronger demand for medical devices over the next decade. Devices that focus on managing HIV/AIDS, heart disease, and stroke are likely to be major segments, as these are the three primary causes of death in the country.

The IVD market in South Africa is estimated at $377 million in 2025, growing at a 4.2% CAGR to reach $463 million by 2030.

South Korea IVD Market

South Korea, with a population of 52 million, boasts a higher per capita GDP than China and is closing in on Japan, underscoring the opportunity for a large and growing IVD market.

The IVD market in South Korea is considered favorable due to its regulatory framework and foreign investment opportunities. The healthcare industry is witnessing strong growth, driven by imports of high-tech equipment. An increasing interest in molecular testing technologies and point-of-care glucose testing is driving market growth. The burden of obesity, diabetes, cardiovascular disease, and cancer is among the major drivers for the market.

Moreover, a national health insurance program covers virtually all residents for basic patient care services, including diagnostic testing. Health and living standards in South Korea are generally good. However, like Japan, the country has a relatively high incidence of age-related medical conditions.

The market for IVD products in South Korea benefits from the country's advanced medical delivery system, which is readily available to more than 80% of the population. Kalorama estimates the IVD market in Korea to be $521 million in 2025 and with 6.9% growth will reach nearly $728 million by 2030.

Turkey IVD Market

Health and living standards in Turkey are generally good. Turkey's healthcare system is strong, with an emphasis on universal coverage and the integration of private healthcare options. The universal health insurance program covers the entire population for inpatient and outpatient services as well as medication. About 2% of residents are covered by private health insurance plans, which offer access to higher-quality, less-crowded procedures. Turkey is usually not impacted by major epidemic problems, but its aging population is vulnerable to common infections such as influenza and tuberculosis.

Vendor sales remain strong, and utilization of private healthcare services has increased. The Turkish Parliament approved an increase in the 2024 Ministry of Health budget, supported by initiatives to improve healthcare delivery for nearly 84 million people in the country, a goal of becoming an authority in digital health systems, and continued growth in bed capacity and hospital construction in recent years.

The market for diagnostics in Turkey is estimated at $1,093 million in 2025 and is expected to grow 6.1% annually to $1,473 million by 2030. Major IVD vendors with participation in Turkey include Roche and Grifols.

United Arab Emirates (UAE) IVD Market

The UAE's healthcare system 2030 strategies are to enhance health services, become a global leader in healthcare innovation, and promote wellness. The UAE's per capita GDP is on par with that of leading Western European nations. Its high oil revenues and moderate foreign policy stance have allowed the UAE to play a vital role in the region's affairs. Six states – Abu Dhabi, Ajman, Al Fujayrah, Ash Shariqah, Dubai, and Umm al Qaywayn – merged in 1971 to form the United Arab Emirates (UAE). They were joined in 1972 by Ra's al Khaymah. There are several factors boosting the market opportunity in this country.

- The population in the UAE is estimated at nearly 10 million
- Diabetes type 2 prevalence in the UAE is relatively high, about 20.7%.
- Obesity rates are continuing to increase, currently representing 32% of the population.
- Young, working-class population with low elderly dependency and aging populations.

Health and living standards in the United Arab Emirates are very good. A comprehensive, government-funded health service and a rapidly developing private health sector cover most residents for basic and essential medical services. More than 87% of the population enjoys ready access to the healthcare system. The UAE now has 40 public hospitals, compared with only 7 in 1970. The Ministry of Health recently launched a multimillion-dollar program to expand health facilities, including hospitals, medical centers, and a trauma center, across the seven emirates.

The UAE has one of the lowest concerns about an aging population, with just 1.9% of the population over the age of 65. The elderly dependency ratio is just 1.5, and the median age of the population is about 38 years.

The market for in vitro diagnostics in the UAE is estimated at $259 million in 2025. Point-of-Care tests capture around 32% of the market, followed by microbiology with 19%, immunochemistry with 19%, and clinical chemistry/hematology/coagulation with 19%

Other Markets to Watch

Chile

More than 18.6 million people reside in Chile, making it the seventh most populous country in Latin America. Over the last two decades, Chile has made great improvements in reducing its poverty rate, which is now lower than that of most Latin American countries. However, its severe income inequality ranks as the worst among members of the Organization for Economic Cooperation and Development. Unequal access to quality education perpetuates this uneven income distribution.

Health expenditures in Chile are around 10.83% of GDP annually. Continued reform of the health system is a priority for the Chilean government, with a focus on modernizing the health system, addressing the private health insurance schemes, and addressing growing expenditures. One of the major public health issues affecting Chile today is the growing obesity rate. According to the National Health Survey, 2024, Chile's obesity rate was estimated at 33.7% of the population and ranked by the OECD as one of the top 10 countries with the highest obesity and overweight rates worldwide.

At present, Chile provides nearly universal health coverage to its inhabitants in two separate subsystems:

- A large public non-profit insurer (the National Health Fund, FONASA) covering between 73% and 75% of the population, including the indigent, low-income and middle-income citizens, and providing health services mostly through public providers. FONASA covers about 14.2 million inhabitants (2019 data)
- For-profit private insurers (ISAPREs) cover about 19% of the population and provide services almost exclusively in the private sector. Each ISAPRES has several health plans, depending on where each member lives and the clinics and/or hospitals a member prefers to use
- Additionally, more than 1.5 million Chileans are either insured through other welfare systems, such as the Armed Forces and the Police, or have commercial health insurance only, or have no insurance

Two types of hospitals are present in Chile: public and private. Generally, hospitals specialize in a particular area of treatment (oncology, geriatric care, etc.). There are about 425 hospitals

in the whole country, 230 in the public sector and 195 in the private sector. Certain private hospitals (usually named "Clinics") do not accept patients with FONASA insurance. Public hospitals accept both FONASA and ISAPRES customers. ISAPRES customers are generally given better accommodation in private. In Chile, social class is important, so people might choose a private room to avoid contact with the lower classes.

The IVD market in Chile is estimated at $290 million in 2025. Major imports for medical devices are generated from the United States, Germany and China. IVD companies offering diagnostic systems and services that meet Chilean market needs with high-quality, cost-effective technology will succeed. Those focusing on meeting the growing demand for telehealth will also find niche growth opportunities.

Colombia

Besides Brazil, Colombia is a target for many IVD companies as a promising emerging market. Colombia is home to more than 49.6 million inhabitants and ranks 29th in the world by population. Roughly 82% of the population is urban, with the urbanization rate increasing by 1% annually. This is partially driven by the shift to service industries as the high fluctuations in pricing and exports in the energy and mining industries have led to higher unemployment and poverty rates, currently about 10% and 36%, respectively. Not surprisingly, healthcare and thus, IVDs are best utilized in the urban areas.

Colombia's health system operates under two schemes, contributory and subsidized. Forty-three percent (43%) of the Colombian population holds formal employment and receives health insurance through the contributory scheme that is paid for by both employees and employers, granting access to private hospitals. Forty-eight percent (48%) of the population, who do not hold formal employment, are subsidized by the public health system.

The Colombian Ministry of Health and Social Protection institutes a 10-year revolving public health plan to guide improvements to the overall health system, reduce health inequities, and propose new objectives. In the latest 10-year plan (2022-2031), the Colombian government plans to continue working toward health equity and focus on improving health in the following areas:

- Mental health and social coexistence
- Food and nutrition security

- Sexuality and sexual and reproductive rights
- Healthy living and communicable diseases
- Public health in emergencies and disasters
- Healthy living and non-communicable conditions
- Expand coverage in the occupational risk systems

Colombia is expected to sustain fast-paced growth in IVD product demand. This trend will partially reflect ongoing improvements in healthcare quality and availability. In addition, the population's high risk of a variety of pathogenic conditions, including bacterial diarrhea, Chagas disease, dengue fever, leishmaniasis, malaria, rabies, Venezuelan equine encephalitis, West Nile virus, and yellow fever, will lead to an increasing volume of related patient testing.

The IVD market in Colombia is estimated to be worth $279 million in 2025. From the IVD perspective, immunoassays are the largest segment and will continue to perform at a rate similar to the total market. By 2030, the Colombian IVD market is expected to reach $333 million, representing 5.1% CAGR.

Indonesia

Next to India and China, Indonesia has the largest economic boom in Asia. It is the 16th-largest country worldwide by area; however, it is the fourth-largest by population, with roughly 270 million inhabitants. Aging populations are a major concern among health systems; Indonesia's health system is no exception. In recent years, the government has placed Indonesian health as a priority agenda item with the construction of facilities and improved equipment and device import pathways. Despite attention to rising demand for health services, the country still lags behind its Asian counterparts in health delivery and access to care. The increased attention to health systems and the growing needs assessment are expected to favorably impact demand for IVD products, resulting in about a 3.7% CAGR over the next five years. For 2025, IVD sales are expected to be worth $307 million.

A distributor is essential for selling into Indonesia as foreign companies cannot make direct sales. There have been several cases where IVD companies with a solid product offering have struggled due to an underperforming, exclusive distributor holding their import license.

The country is moving toward universal healthcare coverage through the Jaminan Kesehatan Nasional program.

Malaysia

A young country in an aging world, with a median age of 29.2 years. The proportion of persons aged 65 and older in Malaysia has risen at an annual rate of 4.6%, faster than Japan (0.3%) and most OECD countries. As is the case worldwide, even the youngest countries are confronting age-related issues. Fertility rates in the country have declined in recent years due to economic development, cost-of-living inflation, and shifting attitudes; these factors are projected to curb future population growth in Malaysia. Malaysians enjoy a universal healthcare system and access to care superior to that available in most of Southeast Asia, with the exception of Singapore, and perhaps on par with Thailand. Per capita health spending in Malaysia is higher than in any other country in Southeast Asia, except Singapore. At over $900 international purchasing power parity (PPP) dollars, Malaysian per capita health spending is higher than in China and significantly higher than in India, but noticeably below spending levels in developed or OECD countries.

Malaysia has a dual healthcare system comprising public and private sectors. The Ministry of Health regulates the public healthcare system that is designed for all citizens and legal residents.

The IVD market, valued at $132 million in 2025, will benefit from increased patient testing volumes aimed at the early detection and treatment of bacterial diarrhea, dengue fever, leptospirosis, and other widespread infectious diseases. Malaysia operates a fairly efficient medical delivery system funded by a national health insurance scheme and supplemental private health plans. The system is readily available to approximately three-fourths of the population.

Peru

According to the National Institute of Statistics, the Peruvian population reached 32.6 million inhabitants in 2024 and is growing at a steady rate of about 0.5%. The more significant demographic shift, though, is the aging population, which accounted for 9.2% in 2024 and will account for 22.7% by 2050. In order to analyze population distribution, it is necessary to bear in mind the country's geographic complexity, which can be broadly divided into coast,

hills, and jungle, with major natural barriers and high infrastructure, communication, and transport costs, making national integration difficult and affecting social cohesion. Today, about 79% of the population lives in urban areas, with the remaining 21% in rural areas, some of which are difficult to reach by public transport.

Over the last decade, the health of the Peruvian population has improved significantly. This improvement has been mainly attributed to the urbanization process, the improvement in educational level, better access to sanitation facilities (such as safe tap water and sewage), changes in lifestyle and demographical changes, and the expansion of the first level of healthcare

According to sources consulted, there are between 1,100 and 1,300 active clinical labs in Peru, of which 60% are located in Lima Capital and the metropolitan area. The National Institute of Health of the Ministry of Health reported 122 laboratories approved for the molecular diagnosis of COVID-19 throughout the country. In the country, there are 58 public laboratories, 6 university laboratories and 60 private laboratories with the capacity to perform molecular detection of SARS-CoV-2.

The IVD market in Peru is valued at $175 million in 2025, with immunoassays accounting for roughly 39% of the market, followed by the combined clinical chemistry, hematology, and coagulation segment. Growth in the Peruvian IVD market is expected to outpace the overall Latin American region.

Philippines

The Philippines is emerging as a fast-growing nation and one of several for IVD companies to target. The healthcare delivery system in the Philippines is dominated by the public sector (at the regional, provincial, municipal, and barangay levels) and supported by private healthcare service providers. The implementation of Universal Health Care is already driving the demand across all sectors of healthcare. However, the Philippines still requires a strong focus on infrastructure and skilled manpower. Efforts to improve upon a substandard medical delivery system that fails to reach more than half of the population, coupled with the widespread need to control high levels of illnesses such as bacterial diarrhea, dengue fever, hepatitis A, malaria, and typhoid fever, will boost growth prospects for a broad range of IVD products (3.7% annual growth).

The Philippine Health Facility Development Plan (PHFDP) 2020-2040 follows the Universal Health Care Act of 2019, including provisions for a needs-based approach to estimating the health facility requirements to address the future burden of disease at both the medium- and long-term level. The plan highlights the following infrastructure and worker goals that will affect the IVD industry over the next several decades:

- By 2040, outpatient visits and inpatient bed-days are expected to increase by 60% mostly due to noncommunicable diseases.
- Increase government spending in health infrastructure and other capital formation; increase private sector spending and support sustained investments in health facilities.
- The national and local governments must spend at least PHP 56 billion every year in the medium-term and encourage the private sector to increase and sustain its investments to substantially reduce the large health infrastructure gap.
- A paradigm shift is needed to support the large public spending challenges without sacrificing the goal of equity and universal access. Health care provider networks of local governments should consider health infrastructure as investments that have income-generating potential.
- Expand rural health units/health centers (RHU/HCs) to expand access for Filipinos to have access to an RHU/HC within 30 minutes of travel time. The country needs an additional 2,400 RHU/HCs by 2025.
- More than 60,000 primary care physicians are needed to meet the current needs for primary care, assuming staffing requirements are based on physicians.
- The country has approximately 105,000 hospital beds with a bed density similar to the poorest countries in the world (1.2 per 1,000 population). An additional 400,000 beds are needed, the majority of which are Level 1 beds, to meet the projected hospital care needs by 2040 (around 2.7 beds per 1,000 population).
- Investing in a framework for allocation of national government resources, anchored on equity.
- Investments for government-run special health facilities are critical to complement primary care and hospital-based general health services.
- Specialty centers for sixteen (16) specialties shall be established: cancer care, cardiovascular care, lung care, renal care and kidney transplant, brain and spine care,

trauma care, burn care, orthopedic care, physical rehabilitation medicine, infectious disease and tropical medicine, toxicology, mental health, geriatric care, neonatal care, dermatology care, and eye care.

- Investment needs for infrastructure and equipment until 2025 total PHP 82 billion to expand DOH hospitals and are designated as National Specialty Centers, Advanced Comprehensive Specialty Centers, and Basic Comprehensive Specialty Centers
- Upgrading and establishment of Specialized Laboratories, including the National, Sub-national, and Regional Reference Laboratories, shall require a total of PHP 1.1 billion.
- Capital investment requirements for Blood Service Facilities and Drug Abuse Treatment and Rehabilitation Facilities in the national, subnational, and regional levels total PHP 3.5 billion and PHP 8.4 billion, respectively.

The IVD market for the Philippines is estimated at $152 million, demonstrating a growth rate of 3.7% from 2025-2030.

Poland

Poland is the largest country in Eastern Europe, with a population of 38.7 million and the largest GDP in the region at $1.6 trillion in PPP terms and $596 billion in constant terms. Poland is a high-revenue-industry economy, with 40% of its GDP generated by the sector. Major industries include manufacturing and mining. Services account for roughly 58% of GDP, while agriculture accounts for about 2%

Poland spends about 6.5% of its GDP, or $37-38 billion, on health care each year. This is relatively low compared with other Western and Eastern European countries; however, spending is likely to increase in the near term due to an aging population, lower birth rates, and rising life expectancy. The Russia-Ukraine conflict has impacted Poland with an increase in Ukrainian residents entering the country, which also expands the health service requirements.

The country continues to explore various options for healthcare reform to meet the growing demand for health services and maintain financial stability. Despite its efforts, implementation continued to be unsuccessful, and financial woes are expected in the forecast.

One reason for the lack of implementation of healthcare reform is the complexity of the proposed changes, including pay structures, network contracting, and citizen participation.

The IVD market in 2025 is estimated by Kalorama Information at $1,047 million and is expected to increase at 5.5% CAGR, reaching $1,370 million by 2030. Factors promoting growth in this market will be a rising incidence of infectious disease, as well as an expanding problem of HAIs in hospitals. IVD products will also drive demand in Poland as a growing share of residents gain access to medical services.

Romania

It is challenging, but as a potential healthcare market, it is worth watching. Kalorama estimates the Romanian IVD market at $428 million in 2025, serving the country's 18.1 million residents. The aging population continues to grow in the country while the overall population declines, a trend similar to that seen across other European countries. It is estimated that about 20% of the population is over the age of 65, and this share will increase to 20% by 2030. The market in Romania will also benefit from the increasing availability of laboratory services. The majority of IVD-related services are best served by the urban population, which represents about 54% of the total Romanian population, with Bucharest accounting for about 1.785 million, or nearly 10% of the population.

Thailand

Despite its relatively small size and regional GDP, Thailand's healthcare expenditure levels, tourist-fueled economy, and position for trade with Southeast Asian nations presage a formidable IVD market. It is the 53rd largest country worldwide yet is ranked 20th in terms of population with nearly 70 million inhabitants. The country is poised to face a growing problem with a shift in aging populations and a high elderly dependency ratio due to the low birth rates over the past decades and just 0.26% population growth; compared to elderly population growth of 4.5%, representing 13% of the population today but nearly 20% by 2030.

A major boost to the health service market, the government has made healthcare even for poor citizens a priority: there is coverage for 99.9% of the population, comprehensive coverage represented by a health package that includes curative services, health promotion, disease prevention and rehabilitation, and full protection of households from financial health

risk. The tax-financed universal health coverage scheme for 75% of the Thai population, which included a generous benefits package, was financially feasible as a closed-end budget through a mix of provider payments and the use of the Diagnostic-Related Group. On the downside, stringent cost containment measures are imposing restrictions on benefits and reimbursement rates for patient tests. The IVD market in Thailand is valued at roughly $199 million in 2025.

Vietnam

This nation has been one of Asia's fastest-growing economies. The official poverty rate in the country fell from 58% in 1993 to under 20% at present. It is the 8th-largest country in Asia by population, accounting for just 2% of the region's total, largely due to the large populations of China and India. The distribution of the population is expected to shift toward the 65-and-over population, which will account for 11% of the total population in 2030, up from 6.9% in 2020, an increase of 5.7 percentage points annually on average. The shift in the aging population is expected to increase overall disease incidence, as older adults are more vulnerable to illness.

Vietnam is considered a complex market for foreign suppliers. The market landscape and regulatory environment require relationships with local distributors or a domestic agent for successful market entry. Despite the barriers, the overall perception of U.S. and European medical equipment is highly favored and accepted. Diagnostic equipment is in high demand and government support for private investments is increasing.

It's not new that Vietnam is an IVD target market, currently worth $137 million in 2025. Roche Diagnostics Vietnam has established a nationwide network in the country for over 20 years and has offices in Hanoi, Da Nag and Ho Chi Min City. Abbott opened offices there for its nutrition division in 1995 and has diagnostics sales across all provinces; bioMérieux has also maintained a long-standing presence in the country. Growth in this market will benefit from stepped-up efforts by internal and external medical groups to reduce cases of bacterial diarrhea, dengue fever, hepatitis A, Japanese encephalitis, malaria, typhoid fever, and other pathogenic conditions. Vietnam is attempting to improve its deficient and imbalanced medical delivery system, which reaches between 35% and 40% of the population.

IVD Market Opportunity by Country

Table 3-25: IVD Market Opportunity, by Country (2025 Market Rank, Country CAGR 2025-2030) (%)

2025 Rank ($ Revenues)	IVD Region	CAGR 2025-2030
23	South Korea	6.9%
11	Brazil	6.5%
16	Turkey	6.1%
1	U.S.	5.8%
2	Germany	5.8%
22	Saudi Arabia	5.8%
5	France	5.7%
19	Sweden	5.6%
31	Finland	5.6%
6	United Kingdom	5.5%
17	Poland	5.5%
30	Ireland	5.5%
7	Italy	5.4%
14	Netherlands	5.4%
15	Switzerland	5.4%
27	Portugal	5.4%
12	India	5.3%
26	Romania	5.3%
9	Spain	5.2%
21	Austria	5.2%
25	Denmark	5.2%
18	Mexico	5.1%

2025 Rank ($ Revenues)	IVD Region	CAGR 2025-2030
33	Hungary	5.1%
20	Belgium	5.0%
45	Luxembourg	5.0%
10	Australia	4.9%
29	Greece	4.9%
41	Ukraine	4.8%
50	Vietnam	4.7%
42	Norway	4.6%
51	Malaysia	4.4%
8	Canada	4.3%
3	China	4.2%
28	South Africa	4.2%
37	United Arab Emirates	4.2%
44	Peru	4.1%
38	Argentina	3.9%
32	Indonesia	3.7%
46	Philippines	3.7%
35	Colombia	3.6%
43	Thailand	3.6%
4	Japan	3.5%
48	Croatia	3.5%
34	Chile	3.2%
49	Iraq	3.1%
13	Russia	2.9%

2025 Rank ($ Revenues)	IVD Region	CAGR 2025-2030
53	Venezuela	2.9%
55	Bulgaria	2.9%
40	Iran	2.8%
24	Egypt	2.6%
54	Slovenia	2.5%
39	Israel	2.4%
52	Singapore	2.4%
47	Slovakia	2.3%
36	Czech Republic	2.1%
56	Jordan	1.3%
57	Belarus	0.6%

Source: Kalorama Information

Chapter 4: Company and Industry Trends

Scope

Advanced technologies are among the most influential factors shaping the in vitro diagnostics (IVD) market. These technological advancements have enabled the industry to evolve beyond traditional diagnostics, playing a critical role in the early identification and assessment of symptoms. A growing trend is the integration of genomics, information technology, and data analytics into routine clinical laboratory medicine, marking a significant shift in how diagnostics are developed and applied.

This chapter highlights a selection of technologies, events, and trends that are poised to shape the future of IVD. While North America, particularly the United States, remains the largest market for clinical diagnostic and healthcare products, the trends discussed here are primarily reflective of the U.S. landscape. Where available, relevant international examples are also provided to offer a broader perspective.

Although it is beyond the scope of this research to quantify the market impact of all the developments discussed, estimates of the potential quantitative effects are included when possible. The remainder of this chapter presents a discussion of key trends and developments that illustrate the evolving direction of clinical IVD laboratory medicine. These are not presented in order of importance but rather as an overview of the dynamic landscape of diagnostic innovation.

Edition-Specific Notes

The Molecular Oncology IVD market is in a period of sustained, high-velocity expansion, growing from $4.1 billion in 2024 to $4.7 billion in 2025 at a double-digit year-over-year growth rate that exceeds the broader IVD sector. This growth is driven by the diversity of oncology assays across clinical, technological, and commercial settings. The rapid adoption of liquid biopsy and circulating tumor DNA (ctDNA) assays is a testament to the growing adoption of personalized medicine. Additionally, maturation in the next-generation sequencing platform segment has prompted vendors to innovate and expand current techniques. From early detection through treatment selection and monitoring, these assays provide a vital component of oncology care plans and long-term outcomes. Minimal residual disease (MRD) testing has emerged as the defining application of this cycle, with tumor-informed assays now capable of detecting cancer recurrence up to two years ahead of conventional imaging. Companion diagnostics are also creating strong, reimbursement-backed revenue streams that support the market's long-term trajectory. Adding to the market opportunity, expanding reimbursement profiles and coverage decisions from high-influence payers such as CMS are supporting a solid commercial opportunity.

Kalorama Information maintains its projection of strong growth in the clinical sequencing segment. Demand is supported by the adoption of clinical applications in precision medicine and rare diseases supporting a CAGR of 9% through 2030. Oncology applications remain one of the leading drivers of the market and industry acceptance is noted through expanded reimbursement and increased attention on regulatory submissions and granted approvals.

Advanced Medicine Without Borders

Clinical and research diagnostics in developing countries, and in particular the emerging countries, as shown in the table below, are the beneficiaries of the trend for IVD companies to expand their reach beyond their traditional borders.

Table 4-1: Key Emerging IVD Markets, 2020-2025 ($ million)

Market	2020	2021	2022	2023	2024	2025
Brazil	1,483	1,701	1,728	1,658	1,733	1,843
China	4,697	6,406	6,602	5,868	5,920	6,276
India	1,156	1,452	1,451	1,299	1,331	1,390
Indonesia	298	327	319	293	298	306
Malaysia	125	135	134	124	127	132
Mexico	697	797	809	770	793	832
Saudi Arabia	584	675	691	612	627	675
South Africa	262	377	392	355	362	377
South Korea	458	511	498	474	487	509
Thailand	196	218	214	193	195	199
Turkey	853	1,054	1,060	992	1,013	1,085
Vietnam	112	125	136	125	131	136

Source: Kalorama Information

As growth in developed markets such as the U.S., Europe, and Japan has matured, IVD companies have increasingly looked to international markets to expand their product portfolios and extend their commercial reach. This trend applies not only to large multinational firms but also to second-tier and emerging companies introducing advanced diagnostic technologies in developing regions. Expansion strategies have evolved beyond traditional distribution agreements to include localized manufacturing, strategic partnerships, and in-country product development efforts tailored to regional needs.

China remains a central focus of this global expansion strategy due to the size of its healthcare system, ongoing investment in clinical infrastructure, and strong demand for advanced diagnostics. However, the market has become more complex and competitive, shaped by government policies, pricing controls, and increasing domestic innovation. Companies including bioMérieux, QIAGEN, Siemens Healthineers, Oxford Nanopore Technologies, and others have continued to pursue opportunities in China through a combination of

partnerships, localized operations, and targeted investment, reflecting both the potential and the challenges of operating in this rapidly evolving market.

Many companies are increasingly diversifying beyond China into other high-growth regions such as India, Southeast Asia, the Middle East, and Latin America, both to capture new demand and to mitigate geographic and policy risk. This shift reflects a broader move away from export-driven models toward building localized systems that include manufacturing, research and development, and supply chain capabilities aligned with regional regulatory and procurement requirements. Government policies that prioritize domestic production and technology transfer are further influencing market entry strategies, while the expansion of private healthcare systems and independent laboratory networks is accelerating the adoption of advanced diagnostics. In addition, the growing role of digital health, connectivity, and cloud-based platforms is enabling companies to address infrastructure gaps and deliver more integrated diagnostic solutions, reinforcing the importance of flexible, region-specific strategies in global IVD expansion.

China Market Update

China is one of the largest IVD markets globally and a key region in the Asia Pacific; however, growth has slowed relative to earlier revenue expectations. The market has experienced pricing pressure and slower expansion due to healthcare reforms and centralized and volume-based procurement programs. The country has implemented increased cost controls, particularly affecting reagent pricing and routine testing. While the number of domestic IVD companies has continued to grow, consolidation is beginning to emerge as smaller players face margin pressure and increased regulatory requirements. The decline in testing volumes following the COVID-19 pandemic has also contributed to slower growth, particularly in molecular diagnostics.

Despite this slowdown, demand for IVD remains strong. China's aging population and rising prevalence of chronic diseases such as diabetes, cardiovascular disease, and cancer continue to influence long-term demand for diagnostic testing. At the same time, the expansion of healthcare access and ongoing investment in hospital infrastructure are driving growth in test volumes, even as revenue growth is constrained by pricing dynamics. The market is increasingly segmented, with routine testing experiencing pricing pressure while higher-value areas such as molecular diagnostics, oncology testing, and specialty immunoassays continue to grow.

Historically, multinational companies dominated the Chinese IVD market, but domestic manufacturers have significantly increased their market share over the past decade. Local companies such as Shanghai Kehua Bio-Engineering, DaAn Gene, Runda Medical, Autobio Diagnostics, Mindray, GeneCast Biotechnology, WuXi AppTec, and Wondfo Biotech have strengthened their positions through competitive pricing, government support, and expanding product portfolios. Many of these companies are now competing directly with global firms in core laboratory, molecular diagnostics, and point-of-care testing segments. At the same time, localization has become a critical strategic priority, with both domestic and multinational companies expanding local manufacturing, partnerships, and supply chain capabilities to align with regulatory requirements and procurement preferences.

Companies such as Abbott, BD, Bio-Rad, bioMérieux, Danaher, Revvity, QIAGEN, Roche, and Thermo Fisher Scientific, maintain a strong presence in China, particularly in high-end instrumentation, advanced molecular diagnostics, and premium testing segments. However, they face increasing competition from domestic manufacturers, as well as ongoing pricing and reimbursement pressures. Investment in laboratory automation, digital infrastructure, and artificial intelligence is also increasing, particularly in large hospital networks, supporting more standardized workflows and improved operational efficiency.

China continues to see an uptick in chronic lifestyle diseases. Companies such as Roche offer integrated solutions like the cobas pro platform, a scalable and modular system designed for mid- to high-volume clinical chemistry and immunoassay testing. While demand for advanced diagnostic platforms remains steady, purchasing decisions are increasingly influenced by cost efficiency, local sourcing preferences, and government procurement policies. The market has experienced pricing pressure and slower expansion due to healthcare reforms, centralized and volume-based procurement programs, and increased cost controls, particularly affecting reagent pricing and routine testing segments.

Direct to Consumer Genetic Test Services

Advances in genomics have led to an increase in genetic test services that predict a person's risk of developing various chronic diseases such as diabetes, cardiovascular conditions, arthritis, Alzheimer's, breast cancer, celiac disease, and psychological syndromes.

23andMe was a pioneer in this area and has successfully provided many FDA-cleared DTC tests. The company filed for bankruptcy in March 2025. The company was acquired in July 2025 by nonprofit research institute TTAM. Select products are still available from TTAM.

Color offers the Color Extended Kit for $249. It is designed to assess the risk of hereditary cancer and hereditary heart health by looking at 30 different genes, including those associated with colorectal cancer, melanoma, ovarian, pancreatic, stomach, prostate, and uterine cancers.

Other IVD DTC genetic testing companies include Gene by Gene, Genesis HealthCare, Easy DNA, Veritas, and Myriad Genetics

The patient can initiate testing and authorize an independent physician from an external network to order the test or have their physician order it.

Genetic Testing in Disease

Genetic testing is advancing rapidly, opening new avenues for diagnostic capabilities. Sequencing technologies are becoming increasingly accessible and cost-effective, enabling healthcare professionals to perform whole-genome sequencing more routinely. Genetic testing has significantly enhanced personalized medicine in several key areas, including:

- Cancer diagnostics, by identifying specific cancer types and enabling more targeted treatments;
- Pharmacogenetics, by tailoring drug therapies based on an individual's genetic response to medications; and
- Inherited disease detection, by identifying mutations early and enabling timely intervention.

Kalorama Information identifies this field as one with tremendous potential. In the future, genetic testing may become a standard tool in personalized medicine and routine preventative screening.

Genomic Testing

Advances in genomic research and laboratory technology are bringing genomic medicine into routine clinical use. The next step is making sure that this information can be delivered in a practical way so clinicians can use it in everyday decision-making. This depends on systems that can translate complex genomic data into clear, clinically useful results.

Next-generation sequencing has made it possible to analyze large amounts of genetic information quickly and at a lower cost. However, generating data is only part of the process. Interpreting that data and turning it into clinically relevant information requires strong bioinformatics support and reliable analysis tools.

Genomic testing is now used more widely, especially in the diagnosis of rare diseases and in pediatric cases, where it can help shorten the time to diagnosis and improve outcomes. Testing is also moving beyond DNA alone, with increasing use of methods that combine different types of biological data to give a broader view of disease.

In oncology, genomic testing continues to expand through larger gene panels and the use of liquid biopsy for treatment selection and disease monitoring. There is also growing interest in using these tools earlier, including in screening and early detection. Improvements in data analysis are helping laboratories and clinicians handle more complex information and make better use of results.

Laboratory workflows are also improving, with more automation and better integration across different steps in the testing process. This helps reduce turnaround time and simplifies operations. Newer technologies, such as optical genome mapping, are also being introduced to complement sequencing by improving the detection of certain types of genetic changes that may be missed by standard methods.

Gene Editing

Gene editing is a process in which DNA is inserted, deleted, or replaced in the genome of an organism using engineered nucleases. There are three families of engineered nucleases in use today, including:

- Zinc finger nucleases (ZFNs)
- Transcription Activator-like Effector-based nucleases (TALANs)
- CRISPR-Cas System

Gene targeting with ZFNs or TALENs is used to modify defective genes. An example is Sangamo BioSciences, which introduced the Delta 32 mutation (a suppressor of the CCR5 gene, a co-receptor for HIV-1 entry into T cells and therefore enabling HIV infection) using Zinc Finger Nuclease (ZFN). Researchers at SGMO mutated CCR5 in CD4+ T cells, thereby producing an HIV-resistant T-cell population.

CRISPR is a technology used to modify genetic material by making precise changes to DNA. It is based on a natural defense system found in bacteria, which helps protect them from viruses and other foreign genetic material. This system works by recognizing specific DNA sequences from invading organisms and cutting them to prevent infection.

The CRISPR system includes short repeating DNA sequences along with nearby genes known as CRISPR-associated (Cas) genes. These genes produce enzymes that can cut or unwind DNA. Among these enzymes, Cas9 is the most widely used. Originally identified in the bacterium Streptococcus pyogenes, Cas9 can be guided to a specific DNA sequence, where it cuts the DNA, allowing targeted gene modification.

Because of its precision and flexibility, CRISPR-Cas9 has become an important tool for gene editing, enabling researchers to study gene function and develop new approaches in medicine and biotechnology.

Table 4-2: Selected Gene Editing / CRISPR Innovations

Company	Location	Details
Agilent Technologies	U.S.	SureGuide pooled CRISPR libraries for functional genomics
Agilent Technologies	U.S.	Cas9 endonuclease kit
Arbor BioSciences	U.S.	CRISPR/Cas-driven myNGS Guides, controls
Bio-Rad Laboratories	U.S.	ddPCR with CRISPR gene editing
Bio-Rad Laboratories	U.S.	CRISPR applications for ddPCR & flow cytometry
Broad Institute	U.S.	CRISPR-based SHERLOCK Zika in stool, COVID
Caedea Bio	U.S.	CRISPR Chip graphene biosensor
Cepheid	U.S.	GeneXpert sARS-CoV-2, with Sherlock Biosystems
Clontech	U.S.	Guide-it CRISPR/Cas9 Gesicle Production System
DefiniGen	U.K.	CRISPR gene editing disease models
EdiGene	China	Genome editing platforms
Evotec	Germany	Licensed CRISPR gene Cas9 technology from ERS Genomics
Evotec	Germany	CRISPR-Cas0 technology from ERS Genomics
Illumina	U.S.	Desktop Genetics' CRISPR gene editing software
Inscripta	U.S.	new CRISPR enzyme free for research
Locus Biosciences	U.S.	with IDbyDNA, DNA & RNA sequencing, pathogen ID
Mammoth Biosciences	U.S.	CRISPR POC & OTC detection platform
MIT, Broad Institute	U.S.	POC Sherlock, paper-based CR ISPR device, viruses
Origene Technologies	U.S.	CRISPR/Cas9 Genome Editing
Oxford Nanopore Technologies	U.K.	Minion CRISPR sequencing
Promega	U.S.	Broad's CRISPR Cas 9 with knock-in gene editing
Sherlock Biosciences	U.S.	SHERLOCK, smart amplification detection
Sphere Fluidics	UK	Cyto-Mine, CRISPR with single-cell analysis

Company	Location	Details
Thermo Fisher Scientific	U.S.	Invitrogen GeneArt CRISPR products
TwinStrand Biosciences	U.S.	CRISPR-DS sequencing for ovarian cancer
U. of CA, Berkeley	U.S.	POC developing CRISPR chip
U. of North Carolina	U.S.	Gene editing, Hunter or Hurler syndrome

Source: Kalorama Information, company reports

CRISPR as a Diagnostic Tool

One of the most important new applications of CRISPR is in the diagnosis of infectious diseases. CRISPR pioneers Jennifer Doudna and Trevor Martin have co-founded Mammoth Biosciences to develop a device that uses CRISPR to detect infectious diseases, including malaria, tuberculosis, and Zika. The company is working on a credit card-sized paper test and smartphone app combo for disease detection.

Mammoth reported that the theory behind their product development is that CRISPR can be used for more than just gene editing. CRISPR can target precise bits of genetic code, so it can be engineered to detect a genetic sequence belonging to a particular virus, like Zika. When combined with special enzymes, CRISPR can be turned into a precise diagnostic tool.

Mammoth Biosciences is not alone in this endeavor. Researchers around the world are finding innovative ways to employ CRISPR technology to detect diseases in some of the most remote, challenging areas, including Lassa fever, Zika, and dengue fever. Mammoth BioSciences offers DETECTR BOOST SARS-CoV-2 reagent kit. The platform is the first with a high-throughput solution that combines the power of CRISPR with laboratory automation for SARS-CoV-2 testing. It uses Agilent Bravo BenchCel BD liquid handling platform.

Fellow CRISPR pioneer, Feng Zhang at the Massachusetts Institute of Technology, developed a CRISPR paper test offered by SHERLOCK. SHERLOCK is scaling up access to its diagnostic tests at high volume. The company is also working on another test called INSPECTR, which people would be able to use in their homes, rather than in a lab setting. That synthetic biology-based product would be able to provide users with a positive or

negative result on a strip of paper. In March 2022, the company raised $80 million in financing to provide at-home diagnostic testing.

The African Centre of Excellence for Genomics of Infectious Diseases in Nigeria uses a CRISPR diagnostic test to look for Lassa virus in a blood sample.

In 2025, several companies are expected to demonstrate significant advancements in trial data. By using CRISPR in detection of disease, there will likely be improved sensitivity, specificity and speed of CRISPR -based assays. Current CRISPR -based diagnostic tools include:

- SHERLOCK – Sherlock Biosciences (OraSure)
- DETECTR - Mammoth
- COMET - Lunaphore
- CRISPR-Chip – Paragraf

CRISPR and the Food Industry

In the near future, the first foods from plants or animals whose DNA has been "edited" are expected to begin selling. It's a different technology from today's controversial "genetically modified" foods, more like faster breeding that promises to boost nutrition, spur crop growth, make farm animals hardier, and make fruits and vegetables last longer. Now, gene-editing tools promise to alter foods more precisely without necessarily adding foreign DNA, as is the case with genetically modified organisms. Instead, they act like molecular scissors to alter an organism's own genetic code.

The U.S. National Academy of Sciences declared gene editing one of the breakthroughs needed to improve food production so the world can feed billions more people amid a changing climate. Yet governments are wrestling with how to regulate this powerful new tool. After years of confusion and opposition to genetic modification, will shoppers accept gene-edited foods or view them as GMOs in disguise?

Some initiatives include wheat with triple the usual fiber, or that's low in gluten; mushrooms that don't brown; better-producing tomatoes; drought-tolerant corn; rice that no longer absorbs soil pollution as it grows, and infection-resistant animals for human consumption.

Some developmental innovations that are using CRISPR technology include:

- Tropic Biosciences using CRISPR to delete the caffeine production of the gene
- Tomatoes that are spicy
- Wine that does not produce a hangover after overindulgence
- Control of pests
- Producing allergy-free foods such as IngateyGen working on a hypoallergenic peanut using CRISPR
- Revival of extinct species – California Biotech has started a passenger pigeon project

Microbiome

Associations between the human microbiome and inflammatory, metabolic, gastrointestinal, immune, dermatologic, oncologic, and neurologic disease continue to attract significant research and commercial interest. The gut microbiome remains the most studied area, but attention has also expanded to the oral, skin, urogenital, and tumor-associated microbiomes. Microbes in the gut, mouth, skin, and other body sites have been linked to conditions such as inflammatory bowel disease, irritable bowel syndrome, obesity, diabetes, allergies, autoimmune disease, cancer, infectious diarrhea, and mental health disorders. While these associations are biologically important, the field is still working to determine which microbiome signatures are clinically actionable and reproducible enough for routine diagnostic use.

In clinical diagnostics, microbiome testing remains an emerging and relatively narrow market. Most testing is still performed through service providers, academic laboratories, specialty reference laboratories, or research-use platforms. Sequencing-based approaches, including 16S rRNA profiling, shotgun metagenomics, metatranscriptomics, and targeted molecular assays, are being used to study dysbiosis, disease risk, treatment response, and microbial function. However, reimbursement, standardization, interpretation, and clinical utility remain barriers to broad adoption. Consequently, microbiome diagnostics have not yet become mainstream IVD products in the same way as infectious disease molecular assays or oncology companion diagnostics.

Genetic Analysis remains one of the more established companies in microbiome-based diagnostics through its GA-map technology, a gene-based test designed to identify gut dysbiosis associated with conditions such as irritable bowel syndrome and inflammatory bowel disease. Luxia Scientific has also offered CE-marked microbiome testing through its 1test1 platform, which analyzes gut bacterial composition using sequencing-based methods. These products illustrate the movement toward more standardized microbiome testing, although adoption remains limited and the European IVDR environment has increased the burden on companies seeking to maintain or expand clinical claims.

OraSure Technologies remains active in the microbiome field primarily through its DNA Genotek and Diversigen businesses, which include stool and saliva collection devices and microbiome sequencing and analysis services. CoreBiome is generally treated as part of the Diversigen microbiome services brand rather than a separate, standalone business. These

offerings are important for research, pharmaceutical development, clinical studies, and sample collection, but they are not positioned as broad routine diagnostic tests.

Bio-Rad's earlier collaboration with Genetic Analysis and Bioaster reflected the industry's interest in identifying microbiome signatures associated with metabolic diseases, including diabetes and obesity. Thermo Fisher's Applied Biosystems Axiom Microbiome Array also remains relevant as a research tool for broad microbial detection across bacteria, archaea, fungi, protozoa, and viruses. Illumina, Oxford Nanopore, and other sequencing platform providers continue to support microbiome research through sequencing instruments, library preparation tools, and bioinformatics workflows rather than disease-specific microbiome diagnostic kits.

Microbiome links to cancer remain an active area of research. Certain pathogens already have well-established roles in cancer, including Helicobacter pylori in gastric cancer and HPV in cervical, anal, and some head and neck cancers. Beyond these established infectious causes, companies and academic groups continue to study whether tumor-associated or circulating microbial signatures can support early cancer detection, risk stratification, or treatment response monitoring. Companies such as Micronoma and Prescient Metabiomics have pursued microbiome-based cancer diagnostics, although this remains an early-stage field and has not yet produced widely adopted routine screening tests.

The gut-brain axis also remains an active area of research, with studies linking gut microbial composition and microbial metabolites to depression, anxiety, Parkinson's disease, and other neurologic or psychiatric conditions. However, these findings are still largely investigational. Microbiome profiles are not yet used as standard diagnostic tests for mental health or neurologic disease.

Table 4-3: Selected Microbiome Test Innovations

Company	Location	Details
Bio-Rad Laboratories	U.S.	Gut microbiome & CE marked GA-map, genetic analysis
BIOHM Health	U.S.	microbiome autism linkage
CosmosID	U.S.	Collab with Zymo Research microbiome analysis
DayTwo	Israel	Gut microbiome nutrition plan service
Diversigen	U.S.	Collab with Norgen Biotek, microbiome seq and analysis
DNA Genotek / OraSure	U.S.	Omnigene microbiome collection devices
Genetic Analysis	Norway	GA-map microbiome imbalance
GenomeAsia 100K	Singapore	sequencing data with microbiome, personal info for disease risk
Helomics/Precision Therapeutics	U.S.	Cancer with Viome link microbiome with ovarian cancer
Luxia Scientific	France	1test1, bacterial content of the gut microbiome
Microba	Australia	Collab with Macrogen microbiome research services
Microbiome Insights	Canada	next-generation sequencing-based analytical testing
One Codex	U.S.	public portal for microbiome data
OraSure	U.S.	BoosterShot seq, microbiome services
Phase Genomics	U.S.	AI computational platform for microbiome samples
Prescient Medicine	U.S.	Seq with Metabiomics colon cancer
QIAGEN	Netherlands	Biomillenia's proprietary microbiome-on-a-chip technology
Thermo Fisher	U.S.	Applied biosystems Axiom Microbiome array
Thryve Inc. (Ombre)	U.S.	$99 gut health kit, DTC service
Viome	U.S.	DTC microbiome test service stool
Viome	U.S.	Gut microbiome & ovarian cancer, stool

Source: Kalorama Information, company reports

Next-Generation Sequencing

Next-generation sequencing has altered the field of genomics. Although the first clinical NGS system received FDA approval in 2013, making the IVD segment relatively new, there has already been substantial activity in laboratory-developed tests performed by certified clinical laboratories. Much of the current clinical sequencing market consists of instrument sales to reference and specialty laboratories, along with associated reagents, library preparation kits, and consumables.

Clinical NGS adoption is led primarily by Illumina and Thermo Fisher Scientific. Thermo Fisher's Ion Torrent technology began with the Personal Genome Machine and has since advanced to platforms such as the Ion GeneStudio S5 series, which support higher-throughput clinical applications. This technology detects DNA synthesis by measuring pH changes that occur when nucleotides are incorporated, thereby avoiding the need for optical detection systems.

Illumina's platforms use sequencing-by-synthesis chemistry, relying on reversible terminator nucleotides and imaging to generate sequence data. Systems such as MiSeq, MiniSeq, iSeq 100, and the NextSeq series are widely used in clinical and research settings. These platforms are designed to process large numbers of DNA fragments simultaneously, enabling efficient and accurate sequencing workflows.

While PCR played a central role in diagnostic testing during the COVID-19 pandemic, sequencing was essential for tracking and understanding the virus. Many regions continue to require sequencing a portion of positive samples for surveillance purposes.

NGS is especially useful in the study of inherited disorders that involve multiple genes. In conditions such as cardiomyopathies, where many genes contribute to a wide range of symptoms, NGS allows simultaneous analysis of numerous targets in a cost-effective manner. Other methods, such as microarrays, may still be appropriate in certain cases, including some neurological conditions. Selecting the most appropriate testing approach remains an important consideration in clinical practice.

Two common NGS strategies are targeted gene panels and whole-exome sequencing (WES). Targeted panels focus on a defined set of genes, which helps limit incidental findings and simplify interpretation, but they may require updates as new disease-associated genes are

discovered. WES covers a broader portion of the genome and is particularly valuable in rare disease diagnosis, although it may not provide complete coverage of all regions.

NGS has also become an important tool in companion diagnostics. Illumina and Thermo Fisher have worked with pharmaceutical companies to develop tests that identify patients who may benefit from specific therapies. These include assays that analyze genetic variants associated with targeted oncology treatments. At the same time, regulatory frameworks continue to evolve. In the United States, laboratory-developed tests have historically allowed faster market entry, but increasing regulatory oversight may affect the number of competitors and pricing dynamics. Similar regulatory alignment is taking place in Europe and Asia, where requirements for approved systems and kits are becoming more standardized.

Table 4-4: Selected Clinical NGS Platforms on the Market

Company	Platform Details and Assays
Thermo Fisher Scientific (Life Technologies)	Ion PGM Dx (FDA; CE-IVD); Oncomine Dx Target Test, ion semiconductor or sequencing by synthesis (SBS)
Beijing Genomics Institute (BGI)	BGISEQ-100 / BGISEQ-1000; Platform for CFDA-approved BGI NGS assays for NIPT; SBS method
Illumina	MiSeqDx (FDA; CE-IVD); Cystic Fibrosis 139-Variant Assay and MiSeqDx Universal Kit, extended RAS Panel; SBS method NextSeq 550Dx (FDA; CE-IVD); intended only for targeted sequencing of DNA libraries from human DNA
Pac BioSciences	PacBio Sequel II System, Onso
QIAGEN	PyroMark Q24 MDx (CE-IVD marked; pyrosequencing platform for companion assays in oncology), QIAseq Human Exome TR Insights
Vela Diagnostics	Sentosa SQ301; FDA-approved Thermo Fisher Ion Torrent-based platform; also performs CE-IVD marked NGS assays for HIV and HCV genotyping and oncogene panels

Source: Kalorama Information

The realization of a greater clinical sequencing market will depend on a variety of factors, including standardization of regulatory review of clinical sequencing products, the miniaturization of clinical sequencing systems, and technological improvements that reduce hands-on time and automate analysis to reduce the risk of user error. New sequencing tests will also be required to successfully demonstrate their clinical utility to justify

reimbursement, in terms of improved patient outcome when coupled with a particular therapy or to predict patient outcomes that allow patients to consider multiple care strategies. Adaptation of NGS to POC settings is still far off and will require a demonstration of significantly higher utility than other existing POC platforms.

BGI offers its Homologous Recombination Deficiency Detection Kit. The kit is designed to provide qualitative detection of homologous recombination deficiency (HRD) in genomic DNA using high-throughput sequencing. Early HRD detection could predict the efficacy of PARP inhibitors in ovarian and breast cancer patients.

Thermo Fisher Scientific offers its CE-marked Applied Biosystems TaqPath Seq HIV-1 Genotyping Kit. The Applied Biosystems TaqPath Seq HIV-1 Genotyping Kit is a Sanger sequencing-based assay that identifies genetic variants of HIV that are most resistant to antiretroviral therapy.

BGI Genomics markets its GPMeta, a metagenomic sequencing diagnostic tool to detect causative pathogens in clinical microbiological testing. The GPMeta can quickly diagnose pathogens using complex, large-scale mNGS data.

Devyser provides two new products, LynchFAP and BRCA PALB2. These kits offer targeted analysis of genes associated with increased cancer risk with a simple NGS workflow.

Illumina entered into a strategic partnership with Pillar Biosciences for the commercialization of Pillar's oncology portfolio, which can be used on any of Illumina's sequencers. These assays help to identify mutations that create tumor growth.

Agilent sold Resolution Bioscience to Exact Sciences. Resolution Bioscience develops and commercializes next-generation sequencing oncology solutions.

Oxford Nanopore offers TurBOT, a benchtop instrument offering NGS.

Roche entered the market with unique technologies designed for clinical speed and precision. Roche offers the VENIO Edge System with features automated sample prep for liquid biopsy and tissue sequencing applications. Roche also offers Roche Sequencing by Expansion, a fast and accurate sequencing technology based on Xpand DNA for clinical WGS, oncology, and pathogen genomics applications.

Liquid Biopsy

Liquid biopsy is an important emerging technology in patient care and precision medicine. Minimally invasive liquid biopsies of tumor cells and tumor DNA from the bloodstream can enable earlier primary and secondary diagnoses compared to solid tumor biopsies, as well as the detection of metastasis and/or residual disease, and real-time monitoring of treatment effectiveness, which is not practical with solid tumor biopsy methods.

Genomic DNA amplified or sequenced from circulating tumor cells (CTCs), circulating tumor cell DNA (ctDNA) and circulating cell-free DNA (cfDNA) provide complementary information on mutations relevant for the treatment of individual cancer patients. These applications promise to impact clinical protocols and treatment regimens and will likely determine the future standard of care in oncology.

The basic technology of circulating tumor cell testing has come a long way since the first application: in 2004, the FDA approved the CellSearch system for in vitro use of circulating tumor cell count in patients with metastatic breast cancer. In its purist application, liquid biopsy has perfected the detection of rare cells or molecular products in a sea of "other" cells. The CellSearch systems are the first and only clinically validated blood test cleared by the FDA to detect and enumerate circulating tumor cells (CTCs) to help manage patients with metastatic breast, prostate, and colorectal cancers. The China Food and Drug Administration also approved the test for use in monitoring metastatic breast cancer patients.

The term liquid biopsy had not yet been coined, and, in fact, when it was first introduced, the concept of testing for circulating tumor cells was not universally accepted. Perhaps the CellSearch system was ahead of its time, but it also suffered from the owners' inability to translate it into routine clinical use. First offered by Immunicon, the CellSearch Circulating Tumor Cell Kit was exclusively marketed by Veridex, LLC. Then Veridex was acquired by Johnson & Johnson's Janssen Diagnostics.

CellSearch found its most recent home in 2017 when Menarini-Silicon Biosystems, Inc. (Bologna, Italy and San Diego, CA) acquired all the assets and relevant business related to the CELLSEARCH Circulating Tumor Cell System from Janssen Diagnostics, LLC. The CELLSEARCH product line, which includes the CELLTRACKS AUTOPREP SYSTEM, the CELLSEARCH Analyzer II and the CELLSEARCH CTC Kit, is combined with Menarini-Silicon Biosystems' flagship DEPArray NxT System

More recently, circulating DNA in all its forms has overtaken CTC-based techniques in liquid biopsy tumor analysis. The basic science of testing for circulating DNA in blood began with the detection of fetal DNA in maternal peripheral blood. In 1970, researchers at Stanford University discovered a few cells in a pregnant woman's blood that must have come from her developing son, since they contained the male Y sex chromosome.

The extension of this early research became a reality for prenatal testing through the proof-of-principle work by Dennis Lo, M.D., a professor of Medicine and Chemical Pathology at the Chinese University of Hong Kong and Director of the Li Ka Shing Institute of Health Sciences. This discovery has enabled a safer way for prenatal diagnosis of abnormalities in fetal development. More importantly, it pushed the boundaries beyond basic count and established the proof of concept that was critical to the development of the various forms of circulating DNA, as shown below.

Circulating tumor cells are of increasing interest to organizations involved in translational medicine, companion diagnostics and investigational research. Automated workflows are a necessary precondition for the widespread adoption of CTCs as a sample type and for ensuring productivity and consistency in testing.

Circulating tumor DNA is a small fragment of mutated DNA released by tumor cells into the bloodstream.

Cell-free DNA can be applied more broadly than ctDNA. cfDNA will determine the standard of care in oncology, transplant medicine and cardiovascular disease. This field is emerging as one of the most promising and exciting areas of medicine and has already made a huge impact on prenatal care.

A crucial step in isolating cancer cells is also key to enabling liquid biopsy, in which cancer can be detected through a simple blood draw. This would eliminate the discomfort and cost of tissue biopsies, which use needles or surgical procedures as part of cancer diagnosis. The commercialization of sample-collection and quality-control products specifically for liquid-biopsy analyses demonstrates confidence in the technology. Liquid biopsy could also be useful in tracking the efficacy of chemotherapy over the course of time, and for detecting cancer in organs difficult to access through traditional biopsy techniques, including the brain and lungs. However, isolating circulating tumor cells from blood is no easy task, as they are present in extremely small numbers.

Special blood tubes for cfDNA analyses are: Cell-Free DNA BCT tubes manufactured by Streck, Inc., and the K3EDTA tubes from BD Vacutainer. They prevent increases in background gDNA levels caused by temperature fluctuations or agitation that can occur during blood sample storage, shipping and processing. These special blood-collection tubes provide a method for obtaining high-quality stabilized samples for rare DNA target detection and determining accurate cfDNA concentrations.

OraSure Technologies, a participant in point-of-care diagnostics and specimen collection and stabilization devices, acquired Novosanis, an early commercial-stage producer and distributor of urine sample collection devices targeted primarily at liquid biopsy. Novosanis' primary product technology is Colli-Pee, an easy-to-use device designed for the standardized collection of first-void urine in the privacy of the user's home or at a clinic. The initial commercial application is as a collection device for liquid biopsy tests in the prostate and bladder cancer markets.

Bioengineers collaborating with those at the University of Illinois Cancer Center have developed a device that can isolate individual cancer cells from patient blood samples. The microfluidic device separates the various cell types found in blood by size. The product is still in the research phase, but it may one day enable rapid, inexpensive liquid biopsies to help detect cancer and develop targeted treatment plans.

Beckman Coulter Life Sciences entered into a partnership with Apostle Inc. for the launch of Apostle MiniMax High Efficiency Cell-Free DNA Isolation Kit, a magnetic nanoparticle-based kit to extract cfDNA from plasma using manual or automated workflows.

Vela Diagnostics offers its Sentosa SX cfDNA sample prep on SX101 instrument in China.

Sysmex gained marketing approval in Japan for blood-based RAS Gene Mutation Testing for colorectal cancer. The OncoBEAM RAS CRC Kit is used for blood-based molecular testing of circulating tumor DNA for mutations in the RAS gene.

Biocept entered into a collaboration with Quest Diagnostics to provide advanced NGS-based liquid biopsy testing for patients with lung cancer. The Biocept Target Selector NGS-based liquid biopsy assay is a less invasive, lab-developed test that can be used for genomic profiling in patients with advanced non-small cell lung cancer to help qualify them for advanced targeted therapies and to monitor treatment effectiveness.

The AML-MRD-SEQ is System Inostics' CLIA-validated liquid biopsy test for detecting minimal residual disease in acute myeloid leukemia. The test uses a targeted NGS panel and offers reliable, more sensitive detection of molecular MRD.

Foundation Medicine entered into a partnership with Sequanta to provide both liquid and tissue genomic profiling services to China. In the US, the company offers the FoundationOne Tracker with Medicare coverage. FoundationOne Tracker test is a personalized tissue-informed circulating tumor DNA test to monitor cancer patients' response to therapy.

Guardant Health's Shield Test, as a primary blood-based CRC screening test, has proven to be a valuable addition to the market.

Labcorp received de Novo authorization for its PGDx elio plasma focus Dx. This is the first pan-solid tumor liquid biopsy test.

Quality Assurance

Quality control standards and controls are necessary to ensure that an assay is delivering accurate test results. The availability of quality control products is a necessary step in moving a test from research to routine clinical testing. A number of quality control products are coming to market. The leaders are SeraCare Life Sciences and Horizon Discovery.

SeraCare has developed a unique, patent-pending technology that produces a DNA fragment size distribution that closely mimics native cfDNA while reducing DNA damage relative to ultrasonicated material. The result (according to SeraCare) is a renewable source of highly characterized material that exhibits performance similar to that of a patient sample when treated identically. The Seraseq ctDNA v2 requires no special workflow considerations to generate informative data. According to SeraCare it is especially important for validation studies that require strict adherence to standard operating procedures.

Horizon Discovery has developed a range of cell-free DNA Reference Standards, derived from cell lines to closely mimic patient samples. Horizon reports that, with allelic frequencies as low as 0.1%, these Reference Standards are ideal for optimizing and validating liquid biopsy assays.

Twist Bioscience provides circulating tumor DNA reference controls for development of liquid biopsy assays.

Product News

Researchers have pushed the boundaries of blood-based tissue biopsy. Circulating free nucleic acids have extended the reach of this technology beyond DNA to RNA, miRNA and exomes. Although still emerging, circulating nucleic acids are anticipated to become a prominent technology in future molecular diagnostics, and they have, first, in prenatal fetal testing for genetic abnormalities, and now, as the basis of the liquid biopsy in cancer and pathogen analysis.

Liquid biopsy testing has progressed beyond its earlier role as a primarily research tool and is now used in routine clinical practice in select oncology settings. It is widely applied for therapy selection, treatment monitoring, and the detection of resistance mutations, particularly in advanced and metastatic cancers. However, adoption is not yet universal across all tumor types or disease stages, and its use continues to expand as clinical evidence grows. While liquid biopsy remains especially valuable in complex or difficult-to-treat cases, it is increasingly being incorporated earlier in certain settings. At the same time, major cancer centers and healthcare systems continue to build large clinical and genomic datasets to further demonstrate clinical utility, support reimbursement, and guide broader integration into standard diagnostic workflows.

Nevertheless, the diagnostics industry has rallied to support CTCs, ctDNA, and cell-free DNA testing with assays, testing services, sample-preparation reagents, and quality-control materials. It has been 20 years since Johnson & Johnson formed Veridex, LLC to market Immunicon's CellSearch systems for circulating tumor cells in peripheral blood. This was the first commercial CTC system. CellSearch has FDA approval for the prognosis and monitoring of patients with metastatic breast, metastatic colorectal and metastatic prostate cancer.

IVD company efforts have been supported by the U.S. FDA's Breakthrough Devices Program, which was established in 2016 as part of its "Expedited Access Pathway" (EAP). The process helps patients gain more timely access to devices and technologies that provide more effective treatment or diagnosis for life-threatening diseases that otherwise do not exist. The Breakthrough Devices Program expands on the EAP program by making future 510(k) approvals, Premarket Approval applications, and de novo device submissions eligible. So far, several U.S. companies have benefited from this FDA program, including Foundation Medicine, Guardant Health, and Personal Genome Diagnostics.

Market Cleared Products

Roche Diagnostics continues to expand its test offerings in frontier areas. Roche's cobas EGFR Mutation Test v2, cfDNA, PCR, and lung cancer were among the first liquid biopsy tests to receive FDA market clearance. Roche markets three next-generation sequencing (NGS) Avenio research-use liquid biopsy kits that provide insights into different stages and types of cancer. In the future, Roche's Avenio product line of NGS solutions will include instruments and reagents designed to make sequencing simple and accessible for everyday use.

Guardant Health claims to be a leading precision oncology company. In pursuit of its goal to manage cancer across all stages of the disease, Guardant Health offers multiple liquid biopsy-based tests, Guardant360 and GuardantOMNI, for advanced-stage cancer patients, which fuel its development programs for recurrence and early detection, LUNAR-1 and LUNAR-2, respectively. According to Guardant Health, since its launch in 2014, Guardant360 has become the world's market-leading comprehensive liquid biopsy test and has been used by more than 5,000 oncologists, over 40 biopharmaceutical companies, and all 27 of the National Comprehensive Cancer Network Centers. Also, the Guardant360 assay has been ordered more than 70,000 times to help inform which therapies may be effective for patients with advanced-stage solid tumors. It is supported by more than 70 peer-reviewed journal publications, which address its analytical validity, clinical validity, and clinical utility. Guardant360 is also covered by several private payers, including Cigna and several Blue Cross Blue Shield plans.

Bio-Rad Laboratories markets the QXDx AutoDG ddPCR System, which uses Bio-Rad's Droplet Digital PCR technology, and the QXDx BCR-ABL %IS Kit. This is the company's first liquid biopsy assay and Droplet Digital PCR system for diagnostic use.

TFS markets its Ion Torrent Genexus System, an NGS platform featuring an automated specimen-to-report workflow that delivers results in a single day. The company also provides its Oncomine Precision Assay, an innovative pan-cancer panel for the Genexus platform. It enables comprehensive genomic profiling from formalin-fixed, paraffin-embedded (FFPE) tissue and liquid biopsy samples with a single assay.

NeoGenomics offers the RaDaR assay for detecting molecular residual disease and recurrence. The company also has Medicare coverage in the US for the MolDX program,

including reimbursement for RaDaR clinical testing. RaDaR is a precision liquid biopsy assay that tracks a set of up to 48 tumor-specific variants.

Labcorp acquired Person Genome Diagnostics, a cancer genomics lab with a portfolio of comprehensive liquid biopsy and tissue-based products. The addition of PGDx and its technology complements Labcorp's liquid biopsy capabilities and expands its NGS genomic profiling.

Myriad Genetics expanded its partnership with Intermountain Precision Genomics to add liquid biopsy therapy selection to the Precise portfolio solutions. However, in February 2024, Myriad Genetics completed acquisition of select assets from Intermountain Precision Genomics including the Precise Tumor Tests, Precise Liquid Test and the IPG CLIA lab in Utah.

Cell-Free DNA BCT, which received FDA De Novo clearance by the U.S. Food and Drug Administration when paired with the Guardant360 CDx, has quickly become the industry standard to maintain cell-free DNA samples and limit pre-analytical variation.

Pillar Bioscience offers its OncoReveal CDx pan-cancer NGS test as a general solid tumor profiling test. The FDA originally granted approval to OncoReveal in 2021 for a specific therapy for patients with NSCLC and colorectal cancer. The additional approval allows any hospital or lab running and Illumina MiSeq Dx NGS platform to adopt OncoReveal.

Liquid Biopsy in Microbiology

Diagnosis of life-threatening tissue-based infections currently requires invasive sampling of the infected tissue to provide a microbiologic diagnosis. These procedures can lead to high morbidity since they take several days to get a result and in the case of fungal infections even weeks. On the horizon are next-generation sequencing assays to detect pathogen-derived cell-free DNA in peripheral blood of patients. The technique could eventually be used to identify invasive infections such as sepsis, bone and joint infections and post-transplant tissue infections with biopsy-proven invasive fungal infections.

Karius offers a unique test. The company offers a blood-based test for Mycobacterium chimera in addition to its Digital Culture Test, which can detect more than 1,250 pathogens, including Legionella and Mycobacterium tuberculosis, from a single blood draw. Karius claims to produce results within one business day. The tests use next-generation sequencing

to detect cell-free DNA fragments that bacteria, viruses, fungi and other pathogens leave behind in the blood. Karius markets the test to physicians and labs for $2,000. While it is more expensive than traditional tests, Karius doesn't see its product as a first-line diagnostic. Instead, it's most useful in cases where the patient is critically ill and other tests come back negative.

Bio-Rad markets its Celselect Slides, which offer an improved method of enumeration of CTCs in liquid biopsies. The Celselect Slides are designed to be used with Bio-Rad's Genesis Cell Isolation System for use in genomics, digital PCR or stained on-slide for immunofluorescent applications.

Liquid Biopsy Companies in 2022-2025

A number of liquid biopsy companies have made inroads into the market. These include:

- Roche – liquid biopsy that can identify 70 of the most commonly mutated genes in tumors, including microsatellite instability, which helps determine the type of immunotherapy-based treatment needed from a single blood sample.
- QIAGEN - offers a complete workflow to facilitate liquid biopsy research
- Ombre– working on commercializing CancerSEEK, a DNA and protein-based liquid biopsy
- Biocept - test menu focuses on cancer biomarkers that are based on guidelines listed by the National Comprehensive Cancer Network. The results have molecularly characterized tumor cells and identified changes in protein expression, which are important for prognostic and therapeutic applications. Quest Diagnostics offers Biocept's liquid biopsy test for lung cancer.
- Myriad Genetics – liquid biopsy product is a 25-gene test that identifies elevated risks for 8 different types of cancer. The company has developed a suite of liquid biopsy tests.
- QIAGEN offers FFPE and liquid biopsy PIK3CA diagnostics in Europe to enhance precision medicine in advanced breast cancer.
- Guardant Health announced a collaboration with Amgen to develop a liquid biopsy companion diagnostic for AMG 510 (later branded LUMAKRAS), the first-in-class KRAS G12C inhibitor to advance to the clinic. At the time, Amgen was enrolling

patients in a potentially registrational Phase 2 study. Guardant launched Guardant Reveal, the first blood-only liquid biopsy test designed to detect residual and recurrent colorectal cancer from a simple blood draw. Additionally, Guardant360 CDx received CE-IVD marking for comprehensive genomic profiling in solid tumors.

- Guardant entered into a collaboration with Daiichi Sankyo to pursue regulatory approval of Guardant360 CDx as a companion diagnostic for Enhertu, a HER2-directed antibody-drug conjugate, including use in advanced NSCLC. In May 2021, Guardant received FDA approval for Guardant360 CDx as the first and only liquid biopsy companion diagnostic for RYBREVANT, and as the first FDA-approved liquid biopsy CDx for Amgen's LUMAKRAS in advanced NSCLC.
- Guardant expanded its oncology portfolio with the launch of Guardant360 Response, the first commercially available blood-only test to monitor changes in circulating tumor DNA as an early indicator of treatment response, and Guardant360 TissueNext, the company's first tissue-based assay to support biomarker-informed therapy selection when tissue testing is required.
- Myriad Genetics offers myChoice CDx test.
- Biocartis is advancing the Idylla technology toward customization
- Sysmex Inostics developed a liquid biopsy test for the detection of minimal residual disease in AML called AML-MRD-Seq.
- HelioLiver offers a liquid biopsy test for the early detection of liver cancer
- Personalis markets NeXT Personal, a tumor-informed liquid biopsy assay for MRD
- Twist Bioscience provides circulating tumor DNA reference controls for development of liquid biopsy assays
- Angle markets its test (Parsortix) for metastatic breast cancer
- Bio-Rad offers its Celselect Slides, which offer an improved method of enumeration of CTCs in liquid biopsies. The Celselect Slides are designed to be used with Bio-Rad's Genesis Cell Isolation System for use in genomics, digital PCR, or stained on-slide for immunofluorescent applications.
- Foundation Medicine entered into a collaboration with Karyopharm Therapeutics to develop FoundationOne CDx as a companion diagnostic for Xpovio.
- Additionally, Foundation Medicine markets the FoundationOne Liquid CDx to be used as a companion diagnostic to identify patients with ROS1-postive NSCLC or

patients with NTRK fusion-positive solid tumors who do not have a tissue sample available.

- Biocartis provides the Idylla IDH1-2 FLEX Mutation Assay Kit. The assay is the first test developed using the new Idylla FLEX technology, which separates the generic components of an Idylla test from the test-specific components.
- Biocartis markets the Idylla MSI test for use on the Idylla system. The Idylla MSI Test is a fully automated test that provides information on the MSI status of CRC tumors within approximately 150 minutes from just one section of formalin-fixed, paraffin-embedded (FFPE) tumor tissue, without the need for a paired normal tissue sample.
- Biocartis entered into a collaboration with APIS Technologies to develop APIS' Breast Cancer Subtyping assay on Biocartis' rapid Idylla platform. APIS' current Breast Cancer Subtyping Kit is an RNA-based diagnostic assay for detecting mRNA expression of standard biomarkers (HER2, ER, PR, Ki67) and novel proliferative biomarkers from pre-operative core-needle biopsy (CNB) or resected formalin-fixed paraffin-embedded (FFPE) breast tumor tissue.
- Biocartis entered into a collaboration with HiloProbe that will lead to the commercialization of ColoNode, a CE-marked IVD gene expression signature test that can detect nodal metastasis in colorectal cancer.
- FoundationOne Liquid CDx is offered as a companion diagnostic for Exkivity to identify patients with EGFR Exon 20 insertion mutations in advanced NSCLC.
- FoundationOne Liquid CDx is offered to be used as a companion diagnostic for Braftovi in combination with cetuximab to identify BRAF V6oooE alterations in mCRC.
- Foundation Medicine entered into a collaboration with Merck to develop FoundationOne Liquid CDx for several selected marketed and pipeline treatments.
- Additionally, the company offers its tissue-naive ctDNA monitoring assay, FoundationOne Monitor.
- The RaDaR assay is a personalized liquid biopsy for minimal/molecular residual disease MRD and recurrence detection. This was the first pan cancer coverage to be authorized by Blue Shield.
- Foundation Medicine entered into a partnership with Sequanta to provide both liquid and tissue genomic profiling services to China. In the US, the company launched

FoundationOne Tracker with Medicare coverage. FoundationOne Tracker test is a personalized tissue-informed circulating tumor DNA test to monitor cancer patients' response to therapy.

- Guardant Health's Shield Test is a primary blood-based CRC screening for colorectal cancer.
- Labcorp received de Novo authorization for its PGDx elio plasma focus Dx. The is the first and only kitted, pan-solid tumor liquid biopsy test.
- Tempus markets the xT CDx, a 648-gene NGS test for solid tumor profiling.
- Natera offers its ultra-sensitive Signatera Genome assay that can detect circulating tumor DNA

The Future for Liquid Biopsy

The acceptance of liquid biopsy technologies has grown substantially in recent years, largely driven by the increasing availability of clinical and genomic data. As the volume and quality of evidence supporting liquid biopsy continue to expand, so too does its role in cancer diagnostics and management.

The global liquid biopsy market is experiencing robust growth and is expected to continue its upward trajectory. Key factors fueling this expansion include:

- The rising global incidence of cancer,
- The growing demand for precision medicine, and
- A clear shift toward non-invasive diagnostic approaches.

Currently, liquid biopsy is most commonly used in the management of lung, melanoma, breast, ovarian, cervical, and bladder cancers. Despite growing clinical adoption, many liquid biopsy tests have yet to fully demonstrate clinical utility across broader patient populations and indications. For the field to reach its full potential, rigorous quality control—both in test performance and sample collection protocols—is critical. These standards are essential for the routine integration of liquid biopsy into oncology and other emerging medical disciplines.

Looking ahead, the landscape will likely see a surge in strategic collaborations between pharmaceutical and liquid biopsy companies. One prominent example is the partnership

between GRAIL and AstraZeneca, which focuses on developing companion diagnostics to guide targeted therapies.

Innovation is also accelerating, with companies introducing cutting-edge technologies to enhance sensitivity and applicability. Notable examples include:

- Flomics cfRNA + Ai assay for multi-cancer early detection
- University of Chicago's RNA-based CRC screen
- BioFluidica's LiquidScan: A microfluidic chip platform capable of isolating rare biomarkers such as circulating tumor cells (CTCs), cell-free DNA (cfDNA), and exosomes from blood samples.
- Caris Life Sciences' Caris Assure: A comprehensive molecular profiling platform that analyzes DNA, RNA, and proteins, and sequences over 22,000 genes per test—representing one of the most extensive sequencing assays currently available.

For a more in-depth look at NGS and liquid biopsy, please see Kalorama Information's 2025 report *The Worldwide Market for Liquid Biopsy, 7th Edition.*

Information Technology Advances and Artificial Intelligence

As a result of intensive studies from the Human Genome Project, most elements of the human genome, transcriptome, and proteome have now been curated. In parallel, rapid technological advances have made it faster and more affordable than ever to sequence a person's genome. This sequencing process represents the first step in applying genome analysis—regardless of the specific technology used. The industry is still in the early stages of translating this genomic data into actionable laboratory tests.

Information technology plays a critical role in this translation process, serving three essential functions:

- Facilitating data sharing to build well-curated collections of gene variants,
- Supporting the interpretation of those variants to inform testing guidelines, and
- Distributing this information to clinicians to guide patient care.

A thorough discussion of developments in IT and their implications for clinical laboratory medicine could easily fill a report of its own. In this section, however, Kalorama Information provides a high-level overview of key programs and initiatives that illustrate how the intersection of IT and diagnostics is evolving.

Clinical scoring systems and algorithms have long been used in medicine. Recently, however, there has been a surge in the application of machine learning—a subset of artificial intelligence to enhance these tools. Unlike traditional algorithms, which rely on pre-programmed logic, machine learning models analyze vast datasets to identify patterns and derive optimal calculations autonomously. These models are being developed to:

- Predict outcomes such as diagnosis, mortality, or hospital readmission,
- Improve risk assessment tools,
- Reveal underlying contributors to disease progression, and
- Advance precision medicine by forecasting individual responses to treatment.

AI is primarily being implemented as a means to analyze data more efficiently and accurately, uncovering insights that can streamline care from both clinical and operational standpoints. The overarching goal is to enable more precise, personalized patient care.

In recent years, AI companies have developed increasingly sophisticated machine learning techniques aimed at reducing, and in some cases eliminating, inefficiencies in healthcare delivery. The aim of these innovations is to standardize and assist in the interpretation of test results providing any clinician, regardless of specialty, to make informed decisions. Rather than replacing radiologists or pathologists, this technology is designed to augment their capabilities and support complex decision-making processes.

Google has developed Med-PaLM 2, a large language model tailored for healthcare applications, which has been evaluated in collaboration with organizations such as Mayo Clinic and other health systems. While these efforts highlight the growing role of artificial intelligence in medicine, most implementations remain in early deployment or evaluation stages rather than widespread clinical use.

Advances stemming from the Human Genome Project and subsequent research have enabled extensive mapping of the human genome, transcriptome, and proteome, although full functional understanding remains incomplete. At the same time, technological progress has significantly reduced the cost and time required to sequence an individual's genome, making genomic analysis more accessible in clinical settings.

Genomic testing is now an established component of diagnostics in areas such as oncology, rare disease, and reproductive health, but the broader integration of genomic data into routine laboratory testing continues to evolve. The industry is moving beyond data generation toward improving interpretation, clinical validation, and practical application of genomic insights in patient care.

AI in Clinical Practice

More than 950 medical devices have incorporated AI or machine learning software that have been cleared by FDA for clinical adoption. Artificial intelligence is growing at a fast pace, mainly due to the adoption of AI-based technologies. There is a move to connected health, which includes AI. AI has proved to be an invaluable tool to assist physicians in caring for their patients. The advanced capabilities of algorithms are serving to reduce workload and provide testing solutions. It is anticipated that increased use of machine learning and AI will

help to decrease errors and advance IVD technology. However, the lack of skilled AI personnel and reluctance among doctors to utilize these solutions have restrained growth.

Similar to the product commercialization process that is evident in the liquid biopsy market, IVD companies' efforts have been supported by the U.S. FDA's efforts to give products expedited review. This helps patients have more timely access to devices and technology that provide more effective treatment or diagnosis for life-threatening diseases.

Digital pathology products and diabetes management devices were the first to come to market with data interpretation applications. As shown in the table below, the last few years have seen the use of AI interpretation apps extended to a broader range of products including microbiology, disease genetics and cancer precision medicine. The following are of particular interest.

QIAGEN's bioinformatics teams offers new software solutions and adding proprietary cloud-based content to support the latest research and clinical trends in molecular testing, especially the interpretation of large volumes of data from next-generation sequencing. In addition, QIAGEN is integrating these digital technologies with instruments and molecular content to provide seamless Sample-to-Insight workflows following the acquisition of OmicSoft. QIAGEN acquired OmicSoft Corporation, providing access to OmicSoft's multi-omics data management infrastructure solution as well as expertly curated 'omics' data sets that complement QIAGEN's bioinformatics portfolio, which offer insights into complex biological data. OmicSoft is recognized for its suite of software solutions that enable scientists and researchers to efficiently analyze and visualize their own data sets and compare them to massive volumes of publicly available 'omics' data sets, such as The Cancer Genome Atlas operated by the U.S. National Cancer Institute, and share results with colleagues.

A few years ago, Philips announced that The Miami Cancer Institute signed a multiyear agreement to use Royal Philips' IntelliSpace Precision Medicine Genomics software platform in its new genomics laboratory. The partnership will support the oncology genomic testing workflow at the institute, which is part of the Baptist Health South Florida system.

RenalytixAI, a company focused on diagnostics for kidney disease and transplant management, received FDA Breakthrough Device designation for its KidneyIntelX test. The company has stated that this represents one of the first artificial intelligence-based diagnostics developed specifically for kidney disease. KidneyIntelX is intended to support the identification and management of patients with type 2 diabetes who are at risk for rapid

progression of kidney disease. The test combines blood-based biomarkers with electronic health record data, using machine learning to assess risk and guide clinical decision-making. The development of KidneyIntelX has been carried out in collaboration with the Mount Sinai Health System.

Proscia markets DermAI, a module on its Concentriq digital pathology platform that streamlines workflows. DermAI can prescreen and classify skin biopsies. DermAI provides earlier insight into cases and speeds up the turnaround time for patients and physicians. It also helps the pathologist to prioritize the workload.

The CompuCyst is an AI-driven test that helps identify which patients should undergo surgery and which can be safely followed. CompuCyst incorporates mutation status, loss of heterozygosity, aneuploidy, protein markers, and clinical data.

Paige, an AI software company, developed AI algorithms for analyzing pathology slides for prostate cancer, skin cancer and breast cancer. A series of deep learning algorithms was developed with an automated training and testing technique.

Google partnered with Ascension to collect and analyze patient health data using cloud and AI technologies. Microsoft acquired healthcare AI developer Nuance for approximately $19.7 billion to strengthen Microsoft Cloud for Healthcare, and Oracle acquired Cerner in a $28.3 billion deal to expand its healthcare data and cloud capabilities.

Hologic markets the Genius Digital Diagnostics System for cervical cancer screening. The Genius Digital Diagnostics System is the next generation of cervical cancer screening, combining deep learning-based artificial intelligence with advanced volumetric imaging technology to help identify precancerous lesions and cervical cancer cells in women. The Genius Digital Diagnostics System enables seamless, dynamic collaboration across laboratories within a network, connecting pathologists with remote review capabilities so that each patient can benefit from the collective knowledge of geographically dispersed experts. The Genius Digital Diagnostics System consists of the Genius Digital Imager for image acquisition, the Genius Cervical AI algorithm for analyzing images, the Genius Image Management Server for storing images and the Genius Review Station for case review. The complete system is scalable, designed to fit the present and future needs of laboratories.

Agilent Technologies acquired advanced artificial intelligence technology developed by Virtual Control, an AI and machine learning software developer that creates innovative analysis solutions in lab testing. Agilent intends to integrate the software, known as ACIES,

into its industry-leading gas chromatography and mass spectrometry (GS/MS) platforms to improve the productivity, efficiency and accuracy of high-throughput labs the company serves around the world.

To augment its ThinPrep test, Hologic offers the Genius Digital Diagnostics System for cancer screening. It uses AI to thoroughly analyze every cell and point out clinically relevant objects based on its algorithm. The Genius Digital Diagnostics System is the first and only FDA-cleared digital cytology system that combines deep-learning-based AI with advanced volumetric imaging technology to identify pre-cancerous lesions and cervical cancer cells.

Trinity entered into a strategic collaboration with PulseAI, a medical artificial intelligence company. The collaboration has helped Trinity develop its AI-driven analytical platforms.

Verily provided its first personalized, AI-powered chronic care solution with the launch of Lightpath Metabolic, a program for managing diabetes, hypertension, obesity, and hyperlipidemia.

Table 4-5: Selected AI Market Cleared Tests

Company	Location	Area	Details
Adaptive Biotechnologies	U.S.	ca MRD	clonoSEQ immunosequencing with AI, min residual disease
Clever Culture	Switzerland	micro	APAS platform culture-plate screening & interpretation
Copan Diagnostics	U.S.	micro	PhenoMATRIX culture plate analysis AI
Genome Smart	U.S.	prec med	GenomeBrain link patient with appropriate genetic test
Gnosis Data Analysis	Greece	genome	Just Add Data (JAD) Bio system AI for multi-omics
Google	U.S.	histo	AI research and digital pathology
Ibex Medical	Israel	histo	Second Read (SR) system, AI digital pathology
Individumed	Germany	cancer	AI added to IndivuType multi-omics cancer research platform
IntegraGen	France	sequencing	sequencing data with Google Cloud
IQVIA	U.S.	genome	E360 analytics technology genotypic-phenotypic database
Maxwell Plus	Australia	genome	machine learning with diagnostics, cancer, Alzheimer's, etc.
Medtronic	Ireland	diabetes	Sugar.IQ app with IBM Watson IQcast AI
Philips	Netherlands	cancer	Clinical Pathways, a clinical decision platform, oncology
Philips	Netherlands	genome	IntelliSpace Precision Medicine Genomics software
Qiagen	Netherlands	sequencing	Qiagen Clinical Insight analysis and interpretation solutions
RenalytixAI	U.S.	kidney	KidneyIntelX AI diagnostic for kidney disease
Siemens Healthineers	Germany	sequencing	Fast Track cycler & FastFinder software
Sophia Genetics	Switzerland	cancer	Solid Tumor Solution molecular with AI analysis
UgenTec	Belgium	PCR	Fastfinder real-time PCR interpretation system
Xifin	U.S.	prec med	VisualStrata precision medicine informatics platform

Source: Kalorama Information

There are currently over 1,020 healthcare algorithms approved by the FDA, most of which involve medical imaging. Most of the AI integration has been centered on molecular and digital pathology applications. Clinical chemistry and immunology are the next step. The industry is seeing the development of AI-powered automated hematology analyzers, such as the new DH-615 hematology analyzer from Dymind Biotechnology, which is based on fluorescent nucleic acid staining technology and the company's AI Cube technology.

Kalorama Information expects AI will continue to advance in clinical decision-making. However, there will be speed bumps along the way, such as questions and regulations centered around regulatory, ethical, and medical concerns.

The core clinical IVD areas include digital pathology, as there are FDA-cleared tools to support primary diagnosis in histology and cytology, and scoring biomarkers; hematology, where AI is assisting in blood smear review classification; and microbiology plate reading, where AI auto-releases negative cultures, detects significant colonies, and integrates with MALDI-TOF ID pipelines.

The molecular and genetic testing arena is benefiting from AI-based variant classification, liquid biopsy and ctDNA pattern recognition by filtering sequence noise and enhancing sensitivity for early cancer detection and MRD monitoring.

Immunoassays are using AI to detect subtle shifts in serial biomarkers to alert to early signs of disease progression or relapse.

AI Physician Usage

There has been an uptick in the adoption of AI among physicians. A survey reported that clinical use of AI among physicians has increased to over 80 percent, doubling since 2023 (the last time the survey was conducted). Physicians use AI in two areas, medical research and clinical care documentation. In prior years, physicians were skeptical of AI, but over the past year or so, confidence in AI has grown.

Physicians have found that the biggest advantages of using AI are improved work efficiency and diagnostic accuracy. Although many physicians are cautiously optimistic, Kalorama Information expects that, as the technology improves, AI will continue to find favor with physicians. One of the biggest concerns is patient privacy and the integrity of the patient - physician relationship.

Physicians generally see AI as a helpful tool to automate tasks and speed diagnostic results. However, many are awaiting regulatory directives that establish clear liability frameworks to enable broader adoption and build trust with physicians.

The Regulatory Pathway

As artificial intelligence becomes more widely used in medical tests and devices, regulatory frameworks are still evolving to keep pace with these technologies. Oversight is increasingly focused not only on the performance of a specific product, but also on how the developer designs, trains, and maintains its algorithms. This includes evaluating the data used to build models, validating systems before deployment, and monitoring and updating performance over time with real-world data.

Regulators have expanded their review of AI-enabled medical products in recent years, with a growing number of devices being cleared or authorized for clinical use. Guidance issued over the past few years has begun to establish a more structured approach to software and machine learning in healthcare, outlining expectations for transparency, validation, and ongoing performance management.

Regulatory agencies in the United States, Europe, Canada, and the United Kingdom have also moved toward greater alignment, emphasizing common principles such as risk management, data quality, and clear documentation of how algorithms function. A key focus has been the need for lifecycle oversight, requiring manufacturers to continuously evaluate and update their systems as new data becomes available.

More recent guidance has placed additional emphasis on practical implementation, including how companies manage algorithm changes after deployment and how they demonstrate that updates do not adversely affect safety or effectiveness. Regulators are also encouraging the development of standards and best practices to support innovation while maintaining patient safety.

Product Initiatives

The IVD industry and its partners have embarked on a full-force effort to advance AI-driven tests and devices. In the UK, the country aims to cut cancer deaths by 10% by using AI as the key driver of improved health outcomes. The plan calls for the National Health Service,

the AI industry, and health charities to use data and AI to transform the diagnosis of chronic diseases, with the goal of reducing cancer deaths by around 22,000 each year by 2033.

AI is making inroads into cardiovascular care based on innovations in diagnostics, biomarker detection and prognostic tools. This is an area to watch in the near future for more innovative diagnostic tools to aid in the diagnosis of cardiovascular events.

Table 4-6: Selected AI Product Initiatives in Development and Collaborations

Company	Location	Area	Details
Auron Therapeutics	U.S.	cancer	Elucidata's IT differentiation-based cancer therapies
BGI Genomics	China	cancer	collab with Fred Hutchinson Cancer Research Center
Genomenon	U.S.	genome	Diploid's Moon genome interpretation for rare diseases
Genomenon	U.S.	genome	variants reference datasets on Google BigQuery cloud
Google	U.S.	cancer	Augmented Reality Microscope
Google	U.S.	histo	AI research and digital pathology
Google	U.S.	ptnt mgmt	deep machine learning for electronic medical records
Hitachi Ltd	Japan	ptnt mgmt	risk of hospital readmissions
Hitachi Ltd	Japan	risk	algorithms for disease risk
IBM Watson Health	U.S.	alz	early Alzheimer's detection
IBM Watson Health	U.S.	cancer	collab with Broad Institute, drug resistance in cancer
IBM Watson Health	U.S.	cardiac	collab with Broad Institute, cardiac disease risk
IBM Watson Health	U.S.	public health	AI for public health via patient EHRs
Inspirata	U.S.	histo	Dynamyx digital pathology software
Institut Curie	France	genome	Intel AI tools for a genomics database
Lucence Diagnostics	Singapore	cancer	AI algorithms & database for cancer, liver, breast, gynie
National Institute of Health	U.S.	cancer	early cervical cancer analysis
Natural Cycles Nordic AB	Sweden	womens	Natural Cycles app to determine fertility
Paragon Genomics	U.S.	sequencing	Paragon CleanPlex NGS with Sophia Genetics AI platform
Passport Health	U.S.	womens	preterm birth risk
Phase Genomics	U.S.	microbiome	computational platform for microbiome samples
Project Data Sphere	U.S.	cancer	collab with the U.S. FDA cancer data analysis

Source: Kalorama Information

AI in Liquid Biopsy

Oncology faces two critical challenges: detecting cancers at an early stage when they are still small and more treatable, and providing precision, targeted treatment to cancer patients. One promising solution to these challenges is the integration of machine learning algorithms with liquid biopsy technologies. This combination enhances the ability to detect cell-free DNA and circulating tumor DNA from a simple blood draw.

While liquid biopsies can detect minute traces of tumor DNA, interpreting their significance remains a challenge. Tumors are genetically unique, and many lack a consistent set of known mutations that can clearly identify their type or origin. Furthermore, sequencing these samples generates a large volume of data, some of which may not correlate directly with the tumor's site or type. In this context, machine intelligence becomes an invaluable tool.

Role of AI in Liquid Biopsy Interpretation

Artificial intelligence, particularly machine learning methods, is increasingly used to analyze the large and complex datasets generated by liquid biopsy testing. These tools help identify patterns in circulating tumor DNA and other biomarkers that may be difficult to detect through manual review, supporting faster and more consistent interpretation of results. As more clinical data becomes available, these systems continue to improve, helping refine risk assessment and disease monitoring.

AI-supported analysis is now being incorporated into several liquid biopsy workflows, especially in oncology applications such as genomic profiling, minimal residual disease detection, and early cancer screening. In many cases, these tools are used alongside established testing platforms to support clinical decision-making rather than functioning as stand-alone diagnostics.

While AI is playing an increasingly prominent role in liquid biopsy, most systems are integrated into broader testing platforms rather than being approved as independent diagnostic products. Regulatory frameworks are still developing, with oversight focused on how these tools are validated, monitored, and updated over time.

Industry Leaders and Initiatives

Several companies are pioneering the integration of AI and liquid biopsy:

- CareDx is expanding its transplant care offerings with a focus on AI. It markets blood-based donor-derived cell-free DNA tests to assess transplant organ health.
- GRAIL is conducting large-scale population studies to develop a multi-cancer early detection test. Using machine learning, GRAIL analyzes cfDNA and white blood cell genomes to build a library of normal and cancer-specific mutations. Their goal is to detect cancer before symptoms appear, which significantly improves survival rates. This involves high-intensity sequencing, advanced data science, and broad clinical validation.
- LungLifeAI focuses on the early detection of lung cancer through a single blood test enhanced by AI. Their machine learning platform enables non-invasive diagnostics with an emphasis on early-stage disease, which is critical for improving patient outcomes.
- Predicine and Flagship Biosciences have partnered to combine Predicine's GeneRADAR molecular insights platform with Flagship's AI-enabled cTA digital pathology platform. Their goal is to offer comprehensive biomarker profiling for immuno-oncology clinical trials, aiding treatment stratification and precision medicine. Flagship Biosciences also announced a strategic partnership with Offspring Biosciences to provide end-to-end assay development services, from early target identification to companion diagnostic development, further integrating AI across the clinical research pipeline.

New Liquid Biopsy / AI Products in Development or Recently Launched

Recent developments in liquid biopsy continue to focus on improving disease monitoring, early detection, and integration of advanced data analysis. Tempus has introduced the xM assay, a liquid biopsy test designed to monitor treatment response in patients with advanced cancer by tracking changes in circulating tumor DNA. The test is currently being introduced into clinical and research settings as part of a broader effort to expand longitudinal disease monitoring.

Companies are also developing new approaches that combine multiple types of molecular data to improve clinical insight. Platforms that integrate gene expression profiling with circulating tumor DNA analysis are being advanced to support more precise patient stratification and treatment selection, although many of these solutions remain in early stages of commercialization.

New sample types and detection methods are also being explored. Saliva-based and other non-blood collection approaches are under development for cancer screening, while blood-based tests such as Nanostics' ClarityDx are being used to improve risk assessment for diseases such as prostate cancer by combining biomarkers with algorithmic analysis.

Guardant Health continues to expand its liquid biopsy portfolio, including its Shield blood-based colorectal cancer screening test, which is being deployed more broadly through clinical partnerships. The company is also developing multi-cancer screening approaches and expanding the use of its assays in minimal residual disease detection and treatment monitoring.

Adoption of liquid biopsy is increasing at the healthcare system level, with growing use of circulating tumor DNA testing to support treatment decisions in oncology. At the same time, innovation from emerging companies is driving advances in areas such as extracellular vesicle analysis, improved detection of circulating tumor DNA, and microfluidic technologies for isolating rare cells. Many of these newer platforms are still in development but reflect continued expansion of the liquid biopsy field.

Table 4-7: Selected AI/Liquid Biopsy Initiatives

Company	Location	Details
CareDx	U.S.	Cibiltec's (France) Predigraft, AI tool transplant rejection risk
Euroclone Diagnostica	Italy	Precipio's Ice Cold-PCR DNA, liquid biopsy, EU
Freenome	U.S.	machine learning to detect early colorectal cancer
Johns Hopkins	U.S.	pan cancer liquid biopsy Dx with AI analysis
LungLife AI	U.S.	early detection of lung cancer
Predicine	U.S.	Predicine GeneRADAR liquid biopsy & Flagship Biosciences, AI digital pathology

Source: Kalorama Information

Future Trends

Artificial intelligence systems, which simulate human intelligence by learning, reasoning, and self-correction, have the potential to be more accurate than doctors at making diagnoses

and performing surgical interventions. However, AI-based product developers maintain that machines will never replace doctors entirely, because the inter-relational quality of the doctor-patient relationship is vital and cannot be replicated.

Over the past several years, healthcare has witnessed a transformation, shifting from paper-based record systems to electronic records and incorporating digital health monitoring devices and other advanced patient screening systems. These advances have resulted in a data explosion that can best be managed and analyzed using AI. The key driver of these AI implementations is to provide better patient care while reducing costs, administrative headaches, and bottlenecks.

AI in healthcare has huge and wide-reaching potential and the future of healthcare and the future of machine learning and artificial intelligence in medicine are deeply interconnected.

At present, there remains a lack of clinical trust; as a result, AI is rarely used in fully autonomous mode. Trust will be built over time as use increases and results are validated. However, AI use is expected to grow, especially in digital pathology, and the industry is seeing more clinical labs and products using AI to augment results.

Exosome Sequencing

Exosomes are nanoscale extracellular vesicles released by all cell types into biofluids such as plasma, serum, urine, cerebrospinal fluid, and saliva. They act as intercellular messengers and carry a molecular cargo that includes RNA (mRNA, microRNA, lncRNA, and other species), DNA, and proteins from their cell of origin. This cargo reflects the physiological and pathological status of source tissues, making exosomes an exceptionally rich, stable, and noninvasive source of genomic and proteomic biomarkers.

Exosomes have gained significant attention for their diagnostic utility across a wide range of diseases:

- Cancer (primary and metastatic)
- Neurodegenerative disorders (e.g., Alzheimer's)
- Autoimmune diseases
- Cardiovascular, inflammatory, and metabolic disorders
- Preterm birth and neonatal genetic conditions
- Psychiatric and CNS diseases

Their presence in diverse biofluids enables minimally invasive sampling, opening the door to novel diagnostics where traditional biopsies are limited or impractical. Moreover, their cargo is highly stable, even under varying storage conditions, making them ideal candidates for robust clinical tests.

Biotin Interference in Immunoassay Detection Errors

Biotin has become a popular over-the-counter supplement in recent years for a variety of uses, medical or otherwise; the vitamin enhances skin and digestive health, and a deficiency can lead to neurological disorders. Pregnant and lactating women often take it as a dietary supplement, as it is important in perinatal development.

The recommended daily intake of biotin is 300µg, but these supplements can sometimes be sold in megadoses of 5mg to 10 mg, or even more. As part of the B complex of vitamins, biotin is also called Vitamin B7, but is occasionally referred to by its former name, Vitamin H, which can be confusing for patients; it is also often found in multivitamins, which patients may overlook.

Immunoassays efficiently separate immobilized antigens from free antigens using biotin-based mechanisms. A protein called streptavidin is used as the binding site on particles that conjugate to biotinylated antibodies that have themselves bound to target antigens in the assays. However, if there is excess biotin in the sample being tested, it can also bind to the streptavidin, and the now-unbound biotinylated antibodies can be washed away during the regular processing of the immunoassay, leading to an artificially lower signal. In a sandwich assay, this indicates a lower concentration of the target molecule; in a competitive assay, it indicates a higher concentration.

Some companies have taken notice and have begun introducing solutions that do not rely on biotin; Tosoh, in particular, boasts a full line of biotin-free immunoassays. As this issue has really only begun to emerge, such products appear to be rare, but if the trend of using large doses of supplemental biotin continues, we may expect to see more coming to market in the future. Below is a table of assays and devices that employ biotin-free detection methodologies.

Table 4-8: Biotin-free Offerings Currently on the Market

Company	Location	Product	Description
Abbott	US	Architect i2000 analyzer	does not use biotin-streptavidin capture
Diasorin	Italy	Liaison XL analyzer	
Randox Laboratories	UK	Biotin-free Biochip Array technology	uses antibodies bound to a solid substrate (biochip surface) instead of biotin-streptavidin
Revvity	US	AlphaLISA biotin-free detection kits	assays use anti-Digoxin donor beads instead of streptavidin
Tosoh Bioscience	Japan	AIA-PACK assays for cardiac, thyroid, reproductive, tumor, metabolic, kidney, anemia, vitamin D, other applications	assays use "immobilized antibodies" in lieu of streptavidin binding sites on magnetic particles

Source: Kalorama Information

However, on closer inspection, the furor over biotin interference may be exaggerated. Notably, Roche does not offer biotin-free alternatives to their available immunoassays. The company conducted a pharmacokinetic study, measuring and confirming the biotin tolerance thresholds of all of their assays. Among the conclusions reached were that tolerances for some of Roche's assays were even higher than previously documented, and that subjects taking the supplement for five days at 5 mg and 10 mg doses were below the assays' 30 ng mL^{-1} tolerance threshold within 3.5 and 8 hours, respectively. It is also taken into account that the majority of biotin sales are in doses under 2.5 mg, which would have no effect on Roche's immunoassays.

Taking all factors into account, several steps can be taken to mitigate biotin interference-related errors in diagnosis. Adopting biotin-free methodologies may seem like the most obvious approach, but awareness and communication can go a long way as well. Patient records should clearly state whether biotin is being used as a treatment for a condition, and clinicians should ask patients whether they are taking it as a dietary supplement prior to laboratory testing. Furthermore, as stated above, the vitamin's nomenclature varies, and patients should be made aware of this to avoid confusion when assessing their supplemental intake.

The FDA issued an updated safety communication, UPDATE: FDA Warns that Biotin May Interfere with Lab Tests. This update discusses concerns with biotin interference in certain lab tests, namely, troponin levels. Biotin interference can cause false low troponin levels. As a result, the FDA has published a list of FDA-listed troponin IVD devices that are subject to biotin interference but have not addressed this risk. These are listed at https://www.fda.gov/medical-devices/in-vitro-diagnostics/biotin-interference-troponin-lab-tests-assays-subject-biotin-interferenc.

Table 4-9: Biotin Interference with Troponin Lab Tests – Assays Subject to Biotin Interference

Registered Establishment Name	Assay Trade Name(s)/ Listed Name(s)	510(k) Cleared Device Name
INTERNATIONAL POINT OF CARE INC.	Cardiac STATus	SPECTRAL'S TROPONIN I
INTERNATIONAL POINT OF CARE INC.	Cardiac STATus	SPECTRAL'S 2 IN 1 (TNI-MYO)
NANO-DITECH CORPORATION	Nano-CheckTM AMI 3 IN 1 cTnI/CK-MB/Myo Test	NANO-CHECK AMI 3 IN 1 CARDIAC DISEASE TEST FOR CARDIAC TROPONIN I, CREATINE KINASE MB AND MYOGLOBIN
NANO-DITECH CORPORATION	Nano-CheckTM AMI cTnI Test	NANO-CHECK AMI CTNI CARDIAC MARKER TEST
NANO-DITECH CORPORATION	Nano-CheckTM AMI 2 IN 1 cTnI/Myo Test	Nano-Check AMI 2 IN 1 Cardiac Marker Test, cTnI and Myoglobin; NANO-CHECK AMI 2 IN 1 CARDIAC DISEASE TEST FOR CARDIAC TROPONIN I AND MYOGLOBIN
QuidelOrtho	VITROS Immunodiagnostic Products Troponin I ES Reagent Pack; VITROS Immunodiagnostic Products Troponin I ES Calibrators; VITROS Immunodiagnostic Products Troponin I ES Range Verifiers	VITROS TROPONIN I ES ASSAY, INCLUDING REAGENT PACK, CALIBRATORS AND RANGE VERIFIERS, MODELS 680 2301, 2302 AND 2303
PRINCETON BIOMEDITECH CORP.	LifeSign MI Myoglobin/Troponin I	LIFESIGN MI MYOGLOBIN/TROPONIN I RAPID TEST
PRINCETON BIOMEDITECH CORP.	LifeSign MI Troponin I	CARDIAC STATUS TROPONIN I
PRINCETON BIOMEDITECH CORP.	LifeSign MI CK-MB/Myoglobin/Trop I	CARDIAC STATUS CK-MB/MYOGLOBIN/TROPONIN I RAPID TEST
ROCHE DIAGNOSTICS GMBH	CARDIAC Control Troponin-T; Cardiac Reader IQC; CARDIAC READER SYSTEM; Cardiac T Quantitative 10Tests; ROCHE CARDIAC TEST STRIP TROPONIN T; TROPT Sensitive 5 Tests	THE CARDIAC READER SYSTEM
ROCHE DIAGNOSTICS GMBH	Elecsys Troponin T STAT	ROCHE ELECSYS TROPONIN T STAT (SHORT TURNAROUND TIME)
ROCHE DIAGNOSTICS GMBH	Elecsys Troponin I; Elecsys Troponin I STAT	ELECSYS TROPONIN I AND TROPONIN I STAT TEST SYSTEMS

Registered Establishment Name	Assay Trade Name(s)/ Listed Name(s)	510(k) Cleared Device Name
ROCHE DIAGNOSTICS GMBH	Elecsys Troponin T Gen 5 STAT	Elecsys Troponin T Gen 5 STAT Assay, Elecsys Troponin T Gen 5 STAT CalSet, Elecsys PreciControl Troponin, Elecsys Troponin T Gen 5 CalCheck 5
ROCHE DIAGNOSTICS GMBH	ELECSYS TROPONIN T	ELECSYS TROPONIN T
Siemens Healthineers	ADVIA Centaur TnI-Ultra; Atellica IM TnI-Ultra	TNL-ULTRA ASSAY FOR THE ADVIA CENTAUR SYSTEM
Siemens Healthineers	Dimension Vista CTNI Flex reagent cartridge	DIMENSION VISTA CTNI FLEX REAGENT CARTRIDGE
Siemens Healthineers	Dimension EXL LOCI Module TNI Flex reagent cartridge	DIMENSION TNI FLEX REAGENT CARTRIDGE, AND CTNI SAMPLE DILUENT WITH MODELS, RF621, KD692

Source: FDA

Clinical Applications and Liquid Biopsy

In oncology, tumor cells actively release exosomes enriched with tumor-specific RNA and DNA. These tumor-derived exosomes are often more abundant and accessible in blood or urine than cancer cells themselves, offering an alternative or complement to tissue biopsies. This is especially valuable for:

- Monitoring tumor recurrence or treatment resistance
- Identifying actionable mutations for precision therapy
- Screening high-risk populations

Routine exosome-based diagnostics could redefine the liquid biopsy paradigm, extending testing beyond cfDNA to include exoRNA and protein-based markers, particularly for tumors with low shedding or heterogeneous mutations.

A growing number of molecular diagnostics and sequencing companies are leveraging exosome-related biomarkers and platforms:

- Agilent Technologies – Provides exome capture and target enrichment solutions used in oncology and genetic research, supporting next-generation sequencing workflows across a range of disease areas.
- Labcorp – Offers whole exome sequencing services, particularly in pediatric and rare disease diagnostics, and has expanded its genomic testing portfolio through the acquisition of key assets from Invitae, incorporating hereditary disease and oncology sequencing capabilities into its broader diagnostic offerings.
- Sysmex Corporation – Expanding its oncology and molecular diagnostics capabilities, including liquid biopsy-related technologies, with ongoing development efforts in Asia.
- Thermo Fisher Scientific – Offers the Ion AmpliSeq Exome Kit for research use, supporting targeted exome sequencing applications in clinical research and translational studies.
- Illumina – Continues to support high-throughput sequencing with NovaSeq X and NovaSeq X Plus systems, enabling large-scale genomic and exome sequencing in research and clinical settings.
- Ambry Genetics + PacBio – Collaborating on rare disease sequencing initiatives, leveraging long-read sequencing to improve variant detection and genomic insights.

The exosome diagnostics market is in early-stage commercial development but accelerating rapidly, particularly in:

- Oncology
- Neonatal and pediatric disease
- Neurodegenerative diagnostics

Tests are primarily offered as lab-developed services, though regulatory approvals (e.g., CE mark, LDT status) are beginning to appear. The next 3–5 years will likely see the emergence of FDA-cleared exosome tests, deeper AI integration, and multi-analyte diagnostics combining cfDNA, exoRNA, and proteomics.

Traumatic Brain Injury and IVD

Traumatic brain injury (TBI) is caused by an external physical force that disrupts normal brain function, affecting cognitive and physical functions, including thinking and memory, vision, movement, and emotional function. Mild TBI is better known as a concussion, and accounts for 94.5% of all cases. TBI can cause severe cognitive and neurological impairment, reduce quality of life, and affect interpersonal relationships; it has been known to affect judgment and decision-making, it can lead to depression and anxiety, and has been thought to contribute to other psychiatric and neurological issues such as psychosis and Alzheimer's disease. TBIs contribute to about 30% of all injury-related deaths.

Traumatic brain injuries, including concussions, are responsible for over 4.8 million emergency room visits per year. Most of these (40%) are concussions caused by a slip and fall. Traumatic brain injuries are seen in the sports world. Worldwide, there are approximately 10 million people affected by TBI. The primary goal of testing is to detect changes in the brain that could help determine whether it was injured.

Abbott markets its i-STAT TBI Plasma test, a rapid assay designed to help assess patients with suspected mild traumatic brain injury. The test measures key brain injury biomarkers and provides results in less than 20 minutes, supporting faster clinical decision-making in emergency and acute care settings. It is part of Abbott's i-STAT platform, which is widely used for point-of-care testing. In addition, Abbott expanded the use of its i-STAT TBI test to include whole-blood samples, allowing greater flexibility in testing environments. This advancement supports use outside of traditional laboratory settings, including emergency departments, urgent care centers, and field-based environments such as sports medicine, where rapid assessment is critical.

bioMérieux offers the VIDAS TBI assay, a laboratory-based test designed to support evaluation of patients with mild traumatic brain injury. The assay measures biomarkers such as GFAP and UCH-L1, which are released into the bloodstream following brain injury, and is intended to assist clinicians in determining whether further imaging or intervention is needed.

More recent developments continue to expand the role of blood-based biomarkers in brain injury assessment. There is growing interest in integrating these tests into broader clinical workflows, including emergency triage and concussion management. In addition, research

and product development efforts are focused on improving sensitivity, expanding testing to additional patient populations, and enabling use in decentralized and point-of-care settings.

Personalized Medicine

Personalized medicine is also called precision medicine. Personalized medicine has a fairly broad meaning, but it is medicine that uses an individual's unique genetic profile to guide decisions about prevention, diagnosis and treatment of disease. Personalized medicine is an innovative approach to tailoring treatment to each patient's individual characteristics. This is a relatively new field of medicine that combines pharmacology and genetics, and it is gaining momentum.

IVD is an integral part of personalized medicine, as it provides critical information for making treatment decisions. Specific examples where IVD devices provide personalized medicine include blood glucose tests, pregnancy tests, cancer screening and in-home HIV testing.

COVID-19 was instrumental in driving a sharp rise in demand for IVD products, leading to an unprecedented surge in PCR, NGS, and serology-based rapid tests. The pandemic also demonstrated the value of these products and helped to create a very supportive regulatory environment.

Growth in the aging population will likely shift treatments to a more personalized approach tailored to the individual's genetic makeup and lifestyle. This move will likely reduce unnecessary treatments that are expensive and ineffective for the individual. Rising rates of chronic diseases and growing numbers of immunosuppressed individuals will also highlight the need for personalized diagnostics.

One reason personalized medicine is advancing is that patients are demanding more personalized care; the one-size-fits-all model is not meeting their expectations. Patients are becoming increasingly engaged in personally directed care through the use of biometric indices, such as smartphones and smart wearables (e.g., watches, rings, or other monitors). These devices are generating a massive amount of data, providing insights into patient health and providing physicians with patient-specific data.

The growing body of evidence on technologies that provide personalized data is likely to lead to better patient outcomes. Many IVD tests are benefiting from the uptake of personalized medicine, which is expected to continue to grow.

One of the most instrumental advances assisting personalized medicine is wearable diagnostics. Wearables are commonplace these days, with devices such as smart watches that can measure heart rate, oxygen saturation, and sleep patterns. These devices can also detect atrial fibrillation, respiration and body temperature. All of this information can be helpful in the early detection of diseases.

The glucose arena has made significant strides in personalized medicine through continuous glucose monitoring. For those with diabetes, this was a life-changing tool. As technology evolves, it will likely expand the role of comprehensive health monitoring and disease prevention.

Companion Diagnostics

A companion diagnostic is a test that provides information that is essential for safe and effective use of pharmaceutical products. Companion diagnostics can identify patients who may be at risk of increased risk for side effects when dosed with a particular product; identify patients who are most likely to benefit from the particular treatment; and monitor response to treatment during the administration of a drug therapy.

In June 2023, the FDA issued final guidance for oncology drug products used with certain in vitro diagnostic tests, establishing clearer expectations for the co-development and use of companion diagnostics. This guidance remains in effect in 2026 and continues to shape how oncology therapies are paired with diagnostic tests. Since its release, the FDA has taken a more active role in reinforcing requirements for analytical and clinical validation, particularly for tests used to guide treatment decisions. There is also increased regulatory focus on the use of laboratory-developed tests in oncology, with greater emphasis on ensuring that tests informing therapy selection are appropriately reviewed or aligned with FDA standards. As a result, the industry is seeing stronger alignment between drug approvals and companion diagnostic availability, along with increased pressure to support validated, regulatory-compliant testing in clinical practice.

Below is a list of selected approved companion IVD diagnostics.

Table 4-10: Selected FDA Approved Companion Diagnostics 2025

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
AAV5 DetectCDx (ARUP Laboratories)	Hemophilia A Patients - Plasma	ROCTAVIAN (valoctocogene roxaparvovec-rvox) BLA 125720
Abbott RealTime IDH1 (Abbott Molecular, Inc.)	Acute Myeloid Leukemia - Peripheral Blood or Bone Marrow	Tibsovo (ivosidenib) NDA 211192
Abbott RealTime IDH2 (Abbott Molecular, Inc.)	Acute Myeloid Leukemia - Peripheral Blood or Bone Marrow	Rezlidhia (olutasidenib) NDA 215814
Agilent Resolution ctDx FIRST assay (Resolution Bioscience, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Idhifa (enasidenib) NDA 209606
Bond Oracle HER2 IHC System (Leica Biosystems)	Breast Cancer - Tissue	Krazati (adagrasib) NDA 216340
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Ovarian Cancer - Whole Blood	Herceptin (trastuzumab) BLA 103792
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Breast Cancer - Whole Blood	Lynparza (olaparib) NDA 208558
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Ovarian Cancer - Whole Blood	Talzenna (talazoparib) NDA 211651
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Pancreatic Cancer - Whole Blood	Rubraca (rucaparib) NDA 209115
BRACAnalysis CDx (Myriad Genetic Laboratories, Inc.)	Metastatic Castrate Resistant Prostate Cancer (mCRPC) - Whole Blood	Lynparza (olaparib) NDA 208558
cobas 4800 BRAF V600 Mutation Test (Roche Molecular Systems, Inc.)	Melanoma - Tissue	Lynparza (olaparib) NDA 208558
cobas EGFR Mutation Test v1 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Cotellic (cobimetinib) NDA 206192 in combination with Zelboraf (vemurafenib) NDA 202429
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tarceva (erlotinib) NDA 021743
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tagrisso (osimertinib) NDA 208065

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	Iressa (gefitinib) NDA 206995
cobas EGFR Mutation Test v2 (Roche Molecular Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue or Plasma	
cobas EZH2 Mutation Test (Roche Molecular Systems, Inc.)	Follicular Lymphoma Tumor - Tissue	Tarceva (erlotinib) NDA 021743
cobas KRAS Mutation Test (Roche Molecular Systems, Inc.)	Colorectal Cancer - Tissue	Tazverik (tazemetostat) NDA 213400
cobas KRAS Mutation Test (Roche Molecular Systems, Inc.)	Colorectal Cancer - Tissue	Erbitux (cetuximab) BLA 125084
CRCDx RAS Mutation Detection Assay Kit (EntroGen, Inc.)	Colorectal Cancer (CRC) - Tissue	Vectibix (panitumumab) BLA 125147
Dako c-KIT pharmDx (Dako North America, Inc.)	Gastrointestinal Stromal Tumors - Tissue	Gleevec (imatinib mesylate), NDA 021588
Dako EGFR pharmDx Kit (Dako North America, Inc.)	Colorectal Cancer - Tissue	Erbitux (cetuximab) BLA 125084
FerriScan (Resonance Health Analysis Services Pty Ltd)	Non-Transfusion-Dependent Thalassemia - Tissue	Vectibix (panitumumab) BLA 125147
FoundationFocus CDxBRCA Assay (Foundation Medicine, Inc.)	Ovarian Cancer - Tissue	Exjade (deferasirox) NDA 021882
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Rubraca (rucaparib) NDA 209115
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Gilotrif (afatinib) NDA 201292
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Iressa (gefitinib) NDA 206995
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tarceva (erlotinib) NDA 021743
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tagrisso (osimertinib) NDA 208065
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Alecensa (alectinib) NDA 208434
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Xalkori (crizotinib) NDA 202570

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Zykadia (ceritinib) NDA 211225
FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Tafinlar (dabrafenib) NDA 202806 in combination with Mekinist (trametinib) NDA 204114
FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792
FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Perjeta (pertuzumab) BLA 125409
FoundationOne CDx (Foundation Medicine, Inc.)	Colorectal Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427
FoundationOne CDx (Foundation Medicine, Inc.)	Colorectal Cancer - Tissue	Erbitux (cetuximab) BLA 125084
FoundationOne CDx (Foundation Medicine, Inc.)	Melanoma - Tissue	Vectibix (panitumumab) BLA 125147
FoundationOne CDx (Foundation Medicine, Inc.)	Breast Cancer - Tissue	Lynparza (olaparib) NDA 208558
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Piqray (alpelisib) NDA 212526
FoundationOne CDx (Foundation Medicine, Inc.)	Cholangiocarcinoma - Tissue	Tabrecta (capmatinib) NDA 213591
FoundationOne CDx (Foundation Medicine, Inc.)	Metastatic Castrate Resistant Prostate Cancer (mCRPC) - Tissue	Pemazyre (pemigatinib) NDA 213736
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Lynparza (olaparib) NDA 208558
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Keytruda (pembrolizumab) BLA 125514
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	Vitrakvi (larotrectinib) NDA 210861
FoundationOne CDx (Foundation Medicine, Inc.)	Melanoma - Tissue	Keytruda (pembrolizumab) BLA 125514

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tecentriq (atezolizumab) BLA 761034 in combination with Cotellic (cobimetinib) NDA 206192 and Zelboraf (vemurafenib) NDA 202429
FoundationOne CDx (Foundation Medicine, Inc.)	Solid Tumors - Tissue	BRAFTOVI (encorafenib) NDA210496 in combination with MEKTOVI (binimetinib) NDA210498
FoundationOne CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Rozlytrek (entrectinib)
FoundationOne CDx	Prostate Cancer - Tissue	Rozlytrek (entrectinib)
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	AKEEGA (niraparib + abiraterone acetate) NDA 216793
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Exkivity (mobocertinib) NDA 215310
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Metastatic Castrate Resistant Prostate Cancer (mCRPC) - Plasma	BRAFTOVI (encorafenib) NDA210496 in combination with MEKTOVI (binimetinib) NDA210498
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Rubraca (rucaparib) NDA 209115
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Tabrecta (capmatinib) NDA 213591
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Solid Tumors - Plasma	Rozlytrek (entrectinib) NDA 212725
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Rozlytrek (entrectinib) NDA 212725
FoundationOne Liquid CDx (Foundation Medicine, Inc.)	Breast Cancer - Plasma	Alecensa (alectinib) NDA 208434
Guardant360 CDx (Guardant Health, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Rybrevant (amivantamb) BLA 761210
Guardant360 CDx (Guardant Health, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	Lumakras (sotorasib) NDA 214665
Guardant360 CDx (Guardant Health, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Plasma	ENHERTU (fam-trastuzumab deruxtecan-nxki) BLA 761139
Guardant360 CDx (Guardant Health, Inc.)	Breast Cancer - Plasma	Orserdu (elacestrant) NDA 217639

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
HER2 CISH pharmDx Kit (Dako Denmark A/S)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792
HER2 FISH pharmDx Kit (Dako Denmark A/S)	Breast Cancer - Tissue	Perjeta (pertuzumab) BLA 125409
HER2 FISH pharmDx Kit (Dako Denmark A/S)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427
HercepTest (Dako Denmark A/S)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792
HercepTest (Dako Denmark A/S)	Breast Cancer - Tissue	Perjeta (pertuzumab) BLA 125409
HercepTest (Dako Denmark A/S)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427
INFORM HER-2/neu (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792
INFORM HER2 Dual ISH DNA Probe Cocktail (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427
InSite Her-2/neu (CB11) Monoclonal Antibody (BioGenex Laboratories, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792
Ki-67 IHC MIB-1 pharmDx (Dako Omnis) (Agilent Technologies)	Breast Cancer - Tissue	Verzenio (abemaciclib) NDA 208716
KIT D816V Assay (ARUP Laboratories, Inc.)	Aggressive Systemic Mastocytosis - Bone Marrow	Gleevec (imatinib mesylate) NDA 021588
LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies, Inc.)	Acute Myelogenous Leukemia - Peripheral Blood or Bone Marrow	Rydapt (midostaurin) NDA 207997
LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies, Inc.)	Acute Myelogenous Leukemia - Peripheral Blood or Bone Marrow	Xospata (gilterinib) NDA 211349
LeukoStrat CDx FLT3 Mutation Assay (Invivoscribe Technologies, Inc.)	Acute Myelogenous Leukemia (AML) - Peripheral Blood or Bone Marrow	VANFLYTA (quizartinib) NDA 216993
MRDx BCR-ABL Test (MolecularMD Corporation)	Chronic Myeloid Leukemia - Peripheral Blood	Tasigna (nilotinib) NDA 022068
Myriad myChoice CDx (Myriad Genetic Laboratories, Inc.)	Ovarian Cancer - Tissue	Lynparza (olaparib) NDA 208558

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
nAbCyte Anti-AAVRh74var HB-FE Assay (Labcorp Drug Development)	Moderate to severe Hemophilia B patients - Serum	BEQVEZ (fidanacogene elaparvovec) BLA 125786
ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.)	Colorectal Cancer - Tissue	Erbitux (cetuximab) BLA 125084
ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.)	Colorectal Cancer - Tissue	Vectibix (panitumumab) BLA 125147
ONCO/Reveal Dx Lung & Colon Cancer Assay (O/RDx-LCCA) (Pillar Biosciences, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	A tyrosine kinase inhibitor approved by FDA for that indication
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tafinlar (dabrafenib) NDA 202806 in combination with Mekinist (trametinib) NDA 204114
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Xalkori (crizotinib) NDA 202570
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Hernexeos (zongertinib) 2025
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Zegfrovy (sunvozertinib) 2025
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Iressa (gefitinib) NDA 206995
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Gavreto (pralsetinib) NDA 213721
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Rybrevant (amivantamb) BLA 761210
Oncomine Dx Target Test (Life Technologies Corporation)	Cholangiocarcinoma - Tissue	Tibsovo (ivosidenib) NDA 211192
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Exkivity (mobocertinib) NDA 215310
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	ENHERTU (fam-trastuzumab deruxtecan-nxki) BLA 761139
Oncomine Dx Target Test (Life Technologies Corporation)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Retevmo (selpercatinib) NDA 213246

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
Oncomine Dx Target Test (Life Technologies Corporation)	Medullary Thyroid Cancer (MTC) - Tissue	Retevmo (selpercatinib) NDA 213246
Oncomine Dx Target Test (Life Technologies Corporation)	Thyroid Cancer (TC) - Tissue	Retevmo (selpercatinib) NDA 213246
Oncomine Dx Target Test (Life Technologies Corporation)	Anaplastic Thyroid Cancer (ATC) - Tissue	Tafinlar (dabrafenib) NDA 202806 in combination with Mekinist (trametinib) NDA 204114
PathVysion HER-2 DNA Probe Kit (Abbott Molecular Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792
PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792
PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Kadcyla (ado-trastuzumab emtansine) BLA 125427
PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Enhertu (fam-trastuzumab deruxtecan-nxki) BLA 761139
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Keytruda (pembrolizumab) BLA 125514
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Cervical Cancer - Tissue	Keytruda (pembrolizumab) BLA 125514
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Head and Neck Squamous Cell Carcinoma (HNSCC) - Tissue	Keytruda (pembrolizumab) BLA 125514
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Esophageal Squamous Cell Carcinoma (ESCC) - Tissue	Keytruda (pembrolizumab) BLA 125514
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Triple-Negative Breast Cancer (TNBC) - Tissue	Keytruda (pembrolizumab) BLA 125514
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Libtayo (cemiplimab-rwlc) BLA 761097
PD-L1 IHC 22C3 pharmDx (Dako North America, Inc.)	Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma - Tissue	Keytruda (pembrolizumab) BLA 125514

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
PD-L1 IHC 28-8 pharmDx (Dako North America, Inc.)	Non-small cell lung cancer (NSCLC) - Tissue	Opdivo (nivolumab) BLA 125554 in combination with Yervoy (ipilimumab) BLA 125377
PDGFRB FISH Assay (ARUP Laboratories, Inc.)	Myelodysplastic Syndrome/Myeloproliferative Disease - Bone Marrow	Gleevec (imatinib mesylate) NDA 021588
POMC/PCSK1/LEPR CDx Panel (PreventionGenetics, LLC)	Obesity - Blood or Saliva	Imcivree (setmelanotide acetate) NDA 213793
Praxis Extended RAS Panel (Illumina, Inc.)	Colorectal cancer - Tissue	Vectibix (panitumumab) BLA 125147
SeCore CDx HLA Sequencing System (One Lambda Inc.	Uveal Melanoma – Whole Blood	Kimmtrak (tebentafusp-tebn) BLA 761228
SPOT-LIGHT HER2 CISH Kit (Life Technologies Corporation)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792
therascreen BRAF V600E RGQ PCR Kit (QIAGEN GmbH)	Colorectal Cancer - Tissue	Braftovi (encorafenib) NDA 210496 in combination with Erbitux (cetuximab) BLA 125084
therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Gilotrif (afatinib) NDA 201292
therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Iressa (gefitinib) NDA 206995
therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Gilotrif (afatinib) NDA 201292
therascreen EGFR RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Vizimpro (dacomitinib) NDA 211288
therascreen FGFR RGQ RT-PCR Kit (QIAGEN Manchester Ltd.)	Urothelial Cancer - Tissue	Balversa (erdafitinib) NDA 212018
therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.)	Colorectal Cancer - Tissue	Vectibix (panitumumab) BLA 125147
therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Lumakras (sotorasib) NDA 214665
therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.)	Colorectal Cancer - Tissue	Erbitux (cetuximab) BLA 125084
therascreen KRAS RGQ PCR Kit (Qiagen Manchester, Ltd.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Krazati (adagrasib) NDA 216340

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
therascreen PDGFRA RGQ PCR Kit (QIAGEN GmbH)	Gastrointestinal Stromal Tumors (GIST) - Tissue	AYVAKIT (Avapritinib) NDA 212608
therascreen PIK3CA RGQ PCR Kit (QIAGEN GmbH)	Breast Cancer - Tissue or Plasma	Piqray (alpelisib) NDA 212526
THXID BRAF Kit (bioMérieux Inc.)	Melanoma - Tissue	Mekinist (trametinib) NDA 204114
THXID BRAF Kit (bioMérieux Inc.)	Melanoma - Tissue	Tafinlar (dabrafenib) NDA 202806
THXID BRAF Kit (bioMérieux Inc.)	Melanoma - Tissue	Braftovi (encorafenib) NDA 210496 in combination with Mektovi (binimetinib) NDA 210498
Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Xalkori (crizotinib) NDA 202570
Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Zykadia (ceritinib) NDA 211225
Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Alecensa (alectinib) NDA 208434
Ventana ALK (D5F3) CDx Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Lorbrena (lorlatinib) NDA 210868
Ventana FOLR1 (FOLR-2.1) RxDx Assay	Epithelial Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer - Tissue	Elahere (mirvetuximab soravtansine-gynx) BLA 761310
Ventana HER2 Dual ISH DNA Probe Cocktail (Ventana Medical Systems, Inc.)	Breast Cancer - Tissue	Herceptin (trastuzumab) BLA 103792
Ventana Met RxDx Assay	NSCLC	Emerlis(telisotumzumab vedotin 2025
Ventana MMR RxDx Panel (Ventana Medical Systems, Inc.)	Endometrial Carcinoma (EC) - Tissue	Jemperli (dostarlimag-gxly) NDA 761174
Ventana MMR RxDx Panel (Ventana Medical Systems, Inc.)	Solid Tumors	Jemperli (dostarlimag-gxly) NDA 761174
Ventana MMR RxDx Panel (Ventana Medical Systems, Inc.)	Endometrial Carcinoma (EC) - Tissue	Keytruda (pembrolizumab) BLA 125514 in combination with Lenvima (lenvatinib) NDA 206947
Ventana PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.)	Urothelial Carcinoma - Tissue	Tecentriq (atezolizumab) BLA 761034

Diagnostic Name (Manufacturer)	Indication - Sample Type	Drug Trade Name (Generic) NDA / BLA
Ventana PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Tecentriq (atezolizumab) BLA 761034
Vysis ALK Break Apart FISH Probe Kit (Abbott Molecular Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Xalkori (crizotinib) NDA 202570
Vysis ALK Break Apart FISH Probe Kit (Abbott Molecular Inc.)	Non-Small Cell Lung Cancer (NSCLC) - Tissue	Alunbrig (brigatinib) NDA 208772
Vysis CLL FISH Probe Kit (Abbott Molecular, Inc.)	B-cell Chronic Lymphocytic Leukemia - Peripheral Blood	Venclexta (venetoclax) NDA 208573
xT CDx (Tempus Labs, Inc.)	Colorectal Cancer (CRC) - Tissue (Matching Blood/Saliva)	Erbitux (cetuximab) BLA 125084
xT CDx (Tempus Labs, Inc.)	Colorectal Cancer (CRC) - Tissue (Matching Blood/Saliva)	Vectibix (panitumumab) BLA 125147

Source: FDA Kalorama Information

Telehealth

The telehealth industry experienced steady but modest growth prior to the COVID-19 pandemic, which rapidly accelerated adoption and brought virtual care and remote patient monitoring into routine use. Since that time, utilization has stabilized at levels well above pre-pandemic norms. Growth is now more measured, but the market remains strong, supported by continued demand for convenience, expanded use of wearable devices, and a growing focus on managing chronic conditions outside of traditional care settings.

State-level policy support is an important factor, with many states maintaining telehealth coverage requirements and a significant number continuing to support reimbursement policies that pay virtual visits at rates comparable to in-person care. At the federal level, telehealth flexibility for Medicare beneficiaries has been extended beyond the original pandemic period, allowing continued access to services such as home-based virtual visits and expanded provider eligibility. However, these policies remain subject to ongoing legislative review, and long-term reimbursement structures are still being defined.

Private insurers and employers have also incorporated telehealth into standard benefit designs, including coverage within high-deductible health plans, further supporting utilization. At the same time, healthcare providers are increasingly adopting hybrid care models that combine in-person and virtual services, particularly in primary care, behavioral health, and chronic disease management.

Internationally, telehealth adoption continues to expand, with countries such as Australia and others integrating virtual care into routine service delivery, particularly in mental health and community-based care settings.

Technology development remains a key driver of growth. Advances in digital health platforms, artificial intelligence, and connected devices are improving the quality and usability of virtual care. New models, including remote monitoring, virtual triage, and digital-first care pathways, are becoming more common. While telehealth is now a permanent part of the healthcare landscape, its long-term growth will depend on continued policy support, clear reimbursement frameworks, and integration into standard clinical workflows.

Blockchain

Blockchain is a revolutionary concept that can help improve patient outcomes while bridging various entities within the healthcare market. It is not understood by most participants in the industry, but the concept is gaining ground. It is essentially a tool that can securely store data in a distributed ledger, enabling it to be shared across networks. The concept behind blockchain is that it has three components:

- a widely distributed network
- a shared ledger with validated access identities
- digital transactions

Blockchain technology is emerging in many other industries, but it has some unique challenges in healthcare. The storage and transmission of patient data is often centralized through electronic medical records (EMRs). The concept of blockchain is decentralizing databases, making it harder for hackers to steal data. This level of security would directly benefit both caregivers and patients because it can be accessed only with permission. Blockchain could enable improvements in care delivery and cost savings. Although most industry participants would agree that blockchain does offer numerous opportunities, the reality is that in healthcare, change progresses at a snail's pace.

Blockchain in the healthcare arena is still an emerging technology. However, many major vendors in the EMR space and others are moving quickly to embrace blockchain in healthcare systems. Federal IT officials are embracing the technology and promoting its use. Several companies have units dedicated to developing blockchain products, including healthcare applications. Those companies include IBM, Intel, Goggle, Microsoft and others. Examples of companies putting blockchain into action in healthcare:

- Change Healthcare has developed a blockchain technology in healthcare products
- ShoCard and RF Ideas debuted a blockchain technology-enabled mobile credential reader system. ShoCard is a blockchain-based identity system management system that reads badges for in-building applications such as computer access, identification and secure print. This blockchain technology will allow healthcare providers to meet healthcare security compliance guidelines.

Clinical laboratories in particular, which use sophisticated laboratory information management systems and radiology information systems, must be responsive to cybersecurity threats. It will be interesting to see whether device manufacturers and healthcare IT companies can harness blockchain technology in the next few years for clinical labs, as well as for device users such as hospitals and patients.

Blockchain in healthcare is still evolving, according to experts in the field. Blockchain technologies have great potential to improve patient care, reduce costs, and enhance the patient experience. However, there needs to be sufficient groundwork to implement these emerging technologies. Most experts believe that the majority of healthcare participants are not ready for prime time with blockchain, but the industry continues to evolve. For example, Boehringer Ingelheim and IBM Canada are exploring the use of blockchain technology in clinical trials. Both companies believe there is a significant opportunity to improve the quality of clinical trials and record-keeping using blockchain technology by providing a decentralized framework that enables data integrity, provenance, transparency, and patient empowerment through automated processes.

Over the last year, blockchain has continued to evolve, and many approaches have been developed to support its adoption. Over the forecast period, blockchain is expected to transform the healthcare system due to its many potential use cases and evolving technology.

Hospital systems in Europe offer blockchain-based credentialing platforms to verify medical staff across borders, reducing administrative friction

In South Korea, a private blockchain pilot enables patients to securely share their electronic health records between clinics, giving them greater control over their own data

The MediLedger network has expanded in the U.S., enabling pharmaceutical companies and wholesalers to track drugs throughout the supply chain and combat counterfeits.

Substance Abuse

The incidence of substance abuse has increased worldwide and in the United States over the years. The U.S. Department of Health and Human Services estimates there are more than 650,000 emergency department visits each year, with a primary reason for visit stating substance abuse. Additionally, more than 300,000 involved alcohol or major illicit drugs. Cocaine alone accounts for more than 20% of all visits. Worldwide, about 275 million people are estimated to have used an illicit drug at least once in 2016; additionally, about 3.3 million deaths are attributed to the overuse of alcohol each year and nearly 200,000 overdose deaths from drugs.

Substance abuse statistics are improving. The growing public awareness of opioid abuse and an epidemic in the United States is driving a need for testing. During the past several decades, drug abuse and dependence have become critical public health problems as evidenced by newspaper and Internet stories. Although drug abuse has existed throughout history, generally it has involved a relatively small minority of the population.

The overall overdose deaths fell 27% in 2024. This may have been due to investment in treatment access, naloxone distribution and public health funding. There is still a huge number of fentanyl-related overdose deaths.

Biomarkers and Substance Abuse

Genetics may be part of the answer, and their increasing utility might presage an increase in testing. Scientists identified 10 genes that show promise in predicting how patients will respond to opioid pain medications. Using these genetic markers, healthcare providers could potentially tailor opioid therapy better to curb the skyrocketing rate of deaths from these drugs. But it is not just abuse of these medications that can lead to overdoses. Even in patients with severe pain and a legitimate need for opioids, the dose required to alleviate pain varies widely and unpredictably between individuals. This means that clinicians must essentially use a trial-and-error strategy to determine the correct type of opioid and dosage that will help a patient. This approach puts some patients at increased risk of life-threatening side effects such as respiratory depression, while leaving other patients undertreated and in pain.

To date, researchers have identified numerous genes that could potentially guide opioid treatment to make it more precise and safer. Despite this, the medical community has only

developed treatment guidelines based on one of these genes (CYP2D6) and has not determined which of the other genes should be used in practice. A team of researchers led by Ron H.N. van Schaik, PhD, of Erasmus University Medical Center in Rotterdam, the Netherlands, conducted a systematic review of 4,257 studies on opioid genetics. The researchers assessed the utility of each gene studied based on whether (a) several independent studies confirmed the gene's effect on patient opioid response and (b) the gene's frequency in the white population was high enough for use in screening tests. Using these criteria, van Schaik's team pinpointed 10 genes that show the highest potential of refining the way opioids are prescribed and that healthcare providers should focus on implementing clinically. In addition to the well-known CYP2D6, the most notable among these 10 are SLC22A1, the OPRM1 118A>G variant, and COMT.

Research shows that the presence of two inactive SLC22A1 genes leads to high blood concentrations of tramadol's active metabolite and, in children, to significantly lower clearance of morphine. This means that patients with these mutations might be at increased risk of overdosing on tramadol and morphine, particularly if they also have certain CYP2D6 mutations.

HDAC5/SCN4B and Shisa7 are emerging molecular biomarkers tied to relapse and substance-specific addiction. Epigenetic brain-aging clocks offer a novel way to view substance abuse disorders as accelerated neurobiological aging. Multi-omics biomarkers (genomic and proteomic) at Mayo Clinic show promise for personalizing alcohol abuse treatments.

New therapeutic and diagnostic platforms (GLP-1 drugs, DBS, VR) may both reduce cravings and serve as functional biomarkers in treatment trials. This represents a shift from symptom-based intervention to biomarker-informed, precision approaches in addiction treatment.

Clinical Laboratory Testing for Drugs of Abuse

Clinical laboratory tests are widely recommended to curb abuse and are expected to see increased utilization. However, it is not clear yet if this will come to fruition; many physicians working on the front lines of the opioid crisis may not be fully equipped with the knowledge for the task. For example, studies have shown that clinicians misunderstand the very urine immunoassay tests they order for patients.

It is anticipated that drug testing technology will become increasingly sensitive and easier to use, leading to more innovative and effective testing for drugs of abuse. The move from urine testing to oral fluid testing reduces privacy concerns and mitigates some of the issues associated with urine testing. Future drug testing practices must include identifying a greater number of drugs. Drug testing must become less expensive and more resistant to adulteration. Drug tests must rapidly identify newly emerging drugs of abuse.

Healthcare professionals, employers, criminal justice personnel, and sports use drug tests as part of a comprehensive evaluation of individuals to reach a correct decision regarding the individuals' actions, behaviors, or performances.

Table 4-11: Global Drug Abuse Statistics

Drug	Number of Users
All illicit drug use	316,000,000
Cannabis	244,000,000
Opioids	61,000,000
Opiates	19,700,000
Cocaine	25,100,000
Amphetamines	30,000,000
Methylenedioxymethamphetamine (Ecstasy)	21,000,000

Source: WHO, 2023

There are a number of drug abuse test products on the market, encompassing point-of-care, point-of-laboratory, and home-use formats, as well as urine, oral/saliva, blood, and hair testing.

Urine

Urine testing for drugs of abuse is the gold standard of the industry because it is non-invasive, accurate, and reliable. Urine drug testing is most often carried out first by point-of-care devices (e.g., a CLIA-waived collection cup or strip) and by hospital laboratories. The tests

designed for use in hospital laboratories are geared toward the emergency-medicine service, which is concerned with determining drug overdose. These tests detect classes of drugs such as opiates and benzodiazepines for which there are antidotes. The cutoffs used on these tests are set to detect high concentrations of abused drugs. These cutoffs are appropriate for emergency units, where the correlation between the patient's condition and the presence of high drug concentrations enables the treating physician to determine the appropriate supportive care.

Alfa Scientific offers the Instant-view rapid drug tests. The tests are available for POC and at-home diagnostics. These include the Instant-view Drug Screen, which is a rapid test that can be read in four to seven minutes and can test for up to 12 drugs at one time. Adulteration controls are also available in the test kit.

Abbott offers the Alere iCassette, ICup DS IScreen Dip Card and E-Z Split Key Cup tests. The Alere iCup drug screen tests for up to 13 drugs in one device. Most of the company's tests are urine-based. The Alere DDS2 Mobile Test System is a portable analyzer that targets six commonly abused drugs. The company also offers the SEFRIA Fentanyl Urine Drug Screening Test. This was the first cleared fentanyl enzyme immunoassay to utilize SEFRIA technology, thereby making it available in CLIA-certified facilities.

FirstCheck1 offers the First Check line of drug abuse tests. The 6920K Panel 5 Test Cup offers 25 tests per kit and offers a 5-minute qualitative detection of THC, cocaine, opiates, methamphetamines, and PCP. The company also offers the 6000-K Cocaine kit, which includes 25 tests. The test is a one-step, 3-minute qualitative detection of cocaine metabolite in urine. The company offers several other tests similar to the ones mentioned for a variety of other drugs of abuse.

Siemens Healthineers' drug-of-abuse test, the Syva Emit II Plus 6-Acetylmorphine Assay, enables fast, selective testing for heroin use. Urine presence of 6-Acetylmorphine , a heroin metabolite, confirms heroin use; the new assay tests for this metabolite and is intended for qualitative/semi-quantitative determination of 6-AM at a 10 ng/mL cutoff concentration. Providing high specificity without cross-reactivity to morphine, morphine metabolites and many common analgesics, the assay also delivers low analytical sensitivity (down to 1.1 ng/mL) and greater than 99% agreement with the reference method (GC/MS). Siemens also offers the Syva RapidCup, which integrates specimen collection and drugs of abuse tests. The easy-to-use RapidCup enables a rapid drug test to be performed at the point of collection. The Syva RapidCup is available in configurations that can test up to 6 different drugs

simultaneously. The company also offers the Syva RapidTest, which can test up to 10 different drugs simultaneously. The simplicity of the Syva RapidTest enables tests to be performed at POC or other sites where instrumentation for drug screens may not be available.

RX series systems from Randox Laboratories can be used as dedicated analyzers for urine drugs of abuse screening in labs where demands for drug screening are increasing. The Ximola is a compact, fully automated random-access benchtop analyzer offering 400 photometric tests and 240 ISE tests per hour. The system offers Windows-based software, user-defined QC capacity, low water usage, multi-speed stirring, low service requirements, reusable Pyrex cuvettes and multilevel password access.

Many of BTNX's rapid tests are lateral flow tests. The company distributes its products under the Rapid Response brand. The company provides single drug test strips for testing the presence of fentanyl and other drugs. The company also offers Xylazine Test Strips

Shenzhen Superbio Technology markets the Bioeasy platform, which includes rapid tests designed for the qualitative detection of substances such as fentanyl in urine. These types of assays are part of a broader expansion in toxicology testing, particularly in response to the ongoing opioid crisis and the need for rapid screening in both clinical and field settings. In the United States, distribution has been supported through partners such as Carolina Liquid Chemistries, which provides access to select products within its diagnostic portfolio.

Carolina Liquid Chemistries also offers the RYAN immunofluorescence analyzer, a portable system designed for in vitro diagnostic testing of urine samples. The analyzer supports fluorescence-based assays and is intended for use in both laboratory environments and point-of-care settings. Compact instruments such as RYAN reflect a continued shift toward decentralized testing, where rapid results and ease of use are important for clinical decision-making in emergency care, toxicology screening, and outpatient settings.

Blood

Due to the invasiveness of the collection procedure and the cost of laboratory analysis, routine screening of drivers' blood for drugs has generally been viewed as impractical. Forensic laboratories have seen an increasing number of specimens for the determination of drugs in blood as a result of "zero tolerance" laws and better-trained police officers who have been trained to recognize drivers under the influence of drugs. This is especially true in Europe, where several European countries (e.g., Sweden, Germany, and Belgium) have

enacted per se laws for driving under the influence of drugs. These laws stipulate urinalysis as the preliminary screening test and require a blood test if the urine is positive for drugs. Under these laws, any level of a prohibited drug detected in the blood is considered evidence of driving under the influence.

Companies that offer blood analyzers for drugs of abuse include Siemens Syva and Viva Drug Testing Systems line, Thermo Fisher's Indiko fully automated line, and Abbott's Architect line.

Oral

Alfa-Scientific offers: (1) The Oral-view Saliva Multi-Drug of Abuse Test is a rapid lateral flow test that can simultaneously detect up to 8 drugs in human saliva. This test is CE marked and can be sold in Europe. In the United States, this test can be used for forensic use only; (2) The Oral-View Saliva Alcohol Test is FDA cleared and CLIA waived. It is a rapid lateral-flow immunoassay test strip for the detection of alcohol in saliva

1 Step Detect Associates offers Oralert, which is a 10-minute test for the detection of marijuana, cocaine, opiates, methamphetamine, amphetamines, and PCP in saliva. 1 Step Detect Associates also offers Alco-Screen for the detection of alcohol in saliva, and for approximating blood alcohol concentration using a saliva sample.

Confirm Biosciences offers Salivaconfirm, a CE-marked oral-fluid multi-drug test. In the United States, it is available for forensic use only. Salivaconfirm tests for 6 drugs, while Salivaconfirm Premium has an 11-drug panel. Also, the company offers alcohol screening. Two products are available: Saliva Alcohol Test and Breath Alcohol Test

Oasis Diagnostics Corporation has developed a unique proprietary range of oral fluid products, which includes: the SaliChek roadside drugs of abuse testing system, the VerOFy oral fluid rapid test platform, and the VersiSAL split sample saliva / oral fluid collection device. SaliChek is a hand-held reading device that provides electronic readout and hard-copy printout of results generated from specially designed immunochromatographic (ICT) test strips in the VerOFy Rapid Saliva Testing Platform Device. SaliChek incorporates a Pocket-PC with photographic and long-term data storage capabilities. The reader is being configured to accept standardized saliva-based ICT strips in the VerOFy format. The VerOFy Rapid Test Platform is an enabling technology for rapid point-of-care diagnosis using saliva specimens. The VerOFy technology was originally developed for roadside drug-

of-abuse testing, but may be applied to a multitude of diseases, disease states, or biomarkers for use in any setting where immediate results are required.

OraSure Technologies offers several oral fluid-based testing products, including:

- Intercept Oral Fluid Drug Test
- Q.E.D. Saliva Alcohol Test

Jant Pharmacal offers a variety of tests, including the Accustrip CLIA Waived Saliva Alcohol Test Strip and the Accutest Breath Alcohol Detector.

Hair

Confirm Biosciences offers Hairconfirm, a hair follicle multi-drug test. The sample is collected at home and then sent to the company's laboratory using a pre-paid shipping envelope included in the kit. This product line includes five products: HairConfirm, HairConfirm express, HairConfirm with Prescription Drugs, Hairconfirm Business, and Hairconfirm Business with Prescription Drugs. Psychemedics offers several hair drugs of abuse testing products. The company offers a test for alcohol using hair. This test measures average alcohol consumption over a period of approximately three months, indicates the level of alcohol use during that time period and can provide a behavioral indication of excessive use.

Saliva Testing

Thanks to the pandemic, saliva testing has advanced and opened new opportunities for testing various diseases. One of the biggest obstacles to testing patients has been the invasive blood draw. Many patients are uncomfortable with needles, and there is an increased risk for healthcare workers.

Saliva collection and testing are simple, inexpensive, and minimally uncomfortable for the patient. Additionally, as demonstrated during the pandemic, saliva testing was successfully used for COVID-19 testing and has the potential to be used for a variety of diseases, including diabetes and cancer.

Salignostics offers SaliStick, the first rapid saliva-based pregnancy test. The test is based on the company's proprietary technology, which detects the pregnancy hormone β-hCG. The test uses a lateral flow immunoassay platform. Abingdon Health will distribute the test in the EU.

Breath Test Advances

A major part of the success of POC testing relies on developing tests that use patient-friendly sampling techniques. Sampling has been a major hurdle for non-laboratory test systems. Throughout the world, the invasive nature of blood sample collection has long been seen as a hindrance to patient self-testing and also decentralized testing by professionals. For this reason, there has been considerable interest in developing breath-based devices as well as assays using urine, hair, sweat and saliva samples.

A growing demand for quick and easy methods for the primary diagnosis of diseases, such as asthma, chronic obstructive pulmonary disease, and cancer, is contributing to the attraction of breath-based testing devices. In addition, the rising adoption of breath analyzers in smoking cessation programs to detect carbon monoxide in the exhaled air is augmenting the market growth.

In clinical medicine, the urea breath test has long been used to detect Helicobacter pylori (H. pylori). This bacterium, found in the gastrointestinal system, is a main cause of ulcers in these areas. H. pylori produces an enzyme called urease, which breaks urea down into ammonia and carbon dioxide. Patients swallow a tablet containing urea. The amount of carbon dioxide exhaled is measured to detect H. pylori in the stomach. Breath-based testing has the potential to be used to research a range of lung diseases.

The concept of testing odors and exhaled breath is not new. Hippocrates recognized the link between odors and disease processes, such as breath smelling of rotten apples in diabetes, urine odor in kidney failure, and a sewer smell in lung abscess. That is what breathalyzers do when they measure small volatile molecules. Diseases such as lung or breast cancers, liver disease, gastrointestinal problems, and many others could potentially be diagnosed through trace chemicals in exhaled breath.

A leader in breath testing, Menssana Research markets the FDA-cleared Heartsbreath that identifies methylated alkanes, chemicals that are produced when the body is rejecting a newly transplanted heart, and a breath test for asthma that measures nitric oxide, a marker of airway inflammation. Menssana Research is developing BreathLink, a cloud application for the collection, concentration and analysis of volatile organic compounds in human breath. It is used with the Breathscanner, a mobile point-of-care system that can be used anywhere in the world with an Internet connection. The BreathX technology is a personal testing system that can be used at home or in the clinic. The test is indicated for breast cancer, lung cancer, and

pulmonary tuberculosis. These tests are available in the EU and are currently in progress for the FDA app.

The patient simply breathes into it for two minutes. Less than ten minutes later, the system identifies markers of oxidative stress and disease using proprietary algorithms on servers in a central laboratory. All data is sent and received with defense-level encryption.

A clinical initiative, led by NYU Langone Medical Center, aims to determine the effectiveness of a breath test in identifying volatile organic compounds in human breath that are biomarkers of chronic obstructive pulmonary disease. The study employs patented technology developed by Menssana Research.

Bedfont Scientific Limited has developed a line of handheld analyzers and reports it has over 2,000 customers throughout the world healthcare and industrial markets. The analyzers are marketed by a network of 40 distributors in North and South America, Europe, Australia, Japan, the Middle East, and the Far East. The Smokerlyzer is a device that can aid parents in testing their kids for cigarette and marijuana use. Bedfont states the device has been in use for the last 20 years in clinical research and in quit-smoking clinics, and, more recently, by professional counselors in high schools across the U.S. Bedfont offers the device to consumers as a personal breath tester for $59.99.

Bedfont's Gastrolyzer2 is a portable, hand-held Breath Hydrogen Monitor designed to aid in the diagnosis of gastrointestinal disorders caused by bacterial infection. ToxCO+ is a Breath Carbon Monoxide Monitor designed as a compact, portable instrument for the diagnosis of carbon monoxide poisoning by paramedics in the field and in hospital emergency units. It can be used to screen for poisoning without the need for blood tests. NOxBOX+, Inhaled NO Therapy Monitor, provides real-time monitoring of nitric oxide (NO/NO2).

A single exhaled breath contains hundreds, if not thousands, of volatile organic compounds, some of which may be specific biomarkers of disease. Numerous researchers are now exploring this possibility in the hopes of developing non-invasive, easy-to-use, and cost-effective POC breath tests that rapidly detect a variety of diseases. The table below lists some molecules that medical research has linked to various health conditions. Breath analysis offers the promise of a truly revolutionary new tool for improving healthcare without incurring high new costs, since expensive reagents or consumables are not required.

Advances in breath-detection equipment have sparked renewed interest in breath testing. Tuberculosis detection is estimated to experience considerable growth and appear as the

fastest-growing category in this market. The development in this category is because of the increasing incidence of tuberculosis and the rising demand for quick and non-invasive screening devices.

Table 4-12: Selected Disease Markers in Exhaled Breath

Disease	Marker
Asthma	nitric oxide
Breast cancer	alkanes, formaldehyde
Diabetes	acetone
Liver function	Carbonyl sulfide
Organ rejection	ammonia
Schizophrenia	carbon disulfide
Tuberculosis	hydrogen peroxide

Source: Kalorama Information

Micro-Hospital Opportunities

There is an opportunity opening in clinical laboratories due to the growth in the number of micro-hospitals. Micro-hospitals feature 8 to 10 inpatient beds (but can have as many as 25 beds), and range from 15,000 to 50,000 square feet, whereas full-service hospitals are 100,000 square feet or more. At a cost of $7 million to $30 million, micro-hospitals are significantly less expensive than large hospitals to bring to market.

For patients, micro-hospitals offer 24-hour care that cannot be found at health care clinics inside drugstores or at urgent care clinics. By offering emergency rooms and overnight beds, micro-hospitals can treat gastrointestinal pain, broken bones, minor trauma and other illnesses for patients who require only a one- or two-night stay.

Short patient stays are consistent with the trend toward reducing the number and length of hospital visits, in keeping with insurance companies' preferences for managing care. The American Hospital Association says that from 2012 to 2014, hospital inpatient admissions dropped from 34.4 million to 33.1 million, while outpatient hospital visits grew from 674.9 million to 693.1 million.

Micro-hospitals are typically located in urban and suburban areas. Designed to fill coverage gaps, micro-hospitals sometimes meet the needs of Medicaid patients and the underserved, but more often provide convenient locations for well-insured patients who already use the system for outpatient care. Micro-hospitals tend to fill the gap between urgent care centers and full-service hospitals.

These new entities offer opportunities for outside clinical labs. Independent labs might be used more often when faster test results are needed or are in closer proximity. There are also more opportunities for clinical labs to establish working relationships with micro-hospitals that are not affiliated with large health systems.

Emerus is the first and largest operator of micro-hospitals. Its hospitals are organized around the patient-and-family concept. Emerus has 28 facilities nationwide and has served over 4 million patients. It has another 25 facilities in development.

Emerus opened three new neighborhood hospitals in the Philadelphia suburbs in 2025. New facilities are also being built in Las Vegas and San Antonio.

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Sila Realty Trust announced the completion of a healthcare acquisition that includes micro-hospitals. They are located in Arizona and Texas.

Nutex Health is a micro-hospital opened in Green Bay, WI. The facility is putting emphasis on personalized patient care. The new facility is owned by Nutex Health, which operates a nationwide network of micro-hospitals.

There are more than 100 micro or neighborhood hospitals in the U.S. In the U.S., micro-hospitals are expected to grow at a CAGR of 8.1% from 2025-2032. Europe is the second-largest market for micro-hospitals. Growth of micro-hospitals will be influenced by finances, regulations and approvals. The micro-hospitals will need to meet the CMS minimum census requirements and demonstrate consistent growth.

Climate Change and Infectious Disease

Emerging infectious diseases seem to be a recurring theme in global health, and it is no different in 2026. New pathogens continue to evolve and outpace human defenses. Scientists are observing a shift in the geographic spread of infectious diseases. Whether climate change is man-made or a natural occurrence, infectious diseases are appearing well outside where they are expected, in months when they are not expected, and at levels of intensity not anticipated.

Globalization, migration and urbanization are driving the spread of infectious diseases, but higher temperatures and more extreme weather events have also influenced the range and intensity of infectious diseases.

Researchers agree that it is hard to predict the impact of climate deviations on disease patterns. Additionally, surveillance programs are underfunded and inconsistent, based on immediate need. For example, in 1999, when West Nile arrived, there was public outcry over lapsed mosquito surveillance and a surge of new funding. As the threat subsided, there was a return to the status quo. Then, 20 years later, Zika comes in, and everybody wonders why we are not ready for this. So, the scenario begins again with an uptick in surveillance programs and increased funding.

Infections transmitted through water, food, or vectors such as mosquitoes and ticks are highly sensitive to weather and climate conditions. The warmer, wetter, and more variable conditions brought by climate change are therefore making it easier to transmit diseases such as malaria, dengue fever, chikungunya, yellow fever, Zika virus, West Nile virus, and Lyme disease in many parts of the world.

To be better prepared, improved surveillance and better communication among hospitals and local health authorities are needed to improve readiness for outbreaks. Pathogens such as Zika, Lyme disease, or V parahaemolyticus are on the move. Early warning systems and prevention are key to protecting the population.

Climate change is expected to alter the incidence, prevalence, and distribution of infectious diseases worldwide. Clinical labs will continue to be an important participant in the early warning system by developing real-time surveillance systems and rapid POC tests that inform them and make them more robust.

Kickback Schemes

Fraud and abuse remain persistent issues in the healthcare system, including ongoing kickback arrangements and improper referral practices. In recent years, enforcement activity has continued to highlight schemes involving clinical laboratories, telemedicine, durable medical equipment, and pharmacy services. Many of these cases involve attempts to disguise payments through consulting agreements, marketing contracts, or investment structures that obscure the underlying financial relationships. The clinical laboratory sector has been particularly affected, with multiple cases involving payments to physicians or intermediaries in exchange for test referrals. Earlier enforcement actions included allegations against physicians and laboratory operators who used recruiters or third parties to channel payments tied to testing volumes. Large multistate investigations have also uncovered coordinated schemes involving genetic testing, telemedicine services, and billing for unnecessary procedures.

More recent cases in 2024 and 2025 have continued to follow similar patterns, including arrangements where laboratory marketers and physicians were accused of structuring payments as consulting fees to encourage referrals. Additional enforcement actions have targeted pharmacy and durable medical equipment providers, as well as telemarketing-driven schemes that generated fraudulent orders for Medicare beneficiaries. In 2025, federal authorities announced multiple large-scale enforcement actions involving hundreds of individuals and billions of dollars in alleged fraudulent claims across Medicare, Medicaid, and private insurers. These cases included a range of activities such as unnecessary diagnostic testing, false billing, prescription-related kickbacks, and improper use of telemedicine to generate orders for laboratory tests and other services.

The continued focus on fraud and abuse is directly impacting clinical laboratories and diagnostics companies. Organizations are placing greater emphasis on compliance programs, internal audits, and documentation of physician relationships to reduce legal and financial risk. Laboratories are also becoming more cautious in their use of third-party marketers and referral networks, as these arrangements have been a frequent source of enforcement actions. In addition, billing practices and test utilization are under closer review, with increased attention to medical necessity and proper coding. These pressures are contributing to a more disciplined operating environment, in which growth strategies are increasingly tied to transparent business practices and regulatory compliance. Overall, fraud schemes in healthcare continue to evolve in response to regulatory oversight, often becoming more

complex and involving multiple entities across different segments of the industry, underscoring the need for continued vigilance and strong compliance across the diagnostics sector.

Early Sepsis Detection

Sepsis occurs when the body's response to these chemicals is out of balance, triggering changes that can damage multiple organ systems. If sepsis progresses to septic shock, blood pressure drops dramatically. This may lead to death.

Formerly known as blood poisoning, sepsis is a syndrome characterized by an overwhelming systemic patient response to infection, which can rapidly lead to organ failure and ultimately death. It is the major cause of morbidity and death in intensive care patients. Sepsis syndrome is the leading cause of death in United States hospitals, and its incidence has increased consistently over the past 20 years. Responsible for over 350,000 deaths and affecting 2.5 million inpatients annually, sepsis is one of the world's fastest-growing healthcare problems. In the United States alone, the economic impact of sepsis is estimated to be in excess of $62 billion.

Worldwide, there are approximately 49.5 million cases of sepsis and 11 million deaths. In Spain, the incidence is 212 cases per 100,000 inhabitants per year, with mortality rates ranging from 15% to 50%

The diagnosis of sepsis is challenging because it is a heterogeneous condition with different etiologies. Blood and diagnostic tests are used to identify the source and location of the infection. The presence of inflammatory markers is used to indicate infection. Blood and urine cultures help identify the pathogens and distinguish infections SI RS from non-infectious SIRS.

There is evidence that early antibiotic treatment for sepsis improves patient survival. Beckman Coulter introduced its Early Sepsis Indicator which identifies sepsis patients with proven accuracy, providing the opportunity for clinicians to institute treatment when antibiotics are most effective.

Point-of-care testing is also a useful tool for sepsis diagnosis by accurately distinguishing an immune response to infection from an inflammatory response to non-infectious disease. Several analyzers have been introduced to the market, including Siemens' RAPIDPoint 500, Roche's cobas b 221, and ILs GEM Premier 5000. Portable devices have also been introduced, including Nova Biomedical's StatStrip Lactate and Abbott's iSTAT.

Beckman Coulter Diagnostics and Diazyme Laboratories received FDA clearance to market a new procalcitonin (PCT) assay for sepsis detection. The company reported it is the first homogenous PCT assay for use on current Beckman Coulter AU models 480, 680 and 5800 chemistry analyzers.

Cytovale offers IntelliSep Sepsis Test. The test aids in the rapid diagnosis of sepsis in adults in about 10 minutes.

Inflammatix offers the TriVerity Acute Infection and Sepsis Test. The test includes the Myrna instrument and the TriVerity Test. The test results are available in about 30 minutes.

Cepheid markets the Xpert Xpress GBS (Group B Streptococcus) dual target molecular test. The test is a next-generation test that utilizes new dual targets in regions of the GBS genome to improve sensitivity and bacterial strain identification. The test is designed for use on the GeneXpert system.

The leading cause of newborn infection is GBS, and it is hoped that the test will help decrease early-onset sepsis in newborns due to GBS. The test can return results within 30 minutes.

Abionic offers the IVD Capsule PSP for the rapid detection of sepsis. The IVD Capsule PSP runs on the abioSCOPE a nanofluidics platform that measures pancreatic stone protein, an emerging sepsis biomarker.

Medical Diagnostics and 3D Printing

Manufacturers are utilizing 3D printing to customize and improve diagnostics. For example, 3D-printed microfluidic devices are enabling faster, more portable testing. These devices can be customized to detect infectious diseases, monitor chronic conditions, and/or perform genetic and biochemical assays using very small sample sizes, with a quick turnaround time.

3D printing also supports the development of innovative biosensors and diagnostic tools tailored to specific individuals or disease-specific needs. As technology evolves, it may play a significant role in point-of-care diagnostics in remote or resource-limited regions.

Personalized and POC medicine will likely benefit significantly from the integration of 3D printing and medical diagnostics.

Staffing Shortages

The healthcare staffing crisis has intensified over the last few years. Staffing shortages in healthcare are a major concern. The U.S. alone could face a shortage of 124,000 physicians by 2034. Staffing shortages are one of the biggest challenges facing the health care system. There are several concerns that have contributed to the increasing staff shortage problem, including:

- Burnout – heightened by the pandemic
- Early retirements due to stress and disillusioned by the trajectory of the profession
- Aging population – increasing number of elderly requiring more care
- Lack of nursing faculty

The U.S. is not alone in this issue. There are staffing shortages of healthcare workers worldwide. The WHO predicts a shortage of 15 million healthcare workers by 2030. The worst shortages are expected in Africa, the Mediterranean, and the Middle East.

The crisis in healthcare staffing will not be a quick fix. The industry needs to consider long-term strategies and a committed investment in healthcare education.

To combat staffing shortages, the healthcare industry needs to identify and address major drivers, including expanding education and training capacity. Every year, thousands of qualified applicants are turned away due to the lack of faculty, clinical sites, and federal funding for residency positions. There also needs to be an improvement in nurse-to-patient ratios, with flexible scheduling and safe working environments. Understaffed ratios create unsafe environments for both patients and healthcare workers. With the anticipated increase in demand from the aging population, decisive steps will be needed to address this issue.

Tariff Effects on the IVD Industry

Tariffs have become an increasingly important, still-evolving factor shaping the global IVD market, with broad implications for cost structures, supply chains, innovation, and market access. Because the industry is highly globalized and dependent on cross-border sourcing of reagents, components, and finished systems, even modest tariff changes can have immediate downstream effects. While IVD products have historically benefited from relatively low trade barriers due to their role in healthcare, recent geopolitical tensions, shifting trade policies, export controls, and government efforts to strengthen domestic manufacturing have introduced greater uncertainty and complexity.

The most direct impact is rising manufacturing costs, particularly for molecular diagnostics, POC platforms, and genetic testing systems that rely heavily on specialized materials, electronics, and single-source components, as well as for high-volume consumables such as reagents, cartridges, and test kits, where cost increases can compound over time. These added costs are often difficult to absorb, especially for smaller companies, and are frequently passed through the value chain, contributing to higher instrument and test pricing and potential pressure on reimbursement. At the same time, tariffs are disrupting established supply chains, forcing companies to reassess sourcing strategies, qualify alternative suppliers, and increasingly shift toward regional or in-country manufacturing to reduce exposure and improve supply security.

In response, IVD manufacturers are actively implementing mitigation strategies, including dual-sourcing of critical components, diversifying supplier networks, and expanding localized manufacturing hubs across the U.S., Europe, and Asia. Many are also redesigning assays and platforms to reduce dependence on tariff-sensitive inputs, while adopting "make-versus-buy" strategies and forming closer partnerships with key suppliers to secure access to essential materials. Operationally, companies are adjusting logistics through pre-emptive inventory builds, alternative shipping routes, and selective stockpiling to buffer against disruptions, although these measures can increase working capital requirements.

These adjustments can introduce delays in product launches, add regulatory burden due to revalidation requirements when components or manufacturing sites change, and create short-term operational inefficiencies, while also diverting resources from research and development and potentially slowing innovation cycles. The impact is not uniform across the IVD landscape; segments such as molecular diagnostics and advanced POC testing remain

more exposed due to their reliance on complex, globally sourced inputs, while more established areas like routine chemistry and parts of histology tend to be less sensitive.

Tariffs are also interacting with healthcare economics, as laboratories facing fixed or constrained reimbursement become more selective in adopting new tests, often favoring high-throughput, multiplexed, or workflow-efficient solutions that deliver clearer economic value. Despite near-term margin pressure in some cases, these dynamics are driving longer-term structural changes, with companies prioritizing supply chain resilience over pure cost efficiency and building more regionally balanced operating models. While the full impact remains somewhat uncertain and continues to evolve, tariffs are now a structural consideration in IVD market planning through the remainder of the decade, shaping not only cost structures but also where products are made, how quickly they reach the market, and which technologies ultimately gain adoption, with companies that successfully balance cost control, supply chain resilience, and continued innovation better positioned to navigate this increasingly complex global trade environment.

Targeted Testing

The targeted testing market, often referred to as panel-based or syndromic testing, continues to grow and has strong long-term potential. These tests enable the simultaneous detection of multiple pathogens and, increasingly, antimicrobial resistance markers from a single specimen, delivering faster and more clinically actionable results than traditional methods. Their value is driven by speed, streamlined workflows, improved diagnostic confidence, and earlier treatment decisions. While COVID-19 created a temporary surge in demand, the market has transitioned into a post-pandemic phase characterized by more normalized testing volumes, broader clinical adoption across multiple disease areas, and generally steady growth in the mid- to high-single-digit range, with variability by segment and geography.

Respiratory panels remain a major revenue contributor, driven by seasonal testing patterns and continued demand for multiplex detection of viruses such as influenza, RSV, and SARS-CoV-2. Molecular syndromic respiratory panels represent the dominant share of this segment, while rapid antigen and point-of-care molecular tests play an important complementary role in decentralized settings. Key players include Roche, Cepheid, Abbott, and QuidelOrtho.

Non-respiratory panels represent an expanding portion of the market and are increasingly central to growth. These include gastrointestinal infections, bloodstream infections, meningitis/encephalitis, sexually transmitted infections, and antimicrobial resistance panels, along with broader applications in oncology, genetic testing, and transplant diagnostics. Molecular technologies dominate most infectious disease panels, while oncology and genetic panels are increasingly driven by next-generation sequencing and other advanced molecular methods. Key players include bioMérieux, Diasorin, Abbott, Roche, and Siemens Healthineers, among others.

End-user demand remains heavily concentrated in hospitals, particularly in central laboratories and emergency departments, where rapid, comprehensive results support acute care decision-making. Emergency departments continue to drive high volumes of respiratory and bloodstream infection panel testing, while urgent care and outpatient settings are increasingly adopting smaller, faster panels and point-of-care formats as connectivity and ease of use improve. Growth is also supported by antimicrobial stewardship programs, which are driving adoption of panels that combine pathogen identification with resistance markers to guide targeted therapy. At the same time, laboratories are placing greater emphasis on cost-effectiveness and appropriate utilization, focusing panel use in high-impact clinical

scenarios such as sepsis, ICU care, and immunocompromised patients. The concept of panel-based testing is expanding beyond infectious diseases into oncology and genetic testing, where multi-marker panels and liquid biopsy approaches are increasingly integrated into routine clinical practice.

Chapter 5: Point-of-Care (POC) Tests

Scope

Point-of-care (POC) testing in the in vitro diagnostics (IVD) market has a broad and expanding scope, driven by technological innovation, decentralization of healthcare, and the push for faster clinical decision-making. There are general synonyms, including near-patient testing, bedside testing, decentralized testing, and rapid testing. Generally, POC and rapid testing are the terms that are used most often globally. However, near-patient testing is the preferred term in Europe.

The products in this area are generally rapid tests, with results available within 1 hour. The two general categories in POC testing are Professional POC and OTC Self-Testing POC. Home collection methods are also discussed.

Market segments highlighted:

- **Colon cancer screening**
- **Diabetes testing**
- **Infectious disease testing**
- **Lipid testing**
- **Pregnancy/Fertility testing**

These segments include revenues for diagnostic systems, consumables, and service maintenance. However, POC testing for these applications is covered in a separate chapter on that topic in this report. Direct-to-consumer tests are excluded from the market estimates but are covered in Kalorama Information's Direct to Consumer Testing Market.

Overview and Trends

The point-of-care market contributes significantly to the value and revenue of the IVD industry. Advances in miniaturization, connectivity, and assay performance over the past several years have expanded the range of testing that can be performed outside the central laboratory. Globally, the increasing prevalence of chronic and infectious diseases, along with the need for faster clinical decision-making, has driven demand for rapid diagnostic results. Early detection and timely treatment remain the main goals across all areas of diagnostics, and POC testing plays an increasingly critical role in achieving them.

Among IVD segments, POC diagnostics is one of the fastest-growing areas. The COVID-19 pandemic accelerated adoption by driving demand for rapid, accessible testing and by advancing molecular, antigen, and digital diagnostic technologies. As a result, POC testing is now widely viewed as a core extension of traditional laboratory services rather than a niche alternative.

Innovation is expected to expand the capabilities of POC testing, particularly in decentralized and consumer-focused settings. New systems are more sophisticated, offering improved analytical performance, faster turnaround times, and enhanced connectivity. These developments offer broader use in managing both acute and chronic conditions, including infectious diseases, cardiovascular disorders, and metabolic conditions.

POC testing has grown steadily over the past two decades, driven by the need for immediate diagnostic information in a variety of care settings. Technologies that have contributed to this growth include microfluidics, biosensors, lab-on-a-chip systems, and compact molecular platforms. Increasing integration with digital health tools, including smartphones and cloud-based data systems, is further shaping the POC landscape by enabling real-time data sharing and remote clinical oversight.

Decentralized testing, defined as diagnostic testing performed outside the central laboratory, is now a defining feature of modern healthcare delivery. Rapid tests, which often deliver results in less than an hour, are widely used in physician offices, urgent care centers, retail clinics, emergency settings, and increasingly at home. Testing is performed not only by laboratory professionals, but also by physicians, nurses, pharmacists, and patients, depending on the complexity of the test.

The menu of POC tests continues to expand beyond traditional glucose and pregnancy testing to include assays such as HbA1c, cardiac markers including BNP, coagulation markers such as D-dimer, inflammatory markers such as C-reactive protein, and whole-blood lactate. Molecular POC testing has also advanced, with systems now available for respiratory infections, sexually transmitted infections, and other acute conditions. These platforms deliver fast, actionable results when timing is critical and are being used closer to the patient.

Regulatory pathways are contributing to this expansion, with a growing number of devices obtaining CLIA-waived status in the United States and equivalent approvals in other regions. At the same time, many decentralized testing sites continue to use moderately complex systems to expand their diagnostic capabilities. Improvements in instrumentation and assay design now allow some POC systems to deliver quantitative, laboratory-quality results with automated data transfer to electronic medical records and remote care platforms.

In developing regions, POC diagnostics remain especially important due to limited access to centralized laboratories. Basic tests for glucose, hemoglobin, and infectious diseases provide significant clinical value. The increasing availability of portable and smartphone-enabled devices is expected to further expand access, although adoption may be constrained by infrastructure and resource limitations in some areas.

The continued growth of POC testing is driven by broader healthcare trends, including provider consolidation, the expansion of outpatient and retail care models, the increasing use of electronic medical records, and a stronger emphasis on outcome-based care. Diagnostic tests are playing an increasingly important role in guiding therapeutic decisions, particularly as treatment strategies become more personalized. As a result, test adoption is driven by clinical performance, impact on patient outcomes, and overall cost-effectiveness rather than price alone.

Future success in POC testing will depend not only on analytical performance but also on the ability to deliver more value through connectivity, clinical decision support, and integration into care pathways. This is already evident in areas such as diabetes management, where connected glucose-monitoring systems enable ongoing patient engagement and physician oversight. As the test menu expands to include more complex conditions such as cancer and cardiovascular disease, the need for integrated interpretation and clinical support will become even more important.

Despite its advantages, POC testing still faces challenges compared to centralized laboratory testing, including quality control, training requirements, and variability in performance across settings. Nevertheless, the number and scope of POC tests continue to expand. Since the early 1990s, the number of CLIA-waived analytes and systems has increased substantially, now encompassing a broad range of infectious-disease, metabolic, and drug-testing applications.

The POC diagnostics market is expected to continue growing, driven by the need to improve efficiency in acute care, reduce hospital stays, and support faster clinical decision-making. As healthcare delivery shifts toward decentralized and patient-centered models, POC testing will play an increasingly central role in diagnosis, monitoring, and disease management across multiple clinical settings.

POC Industry Drivers

There are many benefits in providing POC and rapid IVD testing. One of the key benefits and market drivers for the POC testing market is the ability to have rapid results that can be used immediately for patient treatment decisions. While this is a major benefit of POC testing, many other factors are also driving the growth of this market. Factors driving the development of POC tests include:

Patient-focused drivers

- Rapid results can be used immediately for patient treatment decisions in physicians' offices and clinics.
- Demand for faster turnaround times for critical test results in hospital locations such as emergency departments and intensive care units.
- Less sample volume (neonatal, pediatric, ICU benefit)
- Varied samples besides blood

Medical/Healthcare-related drivers

- Introduction of POC tests for new targets such as additional infectious diseases and other new analytes, which previously could not be tested in the POC setting. Introduction of new therapies that require rapid feedback with diagnostic tests.
- Growth of precision healthcare and precision medicine, and the need for rapid tests to support this.
- Optimization of drug treatments

Technology drivers

- Advances in miniaturization, microfluidics, molecular, and other technologies have made it possible to expand the numbers and types of tests that can be performed in POC settings.
- Nanotechnology has gained attention in the POC arena, offering unique opportunities for the advancement of POC devices

- Health apps for mobile devices are pushing the development of POC devices

Economic drivers

- Growth in specialty clinics, retail clinics, and other decentralized locations for patient care.
- Economic factors driving the need to reduce the length of patient stays in hospitals, reduce backlog in areas such as emergency departments, as patients wait for test results, etc.
- Reduce postoperative care time

Other drivers

- Need for robust but also simple diagnostic tools for military applications outside of military hospitals.
- Need for disaster preparedness.
- Need for robust but also simple diagnostic tools for developing countries
- Decrease inappropriate use of drugs
- Need for pandemic preparedness
- Expansion in remote areas where healthcare is limited

POC Industry Challenges

There are at least five challenges for the POC market. Those include:

- Cost of tests
- Accuracy
- Specificity and sensitivity of tests
- Lack of trust by healthcare professionals
- Lack of awareness in POC rapid testing

Of these concerns, accuracy has been the key challenge. Advancements in POC technology have allayed some concerns, demonstrating improved accuracy and greater consistency.

Home testing has come to the forefront during the pandemic, but it also raises some concerns, including:

- User error
- Lower accuracy
- Reduced sensitivity and specificity
- Indiscriminate testing by end-users causes more concern for healthcare providers
- Unauthorized tests on the market

Regulatory Challenges

Even though POC testing is often performed by non-laboratory personnel, the clinical laboratory typically retains primary responsibility for oversight, governance, and quality assurance of these programs. This includes establishing and enforcing standardized procedures for specimen collection and labeling, operator training and competency, documentation, quality control, proficiency testing, and infection control. Strong laboratory oversight is essential to ensure consistent test performance, accurate results, and compliance with regulatory requirements. The College of American Pathologists (CAP) maintains an extensive set of accreditation checklists that apply to POC testing, including dedicated point-of-care requirements as well as broader laboratory general and all-common checklist elements that collectively govern areas such as personnel qualifications, calibration and validation, quality management, results reporting, safety, and instrument performance. While the exact number of checklist items evolves with periodic updates, CAP's framework remains one of the most comprehensive for managing decentralized testing environments.

Concerns about the rapid growth of waived testing sites, many operating outside traditional laboratory structures, have persisted, particularly regarding variability in training, oversight, and quality practices. Organizations such as COLA have responded by strengthening accreditation requirements for waived testing, including more explicit expectations for staff competency assessment, documentation, and quality practices, even in low-complexity settings. This reflects a broader industry shift toward increased scrutiny of waived testing as test menus expand and clinical reliance on rapid results grows. Additionally, the expansion of POC testing has increased the importance of device connectivity and data management, with many programs now relying on middleware and informatics systems to automatically transmit results into the LIS and electronic medical record, reduce transcription errors, and monitor QC performance and operator compliance in real time. Laboratories are also placing greater emphasis on ongoing competency assessment due to high operator turnover in decentralized settings, using standardized training programs and system-based controls to ensure only qualified personnel perform testing.

The use of blood glucose meters has been a key example of the regulatory and clinical challenges in POC testing, particularly regarding "off-label" use. When devices are used outside their FDA-cleared intended use, such as in critically ill patients when not specifically indicated, they may be subject to higher regulatory requirements under CLIA, effectively treating them as non-waived testing. Over the past decade, regulatory agencies, including the

U.S. Food and Drug Administration, have issued more stringent performance expectations for glucose monitoring systems, especially in hospital settings. Rather than broadly reclassifying all glucose meters as non-waived, the regulatory approach has focused on tightening accuracy standards and encouraging manufacturers to obtain specific clearances for use in critically ill populations. While this initially created confusion among healthcare providers, more recent guidance and improved device performance have helped clarify appropriate use in both ICU and non-ICU settings. In parallel, laboratories are taking a more active role in evaluating which tests are appropriate for decentralized use based on clinical impact, risk, and cost, while also implementing continuous quality monitoring programs that track QC failures, error rates, and turnaround times. Increasing attention is also being paid to utilization management and reimbursement, as POC testing, while clinically valuable, often carries a higher per-test cost than central laboratory testing and must be justified by improved patient care and workflow efficiency.

Professional POC

Outside of glucose testing, professional point-of-care has been successful on a number of fronts. The 2025 professional POC market, including glucose, is estimated at $13.5 billion. The POC professional market will grow at 4.4% annually, reaching $16.8 billion in 2030.

The fastest growing segments in the professional POC market include:

- Hematology– 5.2%
- HbA1c – 8.4%
- Infectious disease – 5.4%
- Fecal occult blood testing – 5.4%

Table 5-1: Worldwide Professional POC Test Sales, by Category, 2025 -2030 ($ million)

[Cardiac Markers; Cholesterol; Coagulation; Critical Care POC; Drugs of Abuse; Fecal Occult Blood; Fertility; Glucose; HbA1c POC; Hematology; Infectious Diseases; Urinalysis; Others]

Category	2025	% Mkt	2030	% Mkt	CAGR
Fecal Occult Blood	3,057	23%	3,988	24%	5%
Infectious Diseases	2,720	20%	3,542	21%	5%
Glucose	2,272	17%	2,640	16%	3%
Critical Care POC	1,074	8%	1,176	7%	2%
Hematology	876	6%	1,127	7%	5%
Coagulation	805	6%	892	5%	2%
Cardiac Markers	751	6%	895	5%	4%
HbA1c POC	615	5%	925	6%	8%
Drugs of Abuse	506	4%	556	3%	2%
Cholesterol	278	2%	335	2%	4%
Urinalysis	181	1%	209	1%	3%
Fertility	170	1%	175	1%	1%
Others[1]	232	2%	291	2%	5%
Total	**13,537**	**100%**	**16,751**	**100%**	**4%**

Note: [1] FSH, TSH, cancer, etc.

Source: Kalorama Information

Point-of-care tests were growing rapidly before the COVID-19 pandemic, but test manufacturers have stepped up the development of reliable POC tests to answer the call for rapid and easy-to-use devices to facilitate testing outside the laboratory. This has helped to spotlight the ease and quality of all FDA-cleared POC tests.

Throughout 2022, demand for POC products continued despite a significant decrease in COVID-19 tests compared with the prior year. This continued into the subsequent years of 2023, 2024, 2025 and continuing into 2026.

With lower device costs and improved data systems, point-of-care testing is becoming a practical and cost-effective alternative to traditional lab testing across clinics, hospitals, and home care settings.

As the number of POC tests and devices continues to grow, it's unrealistic to expect users to learn and manage a wide range of systems. That's why there's been a strong push over the past decade toward multipurpose platforms that can run both chemistry and immunoassay tests on a single system. Simple strip-based rapid tests can't meet every near-patient need, and many physicians are looking to expand the range of testing they offer in their offices. This is driving demand for small, easy-to-use, and easy-to-maintain systems for clinics and smaller labs. Advanced technologies like microarrays and lab-on-a-chip platforms are well-positioned to meet that need.

A major barrier to increased POC use by professionals, especially outside the hospital, is a lack of correlation with lab-based tests. The growing prevalence of health networks, which comprise hospitals, clinics, and physician offices, increases the need to standardize test results across locations. For example, a cholesterol test result needs to correlate across multiple sites within the health network, regardless of whether the test was administered via a portable device in the physician's office, a semi-automated device in the clinic, or on a hospital's fully automated analyzer in the core laboratory.

Physician office testing (POL) is primarily a phenomenon of the U.S. U.S. statistics indicate there are approximately 120,000 in-office labs. It represents roughly 65% of the global POL market and has demonstrated slightly above-average growth in recent years, at around 4%. The physician lab market includes a variety of institutions beyond physician practices, such as specialty and multispecialty clinics; other primary care and urgent care clinics; and outpatient clinics not located in or associated with a hospital or outpatient surgical services.

Most European cities have small lab and pharmacy-based test services readily available. Physician office testing is not developed in Japan. In emerging markets, physician office testing serves the needs of the middle class.

More tests and technologies have been adapted to serve the needs of physician offices and home testing. It is estimated that U.S. physicians see 2.5 million patients per day. In 60% -

70% of those visits, the physician needs to order diagnostic tests to guide treatment or to monitor the patient. In larger physician practices, these tests are performed on site in a physician's office lab.

Tests used in physician office labs are clinical tools for disease screening, the diagnosis of common infectious diseases (e.g., strep, flu, mono, H. pylori, RSV), or routine monitoring tests for patients with common chronic diseases such as diabetes, cholesterol and colon cancer.

The United States remains the largest single market for IVD and point-of-care testing, and it has played a major role in shaping how rapid tests are developed and introduced. Many new POC products are launched first in the U.S., often working through CLIA waiver pathways before expanding into international markets, where regulatory approaches frequently follow similar models. While the focus on cost control and preventive care contributes to testing closer to the patient, the higher per-test cost of decentralized testing can limit adoption. In some cases, large healthcare systems and payers continue to favor centralized laboratory testing, as it allows them to leverage existing infrastructure and reduce overall costs.

In the U.S., COLA (the Commission on Office Laboratory Accreditation, www.cola.org) accredits nearly 8,000 medical laboratories and provides education programs and standards that enable clinical laboratories to meet U.S. CLIA and other regulatory requirements.

The following table presents a small selection of announced innovations in general professional POC testing platforms and tools. It demonstrates the efforts underway to make POC testing more accessible to physician offices, clinics and in-hospital testing.

Table 5-2: Selected Professional POC Test Innovations (excluding COVID-19 testing)

Company	Location	Area	Details
Abbott	US	Platform	iSTAT
Acon Laboratories	US	urine	Mission U120 Ultra Urine Analyzer
Ativa Medical	US	platform	Ativa Analyzer "micro-lab": microfluidics-based hematology/chemistry
DiaSys Diagnostics GmbH	Germany	platform	InnovaStar; photo-/turbidimetric HbA1c, glucose, hemoglobin
		platform	SensoStar; glucose & lactate
DiaSys Diagnostics India	India	platform	QDx InstaLab, all routine laboratory tests
EKF Diagnostics	UK	ketones	STAT-Site M β-HB, ketones strip & reader
Loop Medical (formerly Qloudlab)	Switzerland	sample prep	Needle-free blood collection
Luoxis Diagnostics Inc. (Aytu Biopharma)	US	biosensor	RedoxSYS Diagnostic System, oxidative stress
Polymedco (LSI Medience)	US	Analyzer	Pathfast hs-cTn
Radisens Diagnostics	Ireland	platform	Gemini all-in-one: immunoassay, biochemistry, hematology
Roche Diagnostics	US	platform	cobas b 101, POL and clinic
Samsung Healthcare	Korea	platform	Samsung LABGEOIB10, chemistry & immunoassays
U Washington	US	app	BiliCam app, phone-linked newborn bilirubin test
vantix DIAGNOSTICS	US	biosensor	vantix POC system, chemistry, immunochemistry, hematology

Source: Kalorama Information, company reports

B&E Biotechnology offers the i-Check handheld blood gas electrolyte analyzer. The product offers microfluidic and electrochemical detection technologies in a single-use cartridge.

PixCell Medical offers direct capillary sampling for its HemoScreen 5-part differential CBC analyzer for POC use with venous and capillary blood. This allows collection of a sample directly from the finger, without an intermediate tube.

Ad Astra Diagnostics markets its QScout rapid hematology system, which provides POC WBC counts and the neutrophil-to-lymphocyte ratio, and differentiates the number and percentage of five types of mature WBCs, as well as immature granulocytes.

Sebia provides its Capillarys 2 DBS automated instrument. The product is intended for detecting normal and abnormal hemoglobin in blood from newborns. The analysis is performed by capillary electrophoresis.

Genalyte offers its TSH immunoassay performed on a silicon chip.

Visby Medical markets its POC respiratory Health Test. The test is a rapid PCR test that detects and differentiates infection caused by influenza A&B, and SARS-CoV-2

OTC Self Testing

The market for POC self-tests is estimated at $23 billion in 2025, with glucose testing accounting for the majority share of the market (29% self, 54.8% continuous). The total OTC self-testing segment is expected to grow 7.0% annually, reaching $32.1 billion by 2030.

Table 5-3: Worldwide POC Self-Test Sales, by Category, 2025-2030($ million)

[Cholesterol; Coagulation; Drugs of Abuse; Fecal Occult Blood; Glucose, Continuous; Glucose, Self; H. pylori; HIV; Other Infectious Disease (inc. COVID-19); Pregnancy; Urinalysis; Other (TSH, Allergy, Autoimmune, etc.)]

Category	2025	% Mkt	2030	% Mkt	CAGR
Glucose, Continuous	12,458	54.7%	20,600	64.2%	11%
Glucose, Self	6,693	29.4%	7,020	21.9%	1%
Other Infectious Disease (inc. COVID-19)	1,904	8.4%	2,502	7.8%	6%
Pregnancy	970	4.3%	1,030	3.2%	1%
Fecal Occult Blood	431	1.9%	562	1.8%	5%
Coagulation	90	0.4%	95	0.3%	1%
Drugs of Abuse	37	0.2%	43	0.1%	3%
Urinalysis	33	0.1%	38	0.1%	3%
HIV	20	0.1%	24	0.1%	4%
Cholesterol	16	0.1%	17	0.1%	1%
H. pylori	6	0.0%	7	0.0%	3%
Other (TSH, Allergy, Autoimmune, etc)	135	0.6%	171	0.5%	5%
Total	**22,793**	**100%**	**32,109**	**100%**	**7%**

Source: Kalorama Information

There are several aspects that are driving the OTC/self-testing POC market in 2025, including:

- As with professional testing, the COVID-19 pandemic contributed to a large increase in POC self-testing for other infectious diseases, namely COVID-19 as more at-home COVID-19 tests entered the market and continue to fuel new growth opportunities.
- At-home testing is surging, both in home collection and in other segments of the POC OTC IVD market.
- Additionally, the continued uptake of CGM contributed the lion's share of revenues for 2025 (55%) and will likely grow to 64% by 2030. throughout the forecast period.

Pregnancy/Fertility Tests

The pregnancy and fertility tests market are dominated by sales generated in the OTC POC segment, accounting for 85% of total sales, compared to professional tests with 15%.

Table 5-4: POC Pregnancy and Fertility Test Market Distribution, by End User, 2025 (%)

[OTC, PRO]

End User	Distribution
OTC	85%
PRO	15%
Total	**100%**

Source: Kalorama Information

North America will remain the largest market for rapid pregnancy test kits in 2025, accounting for almost half of global revenues. Demand for rapid kits will continue to grow in the developing countries of the Asia Pacific, the Middle East, and Africa.

Table 5-5: Pregnancy/Fertility POC Test Sales Distribution, by Global Region, 2025 (%)

[Europe; Japan; United States; Rest of World]

Region	% Mkt
United States	45%
Europe	31%
Japan	7%
RoW	17%
Total	**100%**

Source: Kalorama Information

Rapid pregnancy tests are also used in hospital settings and health clinics. A pregnancy test is performed in hospital emergency departments when a woman may be slated for an emergency surgery or another intervention where it is important to know if she is pregnant. Early detection of pregnancy is also important for caregivers in order to avoid certain medications and procedures that could harm a fetus.

The pregnancy hormone hCG can be detected in urine or blood after implantation, which occurs six to twelve days after fertilization. Quantitative blood tests can detect hCG levels as low as 1 mIU/mL, while urine test strips have published detection thresholds of 10 mIU/mL to 100 mIU/mL, depending on the brand. Therefore, blood-based tests can detect pregnancy approximately two to eight days earlier than commonly available urine-based tests.

Most commercially available rapid pregnancy test immunoassays are used with urine and serum, but not whole blood. In light of the critical need for reliable early pregnancy detection, several whole-blood rapid pregnancy tests have been commercialized.

NowDiagnostics Inc. markets the CE-marked and FDA CLIA-waived AdexusDx human chorionic gonadotropin point-of-care test. It uses a single drop of capillary or whole blood.

Abbott Laboratories offers the i-STAT Total β-hCG test cartridge, a whole-blood, quantitative, handheld pregnancy test for patient testing.

Sekisui offers the OSOM Ultra hCG Test, which provides qualitative hCG results in 3-5 minutes with high accuracy. The OSOM Ultra hCG Combo Test detects hCG B-core fragments, reducing the interference when testing urine samples from later stages of pregnancy.

bioMérieux offers two ranges of rapid tests for pregnancy and fertility. The VIKA fertility panel and Bionexia hCG Urine and Bionexia hCG Combo panels.

Salignostics offers SaliStick, the first rapid saliva-based pregnancy test. The test is based on the company's proprietary technology, which detects the pregnancy hormone β-hCG. The test uses a lateral flow immunoassay platform. Abingdon Health will distribute the test in the EU. The test is available in Europe, South Africa, and Israel. The company has completed an initial 510(k) Q-submission for SaliStick to the FDA.

Colon Cancer Screening

POC testing as preventative medicine is not a new concept, but amid all the controversy surrounding cancer screening, there is evidence that self-tests have increased colon cancer screening.

Routine colorectal cancer screening is something that tens of millions of people in developed countries go through every few years. Almost all developed countries have cancer screening programs that offer free colon cancer screening tests. After the age of 45, patients are encouraged to have a colonoscopy every 5-10 years. Between these colonoscopies, they can use non-invasive tests that can sometimes determine the presence of cancer or even precancers. Currently, three main types of tests are used: fecal occult blood tests (FOBT), fecal immunochemical tests (FIT), and stool DNA tests (sDNA).

Of these three, fecal occult blood tests are used the most frequently, probably because they are inexpensive. The main problem with this test is its high false-positive rate and low precancer detection rate. Another major drawback is poor patient compliance because FOBT requires three stool samples and shipping them to a laboratory. The FIT overcomes many of these limitations. It requires only one sample, and several devices allow the user to run the test at home. These tests are gaining in popularity over the standard guaiac FOB test.

Exact Sciences and Beckman Coulter generate the largest share (84%) of sales in the segment. Because screening for colon cancer represents a potentially huge number of medical laboratory tests each year, many biotech companies have developed FIT test kits that patients can use at home. Therefore, numerous other products are available in lateral-flow-style cassettes.

Helena Laboratories' Colocare test is an easy-to-use paper sheet placed in the toilet bowl with a stool sample. If it turns blue, the user should consult a physician. The test is distributed by Thermo Fisher Scientific.

Colorectal cancer screening has traditionally relied on a combination of structural exams and noninvasive stool-based testing, with colonoscopy and fecal occult blood testing (FOBT) or fecal immunochemical testing (FIT) remaining the most widely used approaches. Screening recommendations have evolved over time, and the U.S. Preventive Services Task Force now recommends that average-risk adults begin screening at age 45 and continue through age 75 using a range of acceptable options, including annual FIT, stool DNA-FIT testing at defined

intervals, CT colonography, flexible sigmoidoscopy, and colonoscopy every 10 years. All of these methods have been shown to reduce colorectal cancer mortality by detecting early-stage cancers and precancerous lesions.

Among noninvasive options, Exact Sciences' stool-based Cologuard test has become a widely adopted screening tool, detecting abnormal DNA and hemoglobin shed into stool from cancerous and precancerous lesions. Newer versions, including next-generation multitarget stool DNA tests, are being developed to improve sensitivity and specificity. Additional innovation includes RNA-based stool testing such as ColoSense from Geneoscopy, as well as growing interest in blood-based screening, highlighted by Guardant Health's Shield test, which offers a noninvasive alternative for patients who may be reluctant to use stool-based methods.

At the same time, FIT- and FOBT-based assays from companies such as Sekisui Diagnostics, Hemosure, and Aidian continue to play an important role due to their low cost, ease of use, and suitability for large-scale screening programs, with ongoing improvements in automation, digital readers, and connectivity. The market continues to shift toward noninvasive, patient-friendly testing strategies to improve compliance, while colonoscopy remains the gold standard for definitive diagnosis and intervention.

Table 5-6: Selected POC Colon Cancer Tests

Company	Details
Beckman Coulter	Hemocult ICT
Biohit Oyj	ColonView
Enterix	InSure One FIT
Exact Sciences	Cologuard
Geneoscopy	ColoSense
Helena Labs	Colocare
Hemosure	Hemosure One-Step FIT
Jant Pharmacal	Accutest iFOBT
Orion Diagnostica (Aidian)	QuikRead go iFOBT cassette test
Polymedco	OC-Light S FIT
ScheBo-Biotech AG	ScheBo-2in1 Quick Test
Sekisui Diagnostics	OSOM iFOB

Source: Kalorama Information

With an increasing prevalence of colon cancer cases across the major countries, a number of new screening tests are either in development or have come to market. This may help address the technical and procedural limitations of currently available colon cancer screening tests and drive the anticipated expansion of this test segment.

The market for in-vitro colorectal cancer screening tests using fecal occult blood in various forms is expected to grow over the next five years, increasing from an estimated $3.5 billion in 2025 to $4.6 billion in 2030 (5.5% annual growth). Proven outcomes, increased competition and advertising of testing are driving this successful category.

Table 5-7: Colon Cancer POC Test Sales Distribution, by Global Region, 2025 (%)

[Europe; Japan; United States; Rest of World]

Region	% Mkt
United States	56%
Europe	28%
Japan	5%
RoW	11%
Total	**100%**

Source: Kalorama Information

Lipid Testing

Lipid testing, and cholesterol in particular, is recognized as a risk marker for cardiac disease. On the other side of the coin, it has been shown that even people without elevated lipid levels may suffer from heart disease. Nevertheless, despite the controversy surrounding this test, physicians continue to include it in a routine workup. Most tests are run on automated clinical lab instruments, but there is a steady demand for cholesterol testing among physicians.

The world market for POC cholesterol testing is estimated at $294 million in 2025 and, with 3.7% annual growth, will reach $352 million in 2030. Despite the high incidence of elevated cholesterol, the self-test market has not evolved as expected, largely due to a barrier: people are reluctant to accept finger-pricking to obtain test results. This may change in the future as technological advancements in specimen collection that are not blood-based enter the market.

Europe and the U.S. share the market about evenly, with 42% and 39%, respectively, in 2025. Japan accounted for 5% of the share, and the ROW accounted for the remaining 14%.

Table 5-8: Lipid POC Test Sales Distribution, by Global Region, 2025 (%)

[Europe; Japan; United States; Rest of World]

Region	% Mkt
Europe	42%
United States	39%
Japan	5%
RoW	14%
Total	**100%**

Source: Kalorama Information

The market leader is the Abbott LDx. The analyzer is included in the CLIA waived test list and is certified by the Cholesterol Reference Method Laboratory Method Network program and Lipid Standardization Program.

Roche Diagnostics historically offered point-of-care cholesterol testing through products such as Accu-Chek InstantPlus and the Reflotron system. The Accu-Chek InstantPlus cholesterol and triglyceride tests used reflectance photometry for quantitative lipid measurements with optional data management capabilities, while the Reflotron functioned as a self-calibrating desktop analyzer designed for near-patient testing in physician offices. The Reflotron platform supported quantitative measurement of multiple routine chemistry parameters with results available within two to three minutes. By 2026, however, both Accu-Chek InstantPlus lipid testing and Reflotron chemistry testing are considered mature systems, with Roche's current near-patient focus centered on glucose and HbA1c rather than lipid panels.

The United States remains the largest single market for IVD and point-of-care testing and continues to play a leading role in the development and introduction of rapid tests. Many new POC products are still launched first in the U.S., often pursuing CLIA waiver status to enable use in decentralized settings before expanding into international markets. While other regions are strengthening their own regulatory frameworks, U.S. approval and commercialization pathways continue to influence global product strategies.

However, healthcare delivery is shifting toward preventive care, faster clinical decision-making, and more testing outside the hospital, all of which support the growth of near-patient testing. The higher per-test cost of decentralized testing, compared with high-volume central lab testing, can still limit broader adoption. Large health systems and payers continue to balance these costs against clinical value and workflow efficiency, and, in many cases, still rely on centralized laboratories, where existing infrastructure and economies of scale help control overall costs.

Drugs of Abuse Testing

Healthcare professionals use drug tests as part of a comprehensive evaluation of individuals to reach a correct decision regarding the individuals' actions, behaviors or performances. The main focus in 2025 for DOA testing is critical care.

They can also be used in the identification of high-risk populations, including those with histories of substance abuse or treatment of mood, anxiety, and/or attention deficit disorders, or in emergency situations.

Only tests for a clinical purpose are considered in Kalorama's traditional IVD analysis. Point-of-Care drugs of abuse testing is estimated at $543 million and is anticipated to grow at 2% over the next five years. It is anticipated that drug testing technology will become increasingly sensitive and easier to use, leading to more innovative and effective testing for drugs of abuse. The move from urine testing to oral fluid testing reduces privacy concerns and mitigates some of the issues associated with urine testing. In the future, drug testing practices must include identification of a larger number of drugs, including newly emerging drugs of abuse, and testing must become less expensive and more resistant to adulteration.

Table 5-9: POC Drugs of Abuse Test Sales Distribution, by Setting, 2025 (%)

[Criminal Justice; Critical Care - Traditional POC; Employment Screening]

Setting	% Mkt
Employment Screening	47%
Critical Care - Traditional POC	31%
Criminal Justice	22%
Total	**100%**

Source: Kalorama Information

Products

There is a wide range of drug-of-abuse testing products on the market in central laboratory, POC, and home-use settings, utilizing multiple specimen types including urine, oral fluid, blood, and hair. Urine and oral fluid testing remain the most commonly used formats due to

ease of collection and established regulatory frameworks, with oral fluid gaining increased traction in workplace and roadside testing because it is less invasive, more difficult to adulterate, and better reflects recent drug use. A large portion of POC and rapid screening assays are CLIA-waived, reflecting their relatively simple immunoassay-based design and suitability for use outside traditional laboratory environments; however, confirmatory testing using more advanced methods such as mass spectrometry remains within high-complexity laboratory settings. In addition, certain products are designated for forensic use only, particularly in workplace or legal testing environments where strict chain-of-custody and documentation requirements apply. Increasingly, rapid testing is being paired with digital readers and connectivity solutions that improve result interpretation, reduce user subjectivity, and enable automatic transmission of results into reporting systems for compliance and recordkeeping.

Thermo Fisher Scientific has continued to expand capabilities in this segment with updates to its TruNarc handheld narcotics analyzer, which uses Raman spectroscopy to identify illicit substances in the field. Recent updates have expanded its detection library to include additional synthetic opioids, including multiple fentanyl analogs and highly potent compounds such as carfentanil. These handheld systems are increasingly used by law enforcement and first responders, reflecting a broader trend toward rapid, on-site drug-identification technologies that operate alongside traditional laboratory workflows. At the same time, centralized laboratories are expanding the use of highly sensitive confirmatory testing methods to keep pace with emerging synthetic drugs, while hair testing continues to serve a niche role in detecting longer-term drug use. The drugs-of-abuse testing market continues to evolve through a combination of expanded test menus, improved detection technologies, and an increased emphasis on compliance, connectivity, and real-time decision-making.

Table 5-10: Drugs of Abuse Tests on the Market

Company	Location	Type	Description	Target
1 Step Detect Associates	US	oral	OrAlert	amp, coc, meth, opi, pcp, thc
			Alco-Screen	etoh
		urine	DTx cassette	amp, bar, coc, meth, opi, thc, etc.
			DTx Dip test single tests	amp, bar, bup, bzo, coc, mdma, meth, mtd, opi, pcp, thc
			one-step lateral flow assay for smokers	nic
			Specimen Validity Test (SVT) for adulterants	assesses creatinine, nitrite, glutaraldehyde, pH, specific gravity, oxidants/pyridinium chlorochromate
Abbott Toxicology	US	urine	SEFRIA Fentanyl urine drug screening test	fen
Abbott Toxicology	US	oral	DDS2 Mobile Test System	amp, bzo, coc, meth, mtd, opi, thc
		urine	iCassette	amp, bar, bzo, coc, mdma, opi, oxy, pcp, ppx, tca, thc
			iCup DS IScreen Dip Card	amp, coc, meth, opi, thc
			E-Z Split Key Cup	amp, bar, bzo, bup, coc, mdma, meth, mop, mtd, opi, oxy, pcp, ppx, tca, thc
			First Check Home Drug Tests	amp, bar, bzo, coc, mdma, meth, mtd, opi, oxy, pcp, tca, thc
Accutech, LLC	US	urine	QuikScreen 5, 7, and 12	amp, coc, opi, pcp, thc + mdma, meth + bar, bzo, oxy, pcp, tca
Alfa Scientific	US	oral	Oral-view Saliva Multi-Drug of Abuse Test	amp, bzo, coc, mdma, meth, mtd, opi, pcp, thc
			Oral-view Saliva Alcohol Test	etoh
		urine	Instant-view Multi-drug test	amp, bar, bzo, coc, meth, opi, oxy, thc

Company	Location	Type	Description	Target
American Bio Medica	US	urine	RapidTOX, RapidONE, RapidTOX Cup, RapidTOX Cup II	amp, bar, bup, bzo, coc, mdma, meth, mtd, opi, oxy, pcp, ppx, tca, thc
Bioscan Screening Systems	US	urine	Professional Premium Marijuana Urine Test	k2, thc
Confirm Biosciences	US	hair	Hairconfirm and Hairconfirm with Prescription Drugs	amp, coc, mdma, meth, opi, pcp, thc + hyd, oxy, hym
		oral	Salivaconfirm 6-drug panel; Salivaconfirm Premium 11-drug panel	amp, bzo, coc, mdma, opi, thc + bar, bup, etoh, fen, k2, meth, mtd, oxy, pcp
		oral	Saliva and Breath Alcohol tests	etoh
Healgen Scientific		urine	Multipanel DOA Urine Testing Cups	amp, bar, bup, bzo, coc, eddp, mdma, mtd, meth, mop, opi, oxy, pcp, ppx, tca, thc
Jant Pharmacal	US	oral/ urine	Accustrip and Accutest panel cups	amp, bar, bzo, coc, etoh, mdma, meth, mtd, nic, opi, oxy, pcp, tca, thc
Mossman Associates	US	urine	NicCheck I	cot, nic
Nymox Pharmaceutical Corp	US	urine	NicAlert immunochomatographic assay	cot
Phamatech	US	urine	Quickscreen multipanel dip card	amp, coc, mdma, meth, opi, thc
Polymed Therapeutics	US	urine	rapid urine drug of abuse tests	amp, bar, bup, bzo, coc, cot, eddp, fen, ket, mdma, meth, mop, mtd, mtq, opi, oxy, pcp, ppx, tca, thc
Princeton BioMeditech	US	urine	Accusign tests	amp, bar, bup, bzo, caf, coc, cot, etoh, meth, mtd, nic, opi, oxy, pcp, tca, thc
Randox Laboratories	UK	urine	RX series analyzers; dedicated for urine drug screening	amp, bar, bzo, coc, eddp, etoh, mdma, mtd, opi, thc
Siemens Healthineers	Germany	blood/ urine	Syva Emit II Plus assays	6am, amp, bar, bup, bzo, coc, etoh, lsd, mdma, mtd, mtq, opi, pcp, ppx, thc

Company	Location	Type	Description	Target
Thermo Fisher	US	blood	Indiko analyzer	6am, amp, bar, bup, bzo, coc, cot, eddp, etoh, mdma, meth, mop, mtd, opi, oxy, pcp, ppx, thc

Note: 6am=6-acetylmorphine (heroin), ace=acetaminophen, amp=amphetamines, bar=barbiturates, caf=caffeine, coc=cocaine, cot=cotinine (nicotine metabolite), eddp=methadone metabolite, etoh=ethanol (alcohol), fen=fentanyl, hyd=hydrocodone, hym=hydromorphone, k2=spice (synthetic marijuana), ket=ketamine, lsd=lysergic acid diethylamide, mdma=ecstasy, meth=methamphetamine, mop=morphine, mtd=methadone, mtq=methaqualone, nic=nicotine, opi=opiates, oxy=oxycodone, pcp=phencyclidine, ppx=propoxyphene, sal=salicylate (aspirin), tca=tricyclic antidepressants, thc=marijuana

Source: Kalorama Information

Urine testing has long been the most widely used method in drugs-of-abuse testing due to its non-invasive collection, relatively low cost, and well-established regulatory acceptance. Urine drug testing is commonly used for initial screening in POC settings and hospital laboratories, particularly in emergency medicine where rapid identification of drug classes such as opioids and benzodiazepines can guide treatment decisions. In these settings, assay cutoffs are often designed to detect clinically relevant or higher concentrations of drugs, aligning with the needs of acute care rather than forensic sensitivity.

Blood testing, while more invasive and costly, plays a critical role in forensic and legal contexts because it more closely reflects active impairment. In regions with zero-tolerance or, per se, drug-driving laws, including parts of Europe, urine screening is often followed by confirmatory blood testing, leading to increased demand for toxicology analysis in forensic laboratories. At the same time, oral fluid testing has gained significant traction as a less invasive alternative that better reflects recent drug use compared to urine and is more difficult to adulterate, making it increasingly accepted in workplace and roadside testing programs. Regulatory momentum has supported this shift, with updates from agencies such as the U.S. Department of Transportation allowing oral fluid testing as an alternative to urine in regulated workplace programs.

Hair testing continues to serve a niche role, particularly in workplace and forensic settings, due to its resistance to adulteration and its ability to detect drug use over an extended window of up to several months. However, it is less useful for identifying recent use because drugs take several days to incorporate into hair. Oral fluid testing, while convenient and increasingly accepted, still presents analytical challenges due to lower drug concentrations and variability in detection windows, though improvements in assay sensitivity are helping address these limitations.

OraSure Technologies was an early leader in oral fluid testing with its Intercept system, which helped establish laboratory-based oral fluid drug testing, though product availability and branding have since evolved. Companies such as BTNX and Hangzhou AllTest Biotech have expanded rapid lateral flow testing options, including test strips for emerging drugs such as fentanyl and xylazine, reflecting the ongoing need to address the opioid crisis and the rise of synthetic and adulterant compounds. QuidelOrtho has also expanded its laboratory-based menus to include assays such as fentanyl testing on its clinical chemistry platforms.

The drugs-of-abuse testing landscape is evolving to address a broader and more complex range of substances, including synthetic opioids, novel psychoactive substances, and adulterants that may not be reliably detected by traditional immunoassays. This has increased reliance on high-sensitivity confirmatory testing in centralized laboratories and has driven more frequent updates to screening panels. There is also growing use of testing data for real-time public health surveillance to monitor regional drug trends and detect emerging threats, particularly in response to the opioid crisis. Laboratories are also integrating drug testing more closely into routine clinical workflows through automation and informatics, while placing greater emphasis on result interpretation, as the presence of a drug does not always correlate directly with impairment or clinical effect. The market continues to move toward a more flexible, multi-matrix testing approach supported by both rapid screening technologies and advanced laboratory-based methods.

Table 5-11: Drugs of Abuse POC Test Sales Distribution, by Global Region, 2025 (%)

[Europe; Japan; United States; Rest of World]

Region	% Mkt
United States	49%
Europe	29%
Japan	7%
RoW	15%
Total	**100%**

Source: Kalorama Information

Rapid and POC Infectious Disease Testing

The primary goal of rapid, point-of-care infectious disease testing is to detect pathogens quickly and guide appropriate clinical management, including antimicrobial use. While infectious diseases are often associated with developing regions, they remain a significant source of morbidity and mortality in developed markets such as the United States and Europe, particularly with seasonal outbreaks, hospital-acquired infections, and emerging pathogens. Factors including global travel, migration, antimicrobial resistance, and co-infections continue to increase the need for rapid, accessible diagnostics and sustained public health vigilance. Traditional centralized laboratory testing, while highly sensitive and comprehensive, can fall short in situations requiring immediate decision-making, mass screening, or decentralized care delivery.

The demand for rapid and accurate infectious disease diagnostics has grown, particularly those that can deliver actionable results during the patient visit. Rapid testing improves clinical workflow, provides timely treatment decisions, and helps reduce unnecessary isolation or inappropriate antimicrobial use. In addition, delays associated with centralized testing can lead to loss of follow-up, reinforcing the value of near-patient testing. Historically, many POC assays have been based on immunoassay formats due to their low cost, simplicity, and speed; however, these tests can have lower sensitivity compared to molecular methods, and negative results in certain clinical scenarios may still require confirmation.

More recently, there has been a significant shift toward molecular POC testing, with compact platforms using PCR and isothermal amplification technologies such as LAMP delivering higher sensitivity and specificity in near-patient settings. These systems are increasingly designed for ease of use, minimal hands-on time, and integration with digital health platforms, making them suitable for decentralized environments including clinics, pharmacies, and urgent care settings. At the same time, advances in biosensors and microfluidics are continuing to push the boundaries of rapid diagnostics. A key trend is the expansion of multiplex and syndromic testing, allowing simultaneous detection of multiple pathogens from a single sample, which is particularly valuable in settings where symptoms overlap, such as respiratory or gastrointestinal infections. There is also increasing use of testing outside traditional healthcare environments, including retail clinics and at-home settings, offered by simplified workflows and user-friendly designs.

While true POC antimicrobial susceptibility testing remains limited, progress is being made with emerging rapid phenotypic and genotypic approaches that aim to shorten time to targeted therapy. In centralized laboratories, technologies such as MALDI-based identification and rapid molecular panels have already reduced turnaround times significantly compared to traditional culture-based workflows. At the same time, greater connectivity of POC devices is enabling real-time transmission of results into electronic medical records and public health systems, providing faster clinical decisions and improved outbreak surveillance. Rapid diagnostics are also playing an increasing role in antimicrobial stewardship programs by helping clinicians distinguish between viral and bacterial infections and reduce unnecessary antibiotic use.

Infectious disease diagnostics will remain a critical and evolving segment of the IVD market. Continued emergence of new pathogens, seasonal viral variants, vector-borne diseases, and healthcare-associated infections such as MRSA will continue to demand faster, more accurate, and increasingly decentralized testing solutions. Looking ahead, next-generation technologies, including CRISPR-based diagnostics and advanced biosensors, are expected to further expand the capabilities of POC testing by combining high sensitivity with rapid turnaround times in decentralized settings.

Table 5-12: Innovations in Molecular POC Infectious Disease Diagnostics

Company	Location	Area	Description
Abacus Diagnostica Oy (Uniogen)	Finland	HAI	GenomEra CDX MRSA/SA mecA and mecC detection from blood culture and plate sample
			GenomEra CDX Norovirus detection and differentiation of genogroups I and II
Abbott	US	HAI	C. difficile cartridge for Alere i
		Hepatitis	Alere Determine HBsAg; HBV surface antigen test, whole blood or serum/plasma from fingerstick or venous blood
		HIV	Alere Determine HIV-1/2 AG/AB Combo
			Alere Determine HIV-1/2; one-step serum/plasma or two-step whole blood in 15 minutes
		Other	Influenza A & B assay for ID NOW
			Strep A assay for ID NOW
			RSV rapid molecular test for ID NOW
		Sexual health	Chlamydia trachomatis and Neisseria gonorrhea cartridges for ID NOW
			Abbott Syphilis TP
		Tuberculosis	Abbott TB LAM Ag Test; detects lipoarabinomanna (LAM) antigen in urine in 25 minutes
bioMérieux	France	Sepsis	BioFire FILMARRAY Blood Culture Identification (BCID) panel
Becton-Dickinson	US	HAI	parasite panel (Giardia and Entamoeba) for BD MAX platform
			Carbapenem-resistance and CRE panels
		Other	Veritor and Veritor Plus analyzers with flu, RSA and Strep A applications
		Sexual health	vaginal panel for BD MAX (bacterial vaginosis, trichomoniasis, vulvovaginal candidiasis)
			STD panel for BD MAX; CT/NG/TV

Company	Location	Area	Description
			CT, HPV, and NG assays for BD Viper LT
Cepheid	US	HAI	Xpert MRSA NxG
			Xpert vanA (vancomycin resistance; vanA/B in EU)
			Xpert C. difficile
			Xpert Norovirus
			Xpert Carba-R
		Hepatitis	Xpert HBV and HCV viral load assays
		HIV	Xpert HIV-1 Viral Load
			Xpert HIV-1 Qual
		Other	Xpert Xpress Flu + RSV
			Xpert Streptococcus Group A
			Xpert EV (enteroviral meningitis)
			Xpert assays for pertussis, gastrointestinal pathogens
		Sexual health	Xpert TV for testing symptomatic and asymptomatic men
			CLIA-waived Xpert vaginitis/vaginosis
			CLIA-waived Xpert CT/NG
			CLIA-waived Xpert HPV
		Tropical disease	Xpert Ebola assay
		Tuberculosis	Xpert MTB/RIF; M. tuberculosis and rifampicin resistance
Chembio Diagnostics	US	Hepatitis	Collaboration with FIND to develop and test rapid HCV core antigen diagnostic
		HIV	DPP HIV-Syphilis assay
		Tropical disease	DPP Micro Reader and DPP Zika assay
			DPP Zika/Chikungunya/Dengue IgG/IgM assay

Company	Location	Area	Description
			Oral fluid/saliva test for malaria
			Collaborations with FIND and Massachusetts General Hospital for febrile illness diagnostics
DNA Electronics	UK	Sepsis	LiDia Bloodstream Infection (BSI) panel
DxNA	US	HAI	MRSA/SA test for GeneSTAT platform
Eiken Chemical	Japan	Tuberculosis	collaboration with FIND and HUMAN GmbH to develop LAMP-based TB diagnostic
Fio Corporation	Canada	Tropical disease	Malaria assay for Deki Reader
			Corgenix ReLASV rapid antigen test for Lassa virus adapted for Deki Reader
			Corgenix ReEBOV rapid antigen test for Ebola virus, conducted on Deki Reader
genedrive	UK	Hepatitis	Genedrive HCV ID Kit; hepatitis C from plasma in 90 minutes
		HIV	Genedrive HIV assay
		Sexual health	STI+ for Genedrive platform; CT/NG/HSV
		Tuberculosis	Genedrive MTB/RIF test
			£1.1 million grant from Innovate UK for further development of Genedrive MTF/RIF
Greiner BioOne	Austria	HAI	Superbug CR for Genspeed R2; detects over 70 carbapenemase variants
			VanABC plus for Genspeed R2; single-tube multiplex for vancomycin resistance genes vanA/B/C
Hain Lifescience	Germany	Tuberculosis	GenoType MTBDRplus; detects MTB complex and drug resistance genes in five hours
Hema Diagnostic Systems	US	Hepatitis	RAPID 1-2-3 HEMA EXPRESS Hepatitis B HBsAg test
			RAPID 1-2-3 HEMA EXPRESS Hepatitis C (HCV) test
			RAPID 1-2-3 HEMA CASSETTE Hepatitis B test
			RAPID 1-2-3 HEMA CASSETTE Hepatitis C (HCV) test

Company	Location	Area	Description
		HIV	Rapid 1-2-3 HEMA EXPRESS HIV P24Ab assay
		Sepsis	Rapid 1-2-3 HEMA SEPSIS
		Tropical disease	Rapid 1-2-3 HEMA Cassette Malaria PF, PF/PV
		Tuberculosis	Rapid 1-2-3 HEMA EXPRESS TB-XT rapid lateral flow immunochromatography test
Hibergene Diagnostics	Ireland	HAI	C. difficile assay for HG SWIFT platform
		Other	HG Mycoplasma pneumoniæ for HG SWIFT platform
			HG Meningococcus for HG SWIFT; for bacterial meningitis diagnosis from whole blood, CSF, and nasopharyngeal swab
			HG Pneumo/Meningo Combo; for Neisseria meningitidis and Streptococcus pneumoniæ from CSF
			RSV 1/2 for HG SWIFT
			Influenza A/B for HG Swift
InSilixa	US	HIV	HIV diagnostic and drug resistance genotyping assays
J Mitra & Co Pvt Ltd	India	Tropical disease	Advantage Chikungunya IgM Card
MedMira Inc	Canada	Hepatitis	Multiplo HIV/HCV, Multiplo HBc/HIV/HCV
		Tuberculosis	$1.1M SBIR grant for POC test for antibiotic-resistant MTB
Meridian Bioscience	US	HAI	C. difficile assay for illumigene
		Other	Babesia, Campylobacter, and EHEC assays for illumigene
		Sexual health	HSV-1 and HSV-2 assays for illumigene
			CT/NG assay for illumigene
		Tropical disease	Malaria assay for illumigene
Molbio Diagnostics	India	Hepatitis	Truenat HBV Viral Load
			Truenat HCV Viral Load

Company	Location	Area	Description
		HIV	Truenat HIV Viral Load qPCR test
		Other	Truenat H1N1 qPCR test
			Truenat Salmonella qPCR test
		Sexual health	Truenat HPV qPCR test
			Truenat Chlamydia qPCR test
			Truenat Gonorrhea qPCR test
			Truenat Trichomonas qPCR test
		Tropical disease	Truenat Malaria (P. falciparum) qPCR test
			Truenat Chikungunya qPCR test
			Truenat Dengue qPCR test
		Tuberculosis	Truenat TB resistance qPCR test
MP Biomedicals	US	Hepatitis	FASTSURE HCV DNA Rapid Test
		Tuberculosis	FASTSURE TB DNA Rapid Test
Nanōmix	US	Sepsis	Sepsis panel for eLab platform
QIAGEN	Netherlands	Tuberculosis	Fourth generation QuantiFERON-TB tuberculosis ELISA
QuantuMDx	UK	HIV	Q-POC HIV assay
		Sexual health	CT/NG, other STI assays for Q-POC
		Tropical disease	Q-POC malaria assay
		Tuberculosis	Tuberculosis and multiple drug-resistant TB assays for Q-POC
QuidelOrtho	US	HAI	C. diff, MRSA, Van
			AmpliVue C. difficile assay
		HIV	HIV viral load
		Other	Flu, RSV, and Strep A assays for Sophia FIA platform

Company	Location	Area	Description
			Lyme FIA for human IgM and IgG antibodies to Borrelia burgdorferi, for Sofia platform
			RSV, GI, and transplant infection
			AmpliVue Bordetella pertussis assay
		Sepsis	bloodstream infection
		Sexual health	STD, HSV/VZV/syphilis, and vaginitis
			GBS, TV, HSV 1 & 2 AmpliVue cassettes
			Trichomonas assay for Solana
		Tuberculosis	RSV, GI, TB, and transplant infection
Reagena	Finland	Other	Reagena PC PUUMALA IgM
Rheonix	US	HIV	Rheonix CARD HIV assay
		Sepsis	Rheonix CARD sepsis panel
		Sexual health	Rheonix CARD HPV panel
			Rheonix CARD STI panel; CT/NG/TV and syphilis
		Tropical disease	Rheonix CARD Zika assay
Roche	Switzerland	Hepatitis	LINEAR ARRAY Hepatitis C Virus Genotyping Test for AMPLICOR system
		HIV	MPX, multiplex assay for HIV-1 groups M and O, HIV-2, HBV, and HCV
		Other	cobas Liat Streptococcus A and influenza assays
		Sexual health	cobas TV/MG assay
			cobas CT/NG assay
			cobas HPV assay
		Tropical disease	Zika assay for cobas 6800/8800

Company	Location	Area	Description
		Tuberculosis	Mycobacterium assays for M. tuberculosis, M. avium, and M. intracellular, and for drug resistance
RPS Diagnostics	US	Respiratory	FebriDx
Seegene	Korea	Other	respiratory panel, flu, multiplex pneumonia, MERS CoV PCR reagents
			gastrointestinal panel PCR reagents
		Sepsis	Magicplex Sepsis qPCR test
		Tuberculosis	MTB and multiple drug-resistant tuberculosis PCR reagents
T2 Biosystems	US	Sepsis	T2Bacteria Panel for sepsis-causing pathogens
Ustar Biotechnologies	China	Hepatitis	HCV cartridge for proprietary isothermal platform
		Sexual health	cartridge based isothermal NAAT for C. trachomatis
		Tuberculosis	EasyNAT isothermal diagnostic for M. tuberculosis
Veredus Laboratories	Singapore	Other	VereFlu for VerePLEX Biosystem; 10 influenza A subtypes and IFV B
		Tropical disease	VereFever, for Chikungunya, Dengue, malaria, Zika, et al.
		Tuberculosis	VereMTB; detects and differentiates ten Mycobacterium species, detects rifampicin and isoniazid resistance

Source: Kalorama Information

Products

Rapid tests are available for a diverse range of disease pathogens like HIV, gonorrhea, syphilis, chlamydia, herpes, hepatitis, human papillomavirus, Groups A and B Streptococcus, M. tuberculosis, RSV, influenza, Legionella, mononucleosis, M. pneumoniæ, E. coli, H. pylori, Cryptosporidium, Giardia, C. difficile, S. aureus, Candida, rotavirus, and bacterial meningitis.

The availability of tests produced and offered in developing and developed countries are going to vary, as the prevalence of different illnesses will vary from region to region. Developed countries require tests primarily for respiratory infections; developing countries would like reliable tests for malaria and STDs. Both geographies can use reliable HIV tests. There is one difference: those to be used in developing countries have to be much more reliable than those used elsewhere because there is rarely a lab nearby to confirm negative results.

MeMed markets its MeMed BV test on whole blood samples at the POC. The MeMed Key analyzer can distinguish between bacterial and viral infections in 15 minutes.

Table 5-13: POC Infectious Disease Test Summary by Disease and Technology

Disease / Pathogen	Technology
Chagas disease	Immunochromatographic test
Chlamydia, gonorrhea	NAAT
COVID-19, Influenza, RSV	Antigen / molecular (home & office)
Dengue (NS1 antigen)	Antigen test
HIV, HBV, HCV, EBV, TORCH-H, MMRV, Lyme	Single / multiplex panels
Leptospirosis	IgM ELISA
Malaria, Zika, Rotavirus, Helicobacter, Gonorrhoeae	Antigen / antibody
S. pneumoniae, L. pneumophila	Urine antigen test
Schistosomiasis	Antibody ELISA
Syphilis	Lateral flow antibody; multiplex panels
Trichomoniasis	MDx multiplex panels
Tuberculosis	Molecular
Typhoid, Cholera	Stool immunochromatographic test
Visceral leishmaniasis	Lateral-flow strip

Source: Kalorama Information

HIV and Hepatitis Testing and Monitoring

The highest volumes of molecular infectious disease tests are for HIV, hepatitis and CT/NG. Hepatitis and HIV treatment involves recurrent quantitative molecular testing to determine viral load levels and the effectiveness of implemented therapy.

OraSure has established a strong position in HIV self-testing with its OraQuick HIV Self-Test, which has seen broad adoption in developing markets and plays an important role in expanding access to screening. The test received World Health Organization prequalification, supporting its use in global health programs and procurement by international funding organizations. OraQuick is widely recognized for its ease of use and reliability, offering high specificity and strong overall performance for antibody-based detection, although it does not match the early detection capability of laboratory-based fourth-generation assays. Overall, the product has contributed significantly to increasing HIV testing rates by making screening more accessible in community and home settings.

Atomo Diagnostics has developed the AtomoRapid HIV 1/2 test, a lateral flow immunoassay that integrates sample collection and testing into a single device for professional and self-testing use. The test delivers results in approximately 15 minutes and has demonstrated high sensitivity and specificity in clinical studies. It has been CE marked and deployed across a range of international markets. Atomo has partnered with Access Bio to commercialize the test in professional settings under the CareStart brand in selected regions, and with Owen Mumford to distribute a version under its Simplitude brand. While the test is designed for ease of use in decentralized and home settings, results are read visually, with digital support tools available in some programs.

Encouraged by OraSure's lead in HIV self-testing, Chembio Diagnostics developed its SURE CHECK HIV 1/2 Assay, for which it was awarded CE approval as a self-test. The test is a variation of Chembio's professional use blood based POC HIV tests that is endorsed by the WHO and several other international aid agencies. Chembio also produces the CE-marked Dual Path Platform HIV/Syphilis test, a rapid immunochromatographic test that can simultaneously detect antibodies from HIV types 1 and 2 and/or Treponema pallidum in 15 to 30 minutes from fingerstick or venous whole blood, serum, or plasma.

STDCheck markets the OTC test for HIV 1/2, HSV 1/2, hepatitis A/B/C, gonorrhea, chlamydia, and syphilis. WholeHealth Products provides its HIV 1&2 Rapid Diagnostic Test, oral fluid home test.

Cepheid offers qualitative HIV and HIV viral load assays for its GeneXpert system, producing results in 90 minutes with one-minute hands-on time. The system, by its self-contained nature, requires no liquid waste management.

Roche offers its cobas Plasma Separation Card, a simple and stable device for the collection of plasma for HIV viral load testing, with Roche's cobas AmpliPrep, cobas TaqMan, and cobas 6800/8800 HIV tests. The device requires only a small volume of blood taken the patient's fingertip and can be transported with the need for cold storage, making the Plasma Separation Card ideal for use in remote areas and those of extreme temperature and humidity. Roche is also working on a multiplex assay that detects not only HIV-1 subgroups M and O and HIV-2, but also hepatitis B and C viruses, in a single test. The company offers a CE-marked test for chronic hepatitis C patients designed to determine the genotype (GT1-GT6) of the virus affecting them.

OraSure's OraQuick HCV rapid antibody test was the first hepatitis diagnostic of its kind to be granted a CLIA waiver. The immunochromatic strip-based assay delivers test results for multiple HCV genotypes in fingerstick or venous whole blood in 20 minutes with 98% accuracy.

Other hepatitis diagnostics on the market include Abbott's Determine HBsAg for hepatitis B surface antigen, Cepheid's Xpert HBV and HCV Viral Load cartridges, Hema Diagnostic Systems' Rapid 1-2-3 HEMA Express and Cassette HBV and HCV assays, and MedMira's Multiplo assays for hepatitis and HIV. MolBio Diagnostics currently offers a Truenat HBV viral load assay for its Truelab platform and has a similar test for hepatitis C in development.

Abbott offers the Determine Rapid HIV-1/2 and Determine HBsAG2 test for use with serum, plasma or whole blood for the detection of Hepatitis B surface antigen.

Chembio's DPP HIV-Syphilis System is a single-use, 15-minute screening test for the simultaneous detection of antibodies to HIV types 1 and 2 and the bacteria that cause syphilis, Treponema pallidum. It uses a 10-microliter fingerstick sample of whole blood, venous whole blood, or plasma. The test is highly sensitive and specific, includes a built-in procedural control, can be stored at room temperature, and has a shelf life of up to 24 months.

binx health offers the Sassy Little Box program to enable access to HIV and sexually transmitted infection testing in the Birmingham, Alabama region. The Sassy Little Box, which consists of self-collection materials and easy-to-follow instructions, is distributed to local partnerships and can be used without visiting a clinic.

Abbott markets its HPV test that is run on the company's Alinity m system. The test is approved for fast HPV detection and for use in routine cervical cancer screening. It can also be used in combination with a Pap test, providing information on five risk groups covering the 14 different cancer-causing genotypes of the virus.

Cepheid has a CLIA waiver for Xpert HCV. This is the only molecular test in the US to detect hepatitis C RNA directly from human capillary whole blood.

bioLytical provides its 1-minute INSTI Multiplex HIV and Syphilis Test in Australia.

Tuberculosis

Diagnosing tuberculosis through conventional means is a lengthy and arduous task; it requires a combination of chest x-rays, growth of Mycobacterium tuberculosis in culture, sputum smear microscopy, interferon-γ assay, and the Mandel-Mantoux tuberculin skin test. The last two are rather inconvenient in developing regions, and sputum smear microscopy can be troublesome in HIV patients, children, and patients with low pathogen load. Drug resistance can only be assessed through bacterial culture, which can take six weeks and can be very costly. Efforts to develop a better solution have been underway for years and have been funded by organizations like the Foundation for Innovative New Diagnostics (FIND), Innovate UK, and the Bill & Melinda Gates Foundation. The most promising tests will deliver rapid results with high sensitivity and specificity, but at an affordable cost.

The current generation of decentralized molecular TB diagnostics is largely represented by the Cepheid GeneXpert system and its Xpert MTB/RIF assay, which detect TB and rifampicin resistance in sputum samples. Placed in sub-Saharan Africa, India and Southeast Asia, GeneXpert systems have provided reference and district labs with rapid, high-sensitivity TB and first-line drug resistance testing. Other tests include the Oxford Immunotec TSPOT TB test and the QIAGEN TB test.

genedrive plc offers a tuberculosis diagnostic assay for its CE-marked Genedrive molecular POC platform. The test detects M. tuberculosis complex (MTBC) and rifampicin resistance, providing results in 45-60 minutes.

MP Diagnostics FASTSURE TB DNA Rapid Test is a qualitative isothermal assay kit for detection of M. tuberculosis DNA from human sputum samples; it handles extraction, amplification and hybridization, and detection in less than two and a half hours. The test has

been shown to have sensitivity and specificity of 82.45% and 100%, respectively, and detected positive results in 60% of samples previously found negative by microscopy. The cross-contamination-proof assay is CE-marked and available outside the United States.

Other CE- or FDA-approved TB diagnostic offerings include QIAGEN's fourth-generation QuantiFERON-TB ELISA, MTB and multiple drug-resistant TB detection reagents from Seegene, and the MTBDRplus line-probe assay from Hain Lifescience. When using sputum samples, Hain's product has sensitivities of 97.7% and 95.4% for detecting resistance to rifampicin and isoniazid, respectively, and specificities of 91.9% and 89%, respectively; however, it is less effective in detecting resistance to ofloxacin and amikacin.

Tropical and Neglected Diseases

In recent years, outbreaks in regions such as Brazil, Central and West Africa, and parts of Asia have reinforced the need for more advanced diagnostics for infectious diseases prevalent in developing regions. High-profile diseases in this category include malaria, Ebola, and Zika virus, as well as chikungunya, dengue, West Nile virus, leishmaniasis, Chagas disease, and trypanosomiasis. These infections continue to drive demand for rapid, decentralized diagnostic solutions for use in resource-limited settings and during outbreaks, with growing influence from global health organizations such as the World Health Organization and funding bodies like the Global Fund and FIND, which play a major role in shaping procurement and deployment strategies.

Chagas disease, caused by Trypanosoma cruzi, remains a significant public health concern in Latin America, with increasing recognition in non-endemic regions, including the United States, due to migration and alternative transmission routes such as blood transfusion, organ transplantation, and congenital infection. Efforts to expand access to screening have led to the development of rapid diagnostic tests suitable for decentralized use. Companies such as InBios International have introduced antibody-based rapid tests that can deliver results in approximately 20 minutes, providing screening initiatives in clinics and field settings. These tests improve access but are generally used as initial screens and often require confirmatory laboratory testing. Laboratory-based serological assays from companies including Abbott and QuidelOrtho continue to play a key role in blood donor screening and clinical diagnostics, with the newer integration of Chagas assays into automated immunoassay platforms such as the VITROS systems reflecting a gradual shift toward broader clinical use beyond transfusion safety.

Ebola diagnostics have historically relied on emergency and outbreak-driven pathways, with rapid antigen tests and molecular assays used during active outbreaks. While earlier emergency use authorizations enabled rapid deployment of tests from multiple manufacturers, the market today is more episodic, with diagnostics being scaled up primarily in response to outbreaks rather than maintained as routine high-volume testing. Molecular platforms such as Cepheid's GeneXpert system have played an important role in outbreak response due to their ability to deliver rapid, sensitive results in decentralized settings.

Collaborations between diagnostics companies and regional public health organizations have been critical in expanding access. Chembio Diagnostics, working with Brazil's Oswaldo Cruz Foundation (Fiocruz/Bio-Manguinhos), developed and deployed its DPP platform for diseases including Zika, HIV, dengue, and leishmaniasis. Although the company has undergone structural changes, the DPP technology continues to be used in certain public health programs through local partnerships.

Several companies have pursued molecular and multiplex diagnostics for tropical and vector-borne diseases, including Roche and Veredus Laboratories. Platforms such as VerePLEX and its VereFever panel are designed to detect multiple pathogens associated with febrile illness in a single assay, supporting outbreak response and targeted surveillance, although adoption remains more limited than that of larger syndromic panel platforms. This reflects a broader trend toward multiplex testing for febrile illness, allowing clinicians to differentiate between multiple potential causes of infection in a single test, which is particularly important in regions where co-circulating pathogens are common.

Rapid testing formats play a critical role in these markets due to cost and accessibility advantages, while molecular diagnostics are gradually expanding as platforms become more portable, battery-operated, and easier to use in field settings. These mobile molecular systems are helping bridge the gap between centralized laboratory testing and true POC use in remote environments. In addition, diagnostics are increasingly being integrated into surveillance and outbreak preparedness systems, enabling real-time tracking of disease spread and supporting faster public health responses.

Diagnostics for tropical and emerging infectious diseases remain highly dependent on public health priorities, funding cycles, and outbreak dynamics. The market continues to move toward a combination of low-cost rapid tests for broad screening and more advanced molecular platforms for confirmation and surveillance, with growing interest in next-

generation technologies such as CRISPR-based diagnostics and advanced biosensors that aim to deliver high sensitivity in decentralized settings.

Respiratory Diseases

Improving the treatment of respiratory illnesses in primary health care facilities requires rapid, accurate pathogen diagnosis, and many such facilities are turning to rapid PCR-based assays that have been shown to be more accurate than their rapid antigen counterparts. Some are even CLIA-waived, allowing clinicians to use them in the office rather than sending samples to centralized labs, making for faster, more reliable diagnoses that lead to better treatment.

Respiratory molecular IVD multiplex panels detect multiple respiratory pathogens, typically from nasopharyngeal or nasal swabs. These tests use multiplex PCR technology and are designed to deliver high sensitivity, with results available in approximately 30 to 90 minutes. They are primarily used in emergency rooms, inpatient wards, and intensive care units. The mechanism of action involves amplification and detection of viral and/or bacterial DNA or RNA targets. Molecular multiplex respiratory panels represent the largest and most mature segment of the respiratory panel-based testing market and routinely include three or more in a single run.

Sekisui Diagnostics markets the OSOM Ultra Flu A & B Test, a rapid lateral-flow immunoassay that delivers results in approximately 10–15 minutes. In addition, Sekisui distributes a cassette-based, CLIA-waived molecular influenza A & B assay originally developed by Mesa Biotech. This molecular test is marketed by Sekisui under the Silaris Flu A & B Test name and runs on the Accula platform, enabling rapid near-patient molecular influenza testing.

RPS Diagnostics markets its FebriDx test, which is offered in the EU and other CE mark countries. The FebriDx is a rapid, accurate POC test that provides clinicians with a 10-minute assessment of the body's immune response to an acute respiratory infection from a blood sample. This test aids in the differentiation of viral and bacterial ARI through rapid detection of both Myxovirus resistance protein A and C-reactive protein.

Randox Laboratories offers the Vivalytic POC analyzer, which has been instrumental in coronavirus testing. The Vivalytic platform is capable of both Hi-Plex and Lo-Plex testing.

Genomtec provides its POC respiratory disease test - the Genomtec ID Respiratory 5-Plex molecular diagnostic panel. The test is designed to detect influenza A and B, RSV, Mycoplasma pneumonia, and Chlamydophila pneumonia. The tests are run on the company's portable Genomtec ID Analyzer, with results available in 25 minutes.

Visby Medical offers its respiratory panel test. The test is designed for point-of-care but can also be used in laboratories. The test is an RT-PCR assay that simultaneously detects and differentiates between SARS-CoV-2, influenza A and influenza B viral RNA.

bioMérieux offers its BIOFIRE SPOTFIRE Respiratory Panel. The SPOTFIRE System is designed to be run on the SPOTFIRE R Panel. The panel detects upper respiratory infections such as SARS-CoV-2, influenzas A & B, RSV and rhinovirus.

iHealth markets the company's 3-in-1 COVID-19/Flu A&B /rapid Test Kit for self-testing at home. The test provides results within 15 minutes, and is the first OTC rapid antigen test for COVID-19 and influenza A & B in the U.S.

Wondfo USA offers its WELLlife COVID-19/Influenza A&B Home Test. The test provides a 3 in 1 result in only 10 minutes. It is suitable for treating individuals aged 2 and older within the first 5 days of symptom onset.

WatmindUSA offers its SpeedySwab COVID-+ FLU A&B Self-Test for use at the point of care and OTC. The test provides results within 15 minutes and is designed for individuals aged 2 and older.

Healgen markets its POC COVID-19/Flu A&B Ag Combo Rapid Test Cassette, a lateral flow assay for the qualitative detection and differentiation of SARS-CoV-2 and flu A&B nucleocapsid protein antigens.

bioMérieux provides a CLIA waiver for its BIOFIRE SPOTFIRE respiratory/sore throat panel mini. The product is a multiplex PCR test that detects five of the most common viral and bacterial causes of respiratory or sore throat infections in about 15 minutes.

FDA granted Nano-Ditech EUA for its Flu/COVID Dual POC test. The test is designed for the detection and differentiation of SARS-CoV-2, influenza and influenza B antigens.

QIAGEN offers its QIAstat-Dx Respiratory Panel Mini. Results are available within one hour.

Sepsis and Nosocomial Disease

Diagnosing sepsis is particularly challenging in its early stages, when timely intervention is most critical, because its clinical presentation of fever, respiratory distress, and circulatory instability which overlaps with many other acute conditions. As a result, recent advances in sepsis diagnostics have focused on improving speed and accuracy through pathogen detection, resistance profiling, and host-response biomarkers associated with bloodstream infections.

Multiplex molecular panels have become central to rapid organism identification following blood culture positivity. bioMérieux's BIOFIRE BCID2 panel provides broad detection of sepsis-related bacterial and fungal pathogens, along with key antimicrobial resistance markers, enabling actionable results in approximately 1 hour. Roche's cobas eplex blood culture identification panels similarly support rapid identification and resistance gene detection, reflecting the continued evolution of syndromic testing in microbiology laboratories.

Direct-from-blood diagnostic approaches have also gained attention by eliminating the need for prior blood culture. T2 Biosystems' T2Candida and T2Bacteria panels use a magnetic resonance-based platform to detect fungal and bacterial pathogens directly from whole blood, allowing earlier identification of causative organisms in patients with suspected sepsis.

Host--response and biomarker-based diagnostics are expanding the clinical toolkit. Beckman Coulter's Access procalcitonin assay is widely used to support assessment of infection severity and risk of progression to severe sepsis or septic shock. Newer approaches focus on immune response profiling rather than pathogen detection alone. Cytovale's IntelliSep test evaluates biophysical changes in immune cells to aid rapid sepsis diagnosis in emergency settings, delivering results in approximately ten minutes. Inflammatix's TriVerity system combines gene expression analysis with an integrated instrument platform to distinguish bacterial from viral infections and assess sepsis risk in about 30 minutes.

Emerging technologies continue to push toward faster, culture-free detection. Deepull Diagnostics is developing the UllCORE bloodstream infection test, a molecular platform designed to identify a broad range of pathogens directly from whole blood in roughly one hour, although it remains in advanced development and regulatory review as of 2026.

Despite these advances, many sepsis diagnostic solutions still rely on centralized laboratory infrastructure and molecular workflows. Ongoing innovation focuses on simplifying testing,

reducing turnaround times, and expanding point-of-care capabilities, including integrating compact platforms and host-response diagnostics to enable earlier clinical decision-making and improved patient outcomes.

Sexual Health

Chlamydia and gonorrhea testing has largely transitioned to molecular methods due to the invasiveness and lower sensitivity of culture-based approaches and the limited clinical utility of serology. Nucleic acid amplification tests now dominate the market, offering high sensitivity, rapid turnaround times, and the ability to use non-invasive specimens such as urine and vaginal swabs.

Becton Dickinson offers a broad portfolio of molecular STI diagnostics across its BD MAX and BD Viper platforms. The BD MAX system supports assays for chlamydia and gonorrhea as well as a vaginitis panel that detects bacterial vaginosis, vulvovaginal candidiasis, and Trichomonas vaginalis. The BD Viper system continues to support established ProbeTec assays for chlamydia, gonorrhea, and trichomoniasis. HPV testing is addressed separately through BD's Onclarity assay on the COR system.

QuidelOrtho provides molecular and near-point-of-care STI testing through its AmpliVue and Solana platforms. AmpliVue assays detect Group B Streptococcus and herpes simplex virus, while the Solana system offers rapid Trichomonas testing via isothermal amplification. The company previously developed the Savanna platform as a cartridge-based multiplex PCR system intended for point-of-care testing across sexually transmitted infections and women's health applications; however, in 2025, QuidelOrtho announced it would discontinue further development of the platform and shift its molecular diagnostics strategy toward next-generation ultra-fast PCR technologies. As a result, Savanna is no longer considered an active emerging point-of-care platform in the STI diagnostics market.

Cepheid is a major player in POC molecular STI testing with its Xpert CT/NG assay on the GeneXpert platform, delivering results in approximately 90 minutes. The company has also expanded its women's health menu with the Xpert Xpress MVP panel, which detects bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis from a single sample.

Point-of-care molecular testing has advanced significantly with the introduction of rapid, CLIA-waived systems. binx health's io platform provides chlamydia and gonorrhea results in about 30 minutes directly at the point of care. Visby Medical has further extended access

with a fully self-contained, at-home molecular test for chlamydia, gonorrhea, and trichomoniasis that delivers results in approximately 30 minutes.

Centralized high-throughput molecular testing remains important, with QIAGEN's NeuMoDx systems providing fully automated PCR-based detection of chlamydia and gonorrhea in laboratory settings. Additional specialized systems, such as Bosch's Vivalytic platform, provide multiplex detection of organisms, including Mycoplasma genitalium and Ureaplasma species.

Beyond pathogen detection, serological and biomarker-based assays are important in STI management. Bio-Rad's BioPlex 2200 system provides multiplex syphilis testing, while consumer diagnostics expand access to screening. NOWDiagnostics' First To Know test represents the first FDA-authorized over-the-counter rapid syphilis test for home use, delivering results from a fingerstick sample in approximately 15 minutes.

Roche offers its cobas liat sexually transmitted infection multiplex assay panels. The panels, which include tests for chlamydia, gonorrhea, and mycoplasma genitalium, will be identified from a single sample. The cobas liat CT, NG, and MG STI assays further expand and complement the company's portfolio of solutions for point-of-care diagnostics.

Visby Medical markets its OTC molecular test for chlamydia, gonorrhea and trichomoniasis. The test can be purchased without a prescription and provides results in 30 minutes. This is the first test for chlamydia, gonorrhea and trichomoniasis that can be performed entirely at home.

Waters offers one of the most comprehensive at-home Cervical Cancer screening tool HPV in the U.S. The FDA-cleared Onclarity HPV Self Collection Kit with extended genotyping for at-home use expands access to cervical cancer screening. The kit is tested with the BD Onclarity HPV Assay and processed on the BD COR System.

Lyme Disease

QuidelOrtho markets its POC Sofia Lyme FIA for the rapid differential detection of human IgM and IgG antibodies to Borrelia burgdorferi serum and plasma specimens.

Reagena offers the ReaScan CXCL13, a new diagnostic tool for rapid Lyme disease testing. ReaScan CXCL13 is an immunochromatographic rapid test for the detection of chemokine CCXCL13 in human cerebrospinal fluid. Results are available in 20 minutes.

The table below displays a selection of molecular POC diagnostic tests for infectious diseases that have emerged in recent years.

COVID-19

The U.S. Food and Drug Administration continues to evaluate and transition COVID-19 diagnostics from emergency use authorization to traditional clearance pathways, with a clear shift toward multiplex respiratory testing. The COVID-19 testing market has evolved into a broader respiratory diagnostics segment, in which combination tests for SARS-CoV-2, influenza A/B, and RSV are now widely available in laboratory, point-of-care, and at-home settings. This reflects ongoing clinical demand to differentiate respiratory pathogens with overlapping symptoms using a single test. A number of rapid antigen and molecular multiplex assays have entered the market, including products from companies such as Pfizer (Lucira), Visby Medical, and Aptitude Medical Systems, offering increasingly portable, user-friendly formats with turnaround times of approximately 15 to 30 minutes.

Molecular point-of-care systems have continued to gain traction, with platforms such as Nuclein's DASH system providing rapid PCR-based detection of SARS-CoV-2 and influenza at the POC, and ongoing menu expansion into additional respiratory and infectious disease targets. High-throughput laboratory systems, including Hologic's Panther platform with the Aptima SARS-CoV-2 assay, are important for centralized testing, particularly in hospital and reference laboratory settings. Rapid antigen testing also remains widely used, particularly in home and decentralized settings, with ongoing product introductions and incremental performance improvements.

The market has matured significantly since the peak of the pandemic, with reduced overall testing volumes and consolidation among manufacturers. New product development is now focused less on standalone COVID-19 tests and more on multiplex panels and improved usability, including integration with digital reporting and connectivity tools. A key trend is the continued expansion of respiratory multiplex panels beyond COVID-19 and influenza to include RSV and, in some cases, broader pathogen menus, positioning testing as comprehensive respiratory panel diagnostics rather than single-pathogen detection. Demand has also become more seasonal, with testing volumes increasing during peak respiratory

illness periods as healthcare providers use multiplex testing to guide patient management and isolation decisions more efficiently. For additional information on the multiplex market, see Kalorama Information's *Worldwide IVD Panel-Based Testing: Respiratory/Non-Respiratory, 2020-2030.*

There is also a growing adoption of at-home molecular testing, expanding beyond traditional antigen-based formats and bringing higher-sensitivity testing into the home environment. Connectivity and digital health integration are also becoming more important, with many systems linking results to mobile applications, telehealth platforms, and public health reporting systems. Manufacturers continue to focus on reducing turnaround times and simplifying workflows, with many newer platforms offering true sample-to-answer testing with minimal user intervention, making them increasingly practical for decentralized settings such as clinics, pharmacies, and home use. Overall, the respiratory diagnostics market in 2025–2026 reflects a transition from emergency-driven COVID-19 testing to a more stable, multiplex-driven system that integrates rapid, molecular, and connected testing solutions across care settings.

Market Size and Growth

The world market for rapid infectious disease tests is estimated at $4.8 billion in 2025. With a 7.2% CAGR, this is expected to reach $6.8 billion in 2030. COVID-19 testing has leveled off and now reflects a market that is not dominated by COVID-19 testing, but still contributes 19% of the market. The tests most commonly performed are influenza, HIV, STDs, hepatitis, Strep A, and respiratory viruses, which showed the most gains.

Traditionally, one of the largest segments within POC infectious disease diagnostics is influenza testing and the overall value of the sector is influenced by the demand for tests during the influenza season. Overall, rapid testing for respiratory represents the largest group of test sales – consisting of influenza, COVID-19, and other respiratory – 54% total market share.

Point-of-Care OTC and Professional Use Immunoassays

The POC market includes the following segments:

- patient self-testing / OTC products
- rapid tests used in a professional setting—POL, home care, clinic, etc.
- rapid tests performed in the hospital

This market analysis estimates IVD company sales of POC tests, including those in the home or OTC market and those used by professionals in hospitals, POLs, clinics, etc. It is beyond the scope of this report to separate POC tests run in the hospital from those in physician offices and other patient care sites. These two segments are pooled as a professional POC.

The analysis does not include workplace and criminal justice POC tests and services for drug abuse testing, which generate approximately $1.2 billion in sales (2025), with more than half of those sales generated in the United States.

This chapter covers OTC immunoassays and those performed by professionals in hospitals, physician office labs and clinics. Blood glucose testing is covered in Chapter 5, infectious disease immunoassays are discussed in Chapter 11 and POC tests for routine chemistries are discussed in Chapter 5.

In 2025, the U.S. market accounts for 45%, the European market accounts for approximately 31% of the worldwide market, Japan represents 5% and the ROW accounts for the remaining 19% of the market. Despite market growth outside the U.S., the country remains the largest market for POC immunoassays.

Table 5-14: Global POC Immunoassay Sales Distribution, by Region, 2025 (%)

[Europe; Japan; United States; Rest of World]

Region	% Mkt
United States	45%
Europe	31%
Japan	5%
RoW	19%
Total	**100%**

Source: Kalorama Information

The global market for all POC immunoassay tests (OTC and professional tests) is estimated at $6.5 billion in 2025, with an average annual growth rate of 3.2%. The global market for POC immunoassays is expected to reach $7.6 billion by 2030.

Growth in the global POC immunoassay market will be driven by:

- OraSure Technologies' sales of the most successful saliva-based OTC tests.
- HbA1c sales will show strong performance through the forecast period of 8.5% CAGR to support growth in the professional sector
- The most widely used patient self-tests are for pregnancy and ovulation.
- Manufacturers anticipated consumer acceptance of tests for occult blood, cholesterol, HIV, coagulation/PT and H. pylori.
- Online test services have proliferated for cholesterol, HbA1c and infectious diseases. The consumer buys a kit, sends the sample to a lab and then receives a test result (home-based collection, lab processed).

- Outside North America, consumers will find OTC tests for a wider range of analytes, including allergens, TSH, and FSH.

Worldwide, there has historically been a perception that POC tests are more expensive than centralized laboratory testing and that results generated outside the core lab may not always be fully integrated into the patient's longitudinal medical record. While cost per test is often higher for POC assays, this view has evolved as healthcare systems increasingly recognize the value of faster turnaround times, improved clinical decision-making, reduced length of stay, and more efficient patient throughput. Concerns about loss of results to the historical record have also diminished significantly, as most modern POC systems now incorporate connectivity solutions that transmit results directly into laboratory and hospital information systems and, increasingly, into broader digital health and telehealth platforms.

Earlier concerns about poor correlation between POC and laboratory-based testing have improved, although variability can still exist depending on the analyte and clinical context. For many commonly used assays, including blood gases, glucose, and cardiac markers, correlation with central laboratory systems has strengthened due to advances in technology, calibration, and standardization. However, differences in sample type, methodology, and clinical use still require careful validation and, in some cases, institution-specific correlation protocols.

From a technical standpoint, data communication is now largely well established. Most major POC system manufacturers provide integrated data management platforms that support connectivity, operator management, quality control tracking, and regulatory compliance. Many health systems have implemented centralized POC governance programs, typically led by the laboratory, to oversee device selection, training, competency assessment, and standardization across multiple care settings.

Market acceptance, however, remains influenced by operational factors. Device maintenance, quality-control requirements, operator training, and oversight remain primary challenges, particularly in decentralized environments involving non-laboratory personnel. Operator error and workflow variability remain real-world issues despite technological improvements, reinforcing the need for ongoing training and system safeguards such as operator lockouts and automated QC checks. Newer technologies are addressing these barriers. Advances in microfluidics and lab-on-a-chip designs are moving toward simplified, sample-to-result workflows with minimal user intervention, incorporating built-in calibration, internal quality checks, and connectivity.

Adoption of next-generation POC systems is increasingly tied to demonstrating clear clinical and economic value. While the technology continues to advance, broader uptake depends on reimbursement, workflow integration, and the ability to show measurable improvements in patient outcomes and operational efficiency. POC testing continues to evolve toward a more connected, standardized, and value-driven model that offers decentralized care while maintaining laboratory-level quality oversight.

The market for POC tests is highly diversified and, in many instances, a different set of companies is active in each sub-segment. A review of POC company revenues is provided in Chapter 5.

Table 5-15: Global POC Immunoassay Test Sales, by Test Category, 2025-2030 ($ million)

[OTC/Self Tests (Drugs of Abuse; H. pylori; HIV; Infectious Disease/COVID-19; Pregnancy/Ovulation; Other) and Professional POC (Cardiac Markers; Drugs of Abuse; HbA1c; Infectious Disease/COVID-19; Pregnancy; Other)]

Test Category	2025	Mkt %	2030	Mkt %	CAGR
OTC/Self Tests					
Pregnancy/Ovulation	970	32%	1,030	27%	1%
Drugs of Abuse	37	1%	43	1%	3%
HIV	20	1%	24	1%	4%
H. pylori	6	0%	7	0%	3%
Other Infectious Disease (inc. COVID-19)	1,876	61%	2,468	65%	6%
Other*	168	5%	209	6%	4%
OTC/Self Total	**3,077**	**100%**	**3781**	**100%**	**4%**
Test Category	**2025**	**Mkt %**	**2030**	**Mkt %**	**CAGR**
Professional POC					
Infectious Disease	953	28%	747	20%	-5%
Cardiac Markers	751	22%	895	24%	4%
HbA1c	615	18%	925	24%	9%
Drugs of Abuse	506	15%	556	15%	2%
Pregnancy	170	5%	175	5%	1%
Other**	413	12%	500	13%	4%
Professional POC Total	**3,408**	**100%**	**3,798**	**100%**	**2%**

Note: * Other = UA, FSH, TSH, etc.

Note: ** Other = TSH, PSA, FSH, cancer, etc.

Note: Percentages may not add to 100% due to rounding.

Source: Kalorama Information

The latest trend to overcome reticence for self-testing is direct-to-consumer marketing of lab tests in public venues such as malls and supermarkets. This is primarily a phenomenon of North America. COVID-19 has influenced the uptake of self-testing. Elsewhere in the world, many community labs provide tests requested by consumers. Currently, there are over 2,000 walk-in medical clinics in the U.S. in drug and big-box stores and supermarkets, including CVS, Walgreens, Target, and Kroger.

Collaborations between the hospital and retail world are proliferating. The line between hospital and retail clinic continues to blur, with a new partnership between one of the nation's most prominent health systems and one of its most popular merchants.

Some pioneering U.S. hospitals are forming partnerships with retail clinics to further their reach. Some are finding other alternatives to emulate the convenience and affordability of a retail clinic, whether through renting space in a Walmart, starting their own clinic chains, or offering primary care at more convenient hours.

A selection of immunoassays developed for self-testing is presented below. Of particular interest are the variety of new tests that appeal to special interest groups, such as sleep apnea screening, breast milk assessment, and pregnancy evaluation. This is not a complete list, as new self-test immunoassays for various tests are entering the market regularly.

Table 5-16: Selected Self-Test Immunoassay Innovations

Company	Location	Area	Details
AESKU. Diagnostics	Germany	calcium	Test4D LFIA POCT for calcium, thyroid markers
Biomerica	U.S.	microalbumin	Fortel Microalbumin Screening, urine
Fertility Focus	UK	LH	OvuSense Fertility Monitoring Device, saliva
Happy Vitals	U.S.	nutrition	DTC home testing kit for breast milk
HealthTab	Canada	wellness	pharmacy-based on-site, 21 routine markers
NanoSpeed Diagnostics	U.S.	calcium	Test4D LFIA POCT for calcium, thyroid markers
NanoSpeed Diagnostics	U.S.	vit D	Test4D LFIA POCT for 25-hydroxyvitamin D
NuSomnea	U.S.	apnea	Easy Peezy Pee Test, sleep apnea, urine
Purity Laboratories	U.S.	vit D	Vitamin D blood spot test, home test sent to lab

Source: Kalorama Information

This group of offerings spans consumer wellness testing, femtech devices, early-stage POCT platforms, and legacy rapid assays, with relatively few representing fully validated, regulated clinical diagnostics. Many entries reflect the continued convergence of home testing, pharmacy-based screening, and early biomarker quantification technologies, rather than traditional IVD pathways.

Pregnancy Testing

The most widely used professional and patient self-tests (OTC) for women's health are for pregnancy and ovulation. The professional sector comprises tests used in hospitals, physicians' offices, and clinics. In 2025, the professional sector generated $170 million in sales and, with an average revenue increase of < 1%, will reach $175 million in 2030. The market leader in the professional sector is QuidelOrtho, with a reported share of half the U.S. market. Other players include Meridian Biosciences, Trinity Biotech, bioMérieux and many more.

The OTC sector for pregnancy and ovulation (LH) includes tests available in pharmacies and other retail establishments. This POC test segment is mature and highly competitive. In

2025, this sector generated $970 million in sales and, with a 1.2% increase in revenue, will total $1,030 million in 2030. At least 20 companies are active in the largest self-test segment, except for glucose self-testing.

The top vendors are: Swiss Precision Diagnostics (SPD), Church & Dwight and QuidelOrtho. Furthermore, all major pharmacy chains sell their own home-brand test kits, manufactured by leaders and other OEMs. These private brands sell for half the price of brand-name kits, typically $5-$10 versus $10-$15.

Innovation in this mature market comes from the introduction of digital test devices. SPD's Clearblue digital pregnancy test with Conception Indicator rapid pregnancy test also indicates an approximate date of conception. If the test is positive, "Pregnant" will be indicated in words on the display along with the Conception Indicator result. This is displayed as an estimate of how many weeks have occurred since conception: 1-2 weeks, 2-3 weeks, or 3+ weeks. Digital tests retail for approximately $1 above other brand-name pregnancy tests.

Rapid pregnancy tests are also used in hospital settings and health clinics. A pregnancy test is performed in hospital emergency departments when a woman may be slated for an emergency surgery or another intervention where it is important to know if she is pregnant. Early detection of pregnancy is also important for caregivers in order to avoid certain medications and procedures that could harm a fetus.

The pregnancy hormone hCG can be detected in urine or blood after implantation, which occurs 6 to 12 days after fertilization. Quantitative blood tests can detect hCG levels as low as 1 mIU/mL, while urine test strips have published detection thresholds of 10 mIU/mL to 100 mIU/mL, depending on the brand. Therefore, blood-based tests can detect pregnancy approximately two to eight days earlier than commonly available urine-based tests.

Most commercially available rapid pregnancy test immunoassays are validated for use with urine and serum, but not whole blood. In light of the critical need for reliable early pregnancy detection, several whole-blood rapid pregnancy tests have been commercialized.

Now Diagnostics Inc. markets the CE-marked and FDA CLIA-waived AdexusDx human chorionic gonadotropin (hCG) point-of-care test. It uses a single drop of capillary or whole blood.

Abbott Laboratories' i-STAT Total β-hCG test cartridge is a whole-blood, quantitative, handheld pregnancy test available for patient testing.

Sekisui launched the OSOM Ultra hCG Test which provides qualitative hCG results in 3-5 minutes with highly accurate results. The OSOM Ultra hCG Combo Test detects hCG B-core fragments, reducing the interference when testing urine samples from later stages of pregnancy.

bioMérieux offers two ranges of rapid tests for pregnancy and fertility. The VIKA fertility panel and Bionexia hCG Urine and Bionexia hCG Combo panels.

Actim Oy offers the Actim PROM to detect premature rupture of fetal membranes. Actim PROM identifies even the smallest rupture, and it can be used on all pregnant women, even those with bleeding. The results are available in five minutes.

Salignostics offers SaliStick, the first rapid saliva-based pregnancy test. The test is based on the company's proprietary technology, which detects the pregnancy hormone β-hCG. The test uses a lateral flow immunoassay platform. Abingdon Health will distribute the test in the EU.

Cardiovascular Diagnostics

Despite improvements in treatment and increased public awareness about prevention, cardiovascular disease (CVD) is still the leading cause of death worldwide. CVD causes half of all deaths in several developed countries and is the major cause of adult death in many developing countries. More importantly, many cardiovascular events aren't fatal but may be sufficiently debilitating to seriously affect functional ability. The World Health Organization (WHO) estimates that 25% to 30% of the cardiovascular disease burden arises from disabling sequelae of stroke or other forms of heart disease.

Cardiovascular diagnostics are used in a number of situations and POC tests play an important role in both of these areas of medicine. Physicians use cardiac markers in two ways: to diagnose a cardiac event in a hospital emergency room or to evaluate the risk of a cardiovascular event occurring.

The majority of cardiovascular diagnostics are performed in the laboratory on a variety of systems, including POC devices, specialized coagulation and immunoassay instrumentation,

chemistry/immunoassay workstations, and molecular test systems. High-volume analytes such as acute myocardial infarction enzymes, cholesterol, HDL, LDL, hsCRP, BNP, and homocysteine are available for use on chemistry/immunoassay workstations.

The most commonly used acute-care cardiac tests at the POC are troponins and BNP. Many of these tests, though designed for use outside the main laboratory, are used for rapid testing inside the lab. Problems associated with quality control and training non-laboratory staff have scared off many would-be users. To avoid these issues, many hospitals have installed rapid testing systems in laboratories or established dedicated POC testing teams.

In the global POC cardiac markers test market, Roche is the market leader with about 23% Siemens Healthineers is second with 22%, QuidelOrtho with approximately 18% market share, and Abbott is fourth with 17%. Others include Response Biomedical, a small company that develops, manufactures and markets rapid on-site diagnostic tests for use with its RAMP System for clinical and environmental applications. The RAMP System consists of a portable fluorescent reader and single-use, disposable test cartridges.

An aging population, combined with technological advancements, is fueling this growth as health care providers seek ways to meet demand for high levels of service more cost-effectively. Approximately 2.6 million people die of CVD each year in the seven leading countries: France, Germany, Italy, Japan, Spain, the UK, and the U.S. Thus, the market for CVD tests is concentrated in the developed world. One can therefore expect that these countries account for about 85% of product sales, with the ROW accounting for the remaining 12%. The U.S. and Canada markets make up 45%, European countries 37% and Japan 6%.

A burgeoning middle class in Latin America, India, Asia Pacific, and the Middle East accounts for about 10%-12% of the market, with the rest of the world accounting for the remaining share. From 2025 to 2030, no significant change in the geographic breakdown of cardiac IVDs is anticipated.

Drugs of Abuse/Therapeutic Drug Monitoring

Medical tests for toxicology and drugs of abuse are usually done as a panel on overdose and trauma patients brought into emergency and include: a screen for alcohol, acetaminophen, salicylates, tricyclic antidepressants and individual tests for amitriptyline, amphetamines,

barbiturates, benzodiazepines, cannabinoids, cocaine and metabolites, antidepressants, LSD, methadone, methamphetamine, morphine, opiates and PCP.

These same tests are available to consumers who want to test friends and family members for drug use. They are also used for workplace drug screening and criminal justice markets. This market analysis does not include workplace and criminal justice applications of POC drug abuse tests, but these are included in table 2-1 to provide some sense of the marketplace.

In the past few years, there has been an increasing transition from instrumented screening for drugs to testing with disposable devices. The leader in instrumented tests is Siemens Healthineers' Syva products.

Kalorama estimates the market for POC drug tests performed by professionals for medical purposes and for home testing was $506 million and $37 million, respectively, in 2025. Close to 49% of the market is held in the U.S. In the U.S., all major drugstore chains and retail outlets such as Walmart now offer urine test kits that can detect marijuana, cocaine, ecstasy and a variety of other drugs.

The first generation of LF drug-testing kits used a urine sample. More saliva drug tests have come to market. They continue to gain market acceptance because saliva is less invasive than urine. The leading companies for saliva drug tests are Branan Medical, Interleukin Genetics, Quest, OraSure Technologies and Abbott.

Therefore, Kalorama estimates that drugs of abuse testing using POC devices (professional and OTC) will grow to $543 million in 2030, with the major growth coming from developed nations.

Table 5-17: Infectious Disease POC Test Demand, by Type, 2025 (%)

[C. difficile; COVID-19; E. coli; H. pylori; Hepatitis; HIV; Home Test/OTC; Influenza; Malaria; Other respiratory; STD; Others]

Type	Demand
COVID-19	18.8%
Influenza	18.7%
Other respiratory	16.7%
STD	7.7%
HIV	6.1%
Hepatitis	6.1%
C. difficile	4.3%
Malaria	4.2%
E. coli	2.2%
H. pylori	2.0%
Home Test/OTC	0.9%
Others	12.3%
Total	**100%**

Source: Kalorama Information

In 2025, the U.S. holds about 45% of this market, primarily because POC testing in Europe is underdeveloped. Furthermore, tests used in developing countries are often purchased under government programs at discounted prices, which limits growth in RoW markets.

Table 5-18: Infectious Disease POC Test Sales Distribution, by Global Region, 2025 (%)

[Europe; Japan; United States; Rest of World]

Region	% Mkt
United States	45%
Europe	31%
Japan	5%
RoW	19%
Total	**100%**

Source: Kalorama Information

The market leader in all POC testing is Abbott, with approximately 30% market share in 2025. Dexcom commands 12.8% and Roche holds 6.5%. This is a very fluid market that changes with the severity and type of infectious diseases that are present. There are about 50+ companies that offer infectious disease testing in 2025.

Diabetes Testing – Blood Glucose Monitoring

Diabetes continues to pose a major global health threat, with incidence and complications increasing at alarming rates. According to the International Diabetes Foundation, approximately 589 million people worldwide were living with diabetes as of 2025. This number is expected to surge, with diabetes-related deaths projected to rise within the next decade. WHO now refers to the condition as a global diabetes epidemic.

The burden is especially evident in Europe, where the International Diabetes Federation (IDF) reported that 65 million adults had diabetes in 2025. This number is forecasted to reach 67 million by 2030, reflecting steady growth driven by aging populations, sedentary lifestyles, and poor dietary habits.

In the United States, diabetes remains a leading cause of death. According to the American Diabetes Association, the disease is directly responsible for more than 102,000 deaths annually and contributes to over 282,000 deaths each year.

The IDF Diabetes Atlas provides a stark view of the escalating crisis. By 2025, diabetes is expected to affect 11% of the world's adult population, driven in large part by the adoption of unhealthy lifestyles in developing countries. Currently, about 7 million new cases of diabetes are diagnosed each year. The number of people living with diabetes globally has ballooned from 30 million two decades ago to 589 million today, and the trajectory shows no sign of slowing.

This growing epidemic presents significant economic and healthcare challenges. The IDF estimates that global diabetes-related healthcare expenditures exceed $1 trillion annually. Even more concerning is the estimated 252 million people who remain undiagnosed—many living in low- and middle-income countries with limited access to adequate care. These individuals are at elevated risk of severe complications, including cardiovascular disease, kidney failure, blindness, and limb amputations.

Geographically, the burden of diabetes is uneven but widespread. China leads the world in the total number of people affected, with cases projected to rise from 148 million in 2024 to 151 million by 2045. However, the highest prevalence rates are observed in the Western Pacific region, particularly in Tokelau, Micronesia, and the Marshall Islands, where over a third of adults are affected.

In the Middle East and North Africa (MENA) region, countries such as Kuwait, Saudi Arabia, and Qatar rank among the top 10 globally for diabetes prevalence. Collectively, over 34.6 million people in the MENA region have diabetes, accounting for 10.9% of the global diabetic population. Treating these patients places a heavy burden on regional healthcare systems, with annual costs exceeding $12 billion.

Table 5-19: Glucose POC Test Sales Distribution, by Global Region, 2025 (%)

[Europe; Japan; United States; Rest of World]

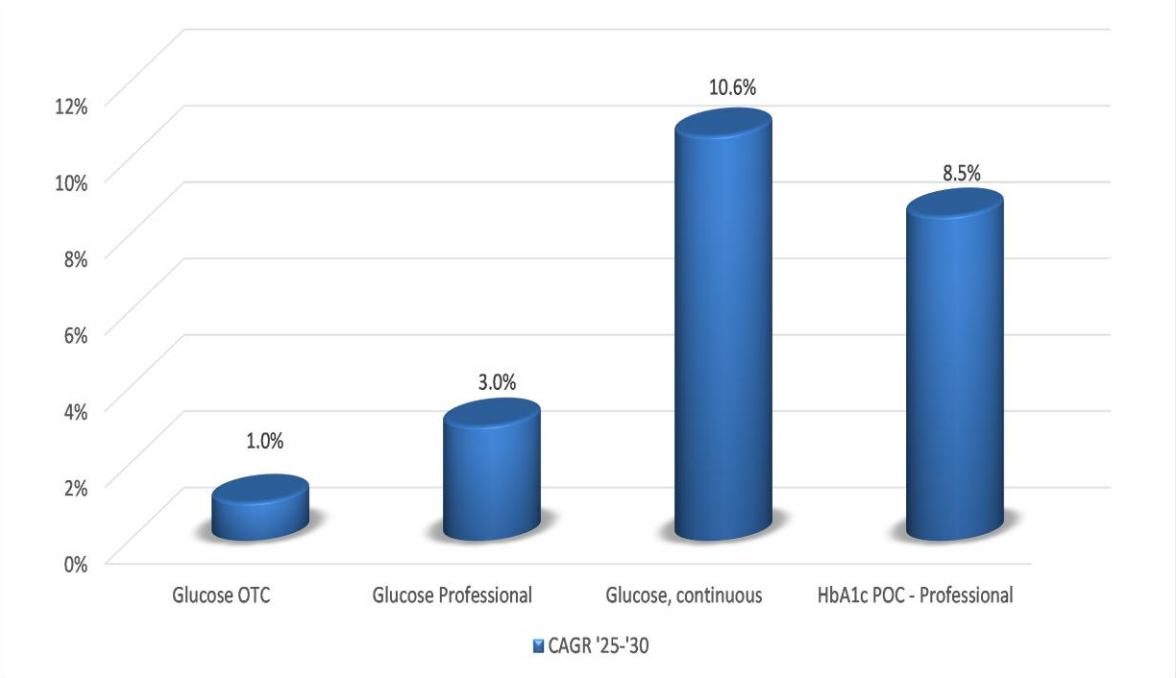
Region	% Mkt
United States	45%
Europe	30%
Japan	3%
RoW	22%
Total	**100%**

Source: Kalorama Information

Low-cost test strips for all the major players are available on a myriad of web-based vendors, including eBay, Amazon, and others. It is estimated that these and other direct-to-consumer channels for all meter brands own about 25% of the market.

Figure 5-1: POC Glucose Testing Market Growth, by Category, 2025-2030 (%)

[Continuous; HbA1c POC, Professional; OTC; Professional]



Source: Kalorama Information

Kalorama anticipates that with increased testing in emerging markets, increased HbA1c and increased continuous glucose monitoring segment, along with intensive government programs that alert the public to the urgency of being screened for diabetes, the market for POC blood glucose testing will be worth $23.3 billion in 2025 and will maintain demand to reach $32.9 billion by 2030.

IT to Aid Diabetes Management

People with diabetes, especially children and adolescents, often find it difficult to control their blood glucose level on a daily basis. There are quite a few factors for diabetics to consider when monitoring and regulating glucose levels: diet and exercise, how much insulin is necessary, the time since the last dose, current glucose levels, and past glucose levels; it's quite a bit to manage.

One solution to help make these important decisions is glucose-testing meters linked to sophisticated algorithms, either on a computer or on a mobile phone. Glucose monitors are considered Class III medical devices by the FDA, which requires the highest amount of regulatory scrutiny. However, the agency loosened restrictions on software that displays glucose monitor data on mobile devices and smartwatches. Now the software simply has to be registered with the FDA and will not require prior marketing approval. Part of the reason for this is that do-it-yourself free applications had appeared and were used without adverse events.

Thus, the newest generation of glucose meters differentiate themselves by providing a long-sought value-added feature. They are interactive and provide more information than just a glucose result, thus allowing patients to participate in tight glucose control. Some of the features include glycemic variability score, a tool often used to show how often blood sugar changes over a period of time and how intense these fluctuations are. Mealtime tagging before and after meals provides more useful information when analyzing glucose readings. Meters alert users when their blood glucose result falls within their pre- and post-meal target ranges, encouraging tighter control. These tools give a complete picture of the effectiveness of drug therapy, as well as how exercise and food portions affect blood glucose and energy levels.

The table below presents a selection of apps and glucose-management information technology tools announced in the past few years.

Table 5-20: Selected Apps and Glucose Management IT

Company	Location	Type	Details
Abbott	US	app	diasend (Sweden) connected app for Abbott's FreeStyle Libre
Biomedtrics, Inc.	US	app	ditto Glucose Data System, meter connect to phone app
DexCom	US	app	Dexcom's Apple Watch app & G5 CGM System
			diasend (Sweden) connected app for G7 CGM System
			Asante Solutions' pump data with DexCom mobile app
Diasend AB	Sweden	app	diasend Connected Apps
Entra Health Systems	US	glucose mgmt	MyHealthPoint, online portal, glucose mgmt
Glytec	US	glucose mgmt	eCMS, Glucommander glucose management IT
iHealth Lab Inc.	US	app	iHealth Align & iHealth Gluco-Smart app
LabStyle Innovations	Israel	app	Dario app on iOS
Medtronic Inc.	US	glucose mgmt	Sugar.IQ smart diabetes assistant, with IBM Watson Health
		app	Medtronic MiniMed Connect meter to pump on iOS/Android
Tactio Health Group	Canada	app	TactioDiabetes, a diabetes management app
Tandem Diabetes Care	US	app	t:simulator app insulin pump connect
TelCare Inc.	US	glucose mgmt	TelCare BGM automatic connect to glucose mgmt team

Source: company reports, Kalorama Information

Diabetes Market Analysis

The POC glucose testing market remains highly competitive, with companies continually introducing features to differentiate their products. Beyond alternate-site testing on forearms, thighs, and other locations, modern meters now focus on enhanced usability, with larger screens, tactile buttons, and voice-assisted functions. High-end devices integrate glucose

management programs, nutrition guidance, alerts, and connectivity features to help users interpret results and take proactive steps in managing their condition. Despite these advances in user experience and support tools, the underlying testing technology, such as enzyme strips and electrochemical detection, has changed very little since the earliest meters. In clinical practice, debates continue over the interpretation of results, as critical value cutoffs vary widely across institutions.

The lure of this large market attracts more and more new products, innovations, and new vendors. In 2025, it is estimated that more than 50 companies worldwide market a glucose meter, and more than 100 companies participate in the glucose market overall. The table below summarizes the market for diabetes testing outside the central laboratory.

Table 5-21: Global Diabetes Sales, by Test Category, 2025-2030 ($ million)

[Glucose OTC; Glucose, continuous; HbA1c Lab; HbA1c POC]

Test Category	2025	% Market	2030	% Market	CAGR
Glucose, continuous	12,458	53%	20,600	63%	10.6%
Glucose OTC	6,693	29%	7,020	21%	1.0%
Glucose Professional	2,272	10%	2,640	8%	3.0%
HbA1c POC	615	3%	925	3%	8.5%
Subtotal	***22,038***	***94%***	***31,185***	***95%***	***7.2%***
HbA1c Lab	1,342	6%	1,700	5%	4.8%
Total	**23,380**	**100%**	**32,885**	**100%**	**7.1%**

Source: Kalorama Information

Kalorama anticipates that, with increased testing in emerging markets and intensive government programs that alert the public to the urgency of screening for diabetes, the market for POC blood glucose testing will grow. The glucose OTC self-testing portion of this market accounts for roughly $6.7 billion in 2025 and, with 1.3% CAGR, will reach an estimated $7.0 billion in 2030. This conservative projection of the self-testing market is due to pricing strategies that continue to reduce the cost of meters and strips. Further, European payers continue to restrict support for glucose testing for non-insulin-dependent diabetics. In

emerging countries, expansion of the market is driven by government-sponsored programs that negotiate the lowest price possible.

Professional BGM in hospitals, physician offices and other test venues continues its presence and occupies some 10% of the market for POC glucose testing. The world market for professional BGM is estimated at $2.3 billion in 2025 and will reach $2.6 billion in 2030, representing 2.6% CAGR.

The continuous blood glucose monitoring segment reached $12.5 billion in 2025 and will see the strongest growth in glucose monitoring, reaching $20.6 billion in 2030 with a CAGR of 10.6% for the forecast period.

POC Glucose Competitors

Three companies (Abbott, Dexcom, and Roche) account for over 65% of the glucose-monitoring diagnostic segment.

Table 5-22: Top Three POC Test Vendors, by Glucose Test Revenues, 2025 ($ million)

Company	Sales
Abbott	7,998
Dexcom	4,662
Roche	1,577

Source: Kalorama Information, company reports

Blood Glucose Self-Testing

The self-testing market for blood glucose is more dynamic than its professional counterpart and will continue to expand due to demographic factors. The aging of the population in most developed countries, new criteria for the diagnosis of diabetes that emphasize lower glucose thresholds, and expansion of monitoring technologies into emerging market populations will all contribute to a growing market.

Although multinational companies dominate the market, the enormous market potential continues to attract new entrants with traditional-type devices and device innovation. The

major companies market their share of innovations, including small sample sizes, talking meters, smartphone apps, integrated lancing devices, and large, numbered display screens.

Table 5-23: Selected Glucose Self-Test Meter Innovations

Company	Location	Details
Abbott	US	FreeStyle Precision Neo
ACON Labs	US	On Call Express/On Call Plus glucose meter
Ascensia Diabetes Care	US	CONTOUR NEXT ONE/PLUS ONE & CONTOUR diabetes app
		CONTOUR Next EZ, advanced biosensor
iHealth Lab Inc.	US	iHealth Gluco+ Wireless Smart Glucose -Monitoring System
DarioHealth	Israel	Dario, cloud-based, diabetes management meter & app
LifeScan Inc.	US	OneTouch Verio Flexmeter with ColorSure technology
Teledoc Health Diabetes Management	US	Livongo glucose meter with pedometer, cloud connection
Trividia Health	US	TRUE METRIX self-monitoring blood glucose system
		TRUE METRIX AIR with phone connection
Philosys	Korea	Gmate SMART blood glucose monitoring system with app
Prodigy Diabetes Care	US	Prodigy Autocode talking meter
Smart Glucose Meter Corp	US	Smart Meter iglucose glucometer

Source: company reports, Kalorama Information

Non-invasive Testing Devices

The expected increase in demand for glucose testing products has renewed interest in noninvasive testing devices that do not require a blood sample. Of interest are new efforts to commercialize transdermal devices, saliva, contact lens, and breath-based systems. Conventional techniques for measuring glucose still involve a fingerstick blood sample, which can cause pain and discomfort for the patient. As a result, some patients are reluctant

to test. Also, noninvasive devices make testing as simple as wearing a watch or putting a finger into a device.

Many companies have attempted to develop non-invasive technologies for glucose monitoring, but commercial success has remained limited. One of the earliest and most well-known examples was the GlucoWatch, introduced in the early 2000s, which ultimately faced technical challenges related to accuracy, reliability, and user comfort.

Efforts to reduce the burden of traditional fingerstick testing have continued, with a range of devices designed to improve convenience and patient compliance. While fully non-invasive glucose monitoring has yet to achieve widespread adoption, minimally invasive continuous glucose monitoring systems have gained strong traction in the market.

Additional non-invasive tools have been developed to support diabetes management. For example, TRIGOcare's Neuropad is a simple, patch-based test that assesses sweat function as an indicator of diabetic peripheral neuropathy. The test is primarily used as a screening tool rather than for glucose monitoring or disease classification.

Table 5-24: Selected Noninvasive Glucose Monitoring Devices

Company	Location	Details
Gentag	US	smartphone NFC-based wearable for type 2 diabetes (dev)
GlucoTrack DF-F	Israel	GlucoTrack DF-F non-invasive blood glucose
Integrity Applications	Israel	GlucoTrack earlobe sensor
Inow Labs	US	Radiofrquency-based glucose detection
Movano	US	Non-invasive RF-based glucose sensing ring
NovioSense BV	Netherlands	NovioScience tear glucose biosensor (dev)

Source: Kalorama Information, company reports

Continuous Glucose Monitoring

Continuous glucose monitoring (CGM) is considered the most significant breakthrough in diabetes management in the past 40 years. CGM augments glucose meter use in diabetes

management by automatically linking to an implanted insulin pump that delivers insulin according to algorithms customized for each person. In the long term, the investment is in non-invasive and implanted glucose-testing products.

The major companies in this segment, Abbott, Medtronic, and Dexcom, are working with multiple generation devices to offer closed-loop continuous glucose monitoring (CGM) systems that involve a meter (sensor), transmitter, and insulin pump. These companies compete in an exciting, emerging test segment. However, the number of companies offering CGM devices has increased.

Kalorama estimates that in 2025, continuous blood glucose systems generated product sales of approximately $12,579 million, compared with approximately $100 million in 2008.

Abbott has been an integral participant in this market, demonstrating year-on-year growth. The diabetes segment generated $6,805 million in 2024 and climbed to $8,098 million in 2025.

The unmet demand for this type of system is also illustrated by Dexcom's revenue track record. The company's first-generation SEVEN continuous blood glucose monitor system was launched in March 2006. Since then, Dexcom has invested in numerous product improvements and worked with insurance companies to secure reimbursement. Dexcom's product sales were $2.2 million in 2006 and estimated at $4.705 million in 2025.

Dexcom marketed its next-generation Dexcom G7 CGM System in 2023. The system is available to Medicare beneficiaries. The Dexcom G7 sports many new features, including a smaller, all-in-one unit that warms up faster than any other CGM on the market. In March 2023, the FDA cleared Abbott's FreeStyle Libre 2 and 3 sensors for integration with automated insulin delivery systems.

Abbott offers the FreeStyle Libre 3 Reader. The FreeStyle Libre 3 Reader is a small handheld device that displays real-time glucose readings directly from a small sensor.

Medtronic offers its MiniMed 780G with Simplera Sync. The new product is a disposable, all-in-one CGM that requires no fingerstick. The MiniMed 780G with Simplera Sync sensor will be available in Europe in the summer of 2024.

Dexcom provides the Dexcom ONE+ in Spain, Belgium, and Poland. The Dexcom ONE+ replaces the previous-generation Dexcom ONE sensor with a more accurate design.

Dexcom offers its Stelo, an over-the-counter CGM that provides insights to a user's smartphone. The product is the first glucose biosensor that doesn't require a prescription.

Dexcom announced that its Dexcom G7 connects directly to an Apple Watch. Dexcom G7 was the first CGM available directly to the Apple Watch.

Abbott markets two over-the-counter CGM systems. The Lingo is a biowearable for consumers aged 18 and older that will track glucose levels and provide personalized insights and customized coaching. The Libre Rio is designed for people over 18 with Type 2 diabetes who do not use insulin and manage their diabetes through lifestyle modifications. The Libre Rio is the first OTC CGM system with a measurement of 40-400 mg/dL.

Abbott entered into a partnership with Medtronic to collaborate on an integrated continuous glucose monitoring system based on Abbott's FreeStyle Libre technology. The collaboration is intended to enable connectivity between Libre CGM sensors and Medtronic's automated insulin-delivery systems and smart insulin-pen platforms, supporting greater interoperability across diabetes-management devices. As of 2026, the partnership remains active, with integrated system development progressing toward regulatory clearance and commercialization.

Abbott's Freestyle Libre 2 and 3 systems are approved for use during medical imaging.

Roche has announced plans to expand its manufacturing operations in Indianapolis, which serves as its North American diagnostics headquarters. The company is investing several hundred million dollars to increase production capacity for its diabetes care portfolio and to support future growth, with the project expected to continue through the end of the decade. The facility is a major global hub for Roche's Accu-Chek products and produces billions of test strips each year. While the expansion supports broader diabetes technologies, Roche's current focus remains centered on established glucose monitoring products rather than large-scale continuous glucose monitoring manufacturing.

Table 5-25: Selected Continuous Blood Glucose System Developments

Company	Location	Details
Abbott Diabetes Care	US	FreeStyle cont gluc with Insulet pump
		FreeStyle Libre Flash Glucose Monitoring System
		FreeStyle Libre View
Ascensia Diabetes Care	US	CONTOUR NEXT LINK
Becton Dickinson	US	Diabetes delivery/infusion technologies
Bigfoot Biomedical (Abbott)	US	Bigfoot Uniity smart pen-cap dosing system to work with FreeStyle Libre 2
Debiotech SA	Switzerland	artificial pancreas with Swiss partners
		waterproof JewelPUMP, patch pump and glucose meter
DexCom, Inc.	US	DexCom G67 Mobile CGM System for adults & children
		G7 for pediatric use
Glucosense Diagnostics	UK	laser sensor noninvasive glucose monitor
Hong Kong Polytechnic University	Hong Kong	glucose biosensor smart textile
Insulet Corporation	US	OmniPod Insulin Management System, new PDM
Medtronic Inc.	US	MiniMed 780G pump with Enlite, insulin suspend
		Guardian Connect app and CGM system
Nemaura Medical	UK	sugarBEAT CGM System body worn sensor patch
Nightscout	US	Nightscout (CGM in the Cloud), an open source, DIY project
NovioSense BV	Netherlands	glucose measurement in tears
Senseonics	US	Eversense 3 implantable CGM system
Tandem Diabetes Care	US	t:connect Diabetes Management app compatible with major meters
TelCare Inc.	US	Telcare Total Diabetes Management Solution

Company	Location	Details
U Virginia	US	phone-controlled artificial pancreas technology
Verily/Google	US	contact lens with Novartis Alcon eye care (paused)
		diabetes management app with Sanofi
		wristband glucose monitor

Source: Kalorama Information, company reports

Blood Glucose Testing by Professionals

Hospital glucose meters share the same strip technology as OTC meters, but the hospital models have much more sophisticated data management capabilities. Shorter hospital stays and increased ambulatory services limit demand for bedside glucose testing. However, there is a growing demand for continuous glucose monitoring in intensive care units. The objective of these systems is to ensure tight glucose control (TGC) in critical care patients. There are probably more than 500 papers on TGC in ICUs published. Some say TGC is good, others say it's not so good, and others say there is a need to be more cautious. Nevertheless, the prevailing consensus is to proceed with TGC, on the belief that it will lead to improved outcomes.

Information from the FDA indicates that the agency has reservations about using POC devices to treat critical care patients, with new FDA guidelines to be issued in the near future. Particularly controversial has been the whole area of point-of-care glucose testing in the ICU because of one of its major uses – TGC.

The major issue is whether POC glucose meters are sufficiently accurate to meet TGC requirements. For this reason, the FDA requires manufacturers to include a notice stating that the devices have not been evaluated in critically ill patients.

Major vendors have added connectivity and other critical-care analytes to their systems intended for use in hospitals. According to Nova Biomedical, StatStrip is the world's most extensively studied and best understood glucose test. After seven years of extensive studies and significant field use, StatStrip Glucose systems were cleared by the FDA as safe and effective for use with all patients in all professional healthcare settings, including intensive and critical care. The device was tested with a wide array of medical conditions, including

cardiopulmonary disease, endocrine disorders, malignancies, obstetric or gynecologic issues, renal disease, surgery, and trauma. Moreover, this device can use arterial or venous whole blood obtained from hospitalized patients of all ages, including neonates, children, and adults.

Table 5-26: Selected Innovations in Hospital-based Glucose Monitoring

Company	Location	Details
Abbott Diagnostics	US	FreeStyle Optium Neo Blood Glucose and Ketone
		FreeStyle Precision Pro Blood Glucose and β-ketone
DexCom, Inc.	US	DexCom CGM
ForaCare Suisse AG	Switzerland	FORA COMFORT pro GD40 blood, Hct control
GlySure Limited	UK	continuous intravascular glucose monitoring system for acute care
Nipro Diagnostics	US	TRUE METRIX PRO Professional Monitoring blood glucose system
Nova Biomedical	US	StatStrip Glucose Hospital Meter System, ICU
Nova Biomedical	US	StatStrip Xpress Glucose Hospital Meter System
Roche Diagnostics	US	ACCU-CHEK meters with meter-level wireless technology

Source: Kalorama Information, company reports

Diabetes Testing – Glycated Hemoglobin

Hemoglobin A1c (HbA1c) is an essential component to both the diagnosis and management of patients with diabetes mellitus. HbA1c is a specific glycated hemoglobin that is modified at the N-terminal valine residue of each β-chain of hemoglobin A. The landmark Diabetes Control and Complications Trial, a major clinical study conducted from 1983 to 1993 and funded by the National Institute of Diabetes and Digestive and Kidney Diseases, showed that keeping blood glucose levels as close to normal as possible slows the onset and progression of the eye, kidney, and nerve damage caused by diabetes.

As a result, measuring A1c has become an integral component of the standard of care for patients with diabetes, and there are a variety of methods to do so. HbA1c methods fall into two broad categories: those that use molecular charge (ion-exchange high-performance liquid chromatography [HPLC], and electrophoresis) and those that use molecular structure (immunoassay and affinity chromatography). Nearly all HbA1c measurements are performed using these methods, though point-of-care devices are also widely used.

This overwhelming growth in the number of diabetics, worldwide and the recognition that they may have some difficulty in managing their disease have spurred incredible research into new tests and a concerted effort to promote glycated hemoglobin (HbA1c) that measures glucose control in diabetics with type 1 diabetes and tests that can detect the first symptoms of diabetes. Therefore, the most common markers for monitoring patients with diabetes are glucose and HbA1c, but additional markers, such as glycated human serum albumin (HSA), have been identified that could address the glycation gap and bridge the time scales of glycemia between transient and 2–3-month measurements.

HbA1c has been used since the 1990s to measure long-term glycemic control in people with diabetes, but glucose was the primary test for diagnosing the disease. New research has included the HbA1c test as a diabetes screening tool, as well as for patient monitoring, and especially in combination with a fasting blood glucose (FBG).

There has been a shift toward immunoassays and point-of-care tests because they are simple to use and widely available, especially in settings where technologies such as HPLC, electrophoresis, and chromatography are not readily accessible. These tests offer several advantages, including the ability to be performed at any time of day without fasting. HbA1c levels are also more stable than fasting plasma glucose and provide a better picture of a patient's average blood glucose over the past two to three months.

The market for HbA1c test devices in this report refers to immunoassay and point-of-care devices. Laboratory testing devices account for the majority share of the market in 2025, about 69% while the global market for point-of-care testing devices totaled approximately 32%.

Table 5-27: Global HbA1c Test Sales Market and Distribution, by Setting, 2025-2030 ($ million)

[HbA1c Lab; HbA1c POC]

Setting	2025	% Market	2030	% Market	CAGR
HbA1c POC	615	31%	925	35%	8.5%
HbA1c Lab	1,342	69%	1,700	65%	4.8%
Total	**1,957**	**100%**	**2,625**	**100%**	**6.0%**

Source: Kalorama Information

The laboratory setting has been the gold standard for HbA1c testing in the past, but with the advent of new technology and increased demand, we are seeing a growing shift toward POC testing. This move is happening across the board and HbA1c testing is no exception. Moreover, POC test devices have contributed significantly to the growth of the overall diagnostics market over the past 10 years. More diagnostic manufacturers have pursued CLIA waiver status for their POC devices and CE Mark for POC or self-use. POC testing appears to be headed for an even bigger role in diagnosis and monitoring of patient care, especially since new technologies are enabling POC devices to produce quantitative, lab-quality test results that can be automatically transferred to an information system, a remote caregiver service for consultation, or an electronic medical record.

Professional HbA1c testing is done through the core laboratory or point-of-care testing. At least 35+ companies offer lab-based and POC HbA1c tests using immunoassay methods. Of particular interest is the migration of the HbA1c test to mass spectrometry. Also, Sysmex Corp. markets an automated HbA1c test on its XN-9000, HbA1c hematology analyzer.

Accurex Biomedical offers the Accurex XpressA1 Analyzer. The device is a handheld HbA1c meter with lab-like accuracy. The system uses boronate affinity chromatography. Results are available in five minutes. The product is CE marked and FDA cleared.

Abbott offers the Afinion 2 HbA1c assay an immediate POC test. The test is CLIA-waived and provides reliable, high-quality results in three minutes. The HbA1c Test cartridge contains all reagents necessary for the measurement of glycated hemoglobin. The assay is run on the Alere Afinion AS100 Analyzer. The Afinion 2 analyzer is a compact, rapid, multi-assay platform that streamlines and simplifies the delivery of actionable, accurate

measurements of hemoglobin A1c (HbA1c) and the albumin-to-creatinine ratio (ACR) at the point of care. The Afinion 2 platform also offers all-in-one connectivity to laboratory and hospital information systems.

Menarini offers the Hb9210 Premier, which uses the borate affinity method. The product features a user-friendly touchscreen with adaptive software. The Premier HB9210 Resolution is an ion-exchange HPLC analyzer featuring automated quantitative hemoglobin A2, F and for the detection of common and rare Hb variants.

Bio-Rad Variant II Hemoglobin Testing System offers automated high-volume HbA1c, and B-thalassemia testing coupled with clinical data management software for accuracy and ease of use.

Convergent Technologies sells the POC HbA1c Analyzer, a portable device for use in a physician's office or a small clinic laboratory. The immunoassay-based test requires only 1µL of whole blood, and the results are displayed in NGSP and IFCC formats along with the eAG values. The time to result is only six minutes.

DiaSys markets the InnovaStar. It is an automated POCT analyzer. It measures up to four tests (glucose, hemoglobin, HbA1c, and CRP) from one sample.

Diazyme offers the SMART HbA1c Analyzer and Assay kit, designed for the quantitative determination of stable HbA1c in whole-blood samples. The system is CLIA-waived and is CE marked.

Drawbridge Health offers the OneDraw A1c Needle-Free Test System. The system consists of the OneDraw blood collection device and the OneDraw A1C test. Blood is collected from the upper arm onto filter paper within the collection device. Samples are sent to the laboratory for the quantitative measurement of HbA1c

EKF Diagnostics' CE-marked, semi-automatic Quo-Lab and fully automatic Quo-Test HbA1c analyzers are compact point-of-care analyzers combining market leading accuracy with easy and affordable patient testing. Both use patented boronate fluorescence quenching technology to measure HbA1c from a 4 µL sample of venous or finger-prick blood. The instruments are designed specifically to meet the needs of clinics and laboratories in emerging economies, where diabetes is an increasingly large public health issue, and is ideal for GP surgeries, diabetes clinics and laboratories.

HemoCue provides the HbA1c 501 System, which is a fully automated POCT system. This system is CE marked and is not available in the US.

OSANG Healthcare offers the CloverA1c Plus and the CloverA1c. The Clover A1c measures HbA1c by using spectrophotometry. The system features boronate affinity chromatography, a one-step measurement and quick test results. It uses capillary or venous blood. The CloverA1c Plus is the newest addition to HbA1c measurement. The new system features a touch color screen, a wider screen, and quick test results.

Roche offers the Tina-quant HbA1cDx Gen. 3 assay as an aid in diagnosing diabetes. The test is run on the cobas series clinical chemistry analyzers. Due to the reagent's high specificity, this test is not affected by interference from common hemoglobin variants such as HbS, HbE, HbC, and HbD.

Siemens offers the DCA Vantage. It is a diagnostic solution for diabetes management, allowing physicians and other clinicians to perform CLIA-waived HbA1c testing; retrieve an instrument-calculated, estimated average glucose (eAG) value; and test albumin and creatinine levels to also determine the albumin-to-creatinine (A:C) ratio. The DCA Vantage provides physicians with insight into patients' glucose management and allows them to screen at-risk diabetic patients for kidney disease. The instrument also features connectivity and security functions for transmitting and managing test results.

PTS offers the A1CNow+ system, which is designed for professionals. The system is CLIA-waived, FDA-cleared, and CE-marked. It is an easy-to-use, portable product that produces results in five minutes.

Pointe Scientific Hemoglobin A1c uses the immunoturbidimetric method in liquid form. It is intended for the quantitative determination of HbA1c. The product is CE marked.

Tosoh Bioscience offers the Tosoh Automated Glycohemoglobin Analyzer HLC-723 GR01 for HbA1c testing. The analyzer is designed for both diabetes diagnosis and long-term glucose monitoring. Results are available in 50 seconds, and it uses Tosoh‘s non-porous ion-exchange HPLC technology. The analyzer is compact with high throughput.

Transasia Biomedical offers the Hb-Vario, which is an HPLC platform for HbA1c testing with HbA2/F flagging. The product produces results in 3.5 minutes and is a compact benchtop model.

Trinity introduced the Tri-STAT, a new POC HbA1c device that can test three samples simultaneously and provide results in 10 minutes. The Tri-STAT 2 offers HbA1c results within minutes using boronate affinity technology.

The self-testing portion is also driven by the availability of mail-in, home-collected sample lab services. These lab services offer diabetics, an essential value-added component of test interpretation and physician consultation without leaving home.

In self-testing for HbA1c, ARKRAY (Kyoto, Japan) offers the ADAMS Hybrid AH-8280, A1c & glucose meter in Japan.

PTS Diagnostics offers the A1CNow Self Check designed for diabetes patients who need to check their HbA1c levels four times per year. Physicians recommend this product for diabetes patients whose treatment plans have changed or who are struggling to meet glycemic goals. The test is administered quarterly at home.

DTI Labs offers the AccuBase A1c Home Mail-in Test Kit, which is FDA-cleared for OTC, CLIA-waived use. It is a non-fasting, fingerstick, whole-blood, mail-in, aqueous-transfer technology test. It is considered highly accurate and very reliable, with over 20 years of industry success.

Now, at least 20 companies offer lab-based and POC HbA1c tests using immunoassay methods. Of particular interest is the possible migration of the HbA1c test to mass spectrometry. Also, Sysmex Corp. received FDA clearance to market an automated HbA1c test on its XN-9000, HbA1c hematology analyzer.

Kalorama estimates that the world market for HbA1c testing lab-based and at the point-of-care by professionals is valued at $2.0 billion in 2025 and with 5.9% annual growth will reach $2.6 billion by 2030. The POC segment occupies about 32% of the total hemoglobin A1c testing market ($622 million) and with a CAGR of 8.2% will reach $922 million in 2030. The increasing adoption and introduction of systems is notable. Because lab-based tests are about half the price of the POC version, this segment actually will grow much faster related to the number of tests performed.

Kalorama was not able to estimate the market share by geographic distribution for POC HbA1c tests with certainty but developed countries collectively account for at least 80% of the total HbA1c testing market. What is certain is that the entire market for HbA1c tests will grow by at least 6% annually over the next five years.

Table 5-28: Selected POC HbA1c Devices

Company	Location	Area	Details
Abbott Diagnostic	US	chem	ARCHITECT hemoglobin A1c
			Afinion 2 HbA1c assay
Beckman Coulter/Danaher	US	chem	Hemoglobin A1c assay
Bio-Rad	US	Prof	Variant II
EKF Diagnostics	UK	prof POC	Quo-Lab HbA1c analyzer
			DiaSpect Tm handheld hemoglobin analyzer
ERBA Diagnostics, Inc.	US	chem	Hb-Vario, Hgb A1c/A2, HPLC automated
Home Access Health	US	DTC	Home Access A1c test
Quantimetrix Corp	US	QC	Dropper A1c Diabetes Control
Randox Laboratories	UK	QC	Acusera HbA1c control
Roche Diagnostics	US	immuno	cobas Integra 800 Tina-quant HbA1cDx
Sebia	France	chem	CAPILLARYS 2 Flex Piercing, Hgb electrophoresis
Sekisui Diagnostics	US	chem	HbA1c assay
Siemens Healthineers	US	chem	DCA HbA1c test, diabetes diagnosis
Sysmex Corp	Japan	hemato	Sysmex XN-9000 HbA1c automated track
Tosoh Corp	Japan	HPLC	Tosoh HPLC HbA1c, diabetes diagnosis
		chem	HbA1c on AIA immunoanalyzers

Source: Kalorama Information, company reports

Genes and Other Markers of Diabetes

Diabetes is not generally considered an inherited disease, yet it can run in families. Research has shown that about 80% of people with type 1 diabetes have no family members with the disease. The remaining 20% have at least one family member with diabetes.

Yet, some people are born more likely to get diabetes than others; they inherit a predisposition to the disease, and then something in the environment triggers it. Environmental risk factors such as diet, viral infection and others are thought to act as either initiators or accelerators of beta cell autoimmunity. Therefore, the onset of type 1 diabetes is attributed to both an inherited risk and external triggers. The hunt for these genetic and environmental risk factors is ongoing.

Physicians sometimes screen for autoantibodies to insulin or beta cells. The antibodies indicate a very high risk for developing type 1 diabetes and can be present up to eight years before symptoms develop. According to the American Diabetes Association, four autoantibodies are markers of beta cell autoimmunity in type 1 diabetes: islet cell antibodies (ICA, against cytoplasmic proteins in the beta cell), antibodies to glutamic acid decarboxylase (GAD-65), insulin autoantibodies (IAA), and IA-2A antibodies to protein tyrosine phosphatase. Autoantibodies against GAD-65 are found in 80% of patients with type 1 diabetes at clinical presentation.

Presence of ICA and IA-2A at diagnosis for type 1 diabetes ranges from 69%-90% and 54%-75%, respectively. IAA prevalence correlates inversely with age at onset of diabetes; it is usually the first marker in young children at risk for diabetes and is found in approximately 70% of young children at the time of diagnosis. There is some evidence that these autoantibodies may be present several years before a patient develops the symptoms of diabetes, but there does not appear to be a trend to screen children thought to be at risk.

Immunoassays for these proteins are not part of the routine workup for people with diabetes; they are used when an individual appears not to respond to insulin therapy as expected and in clinical research. For this reason, there is not enough data to estimate the market for these tests with certainty. The same goes for the various genetic markers discussed below.

Some 18 regions of the genome have been linked with influencing type 1 diabetes risk. These regions, each of which may contain several genes, have been labeled IDDM1 to IDDM18.

The most studied is IDDM1, which contains the HLA genes that encode immune response proteins. HLA genes encode molecules that are crucial to the immune system. These molecules display short chains of amino acids on the cell surface, allowing immune cells to analyze them. When the immune cells find an inappropriate chain, they begin attacking. Without HLA genes, immune cells would not find the chains of viruses, bacteria, or tumor cells. On the other hand, inheriting certain HLA gene variants increases the probability that immune cells will attack the body's healthy cells. This is how IDDM1 contributes to the immune attack on beta cells and thus to type 1 diabetes.

Variations in HLA genes are an important genetic risk factor, but they alone do not account for the disease and other genes are involved. There are two other non-HLA genes that have been identified thus far. One of these non-HLA genes, IDDM2, is the insulin gene, and the other non-HLA gene maps close to CTLA4, which has a regulatory role in the immune response.

With rising obesity levels, it is sometimes difficult for doctors to distinguish between type 1 diabetes, which requires treatment with insulin injections, and type 2 diabetes, which can be controlled through diet and weight loss. Genetics may provide some clues and options

Micro ribonucleic acids (miRNAs) carry snippets of genetic information across cells and are regularly released into the bloodstream, and in diabetes, the levels of some of these miRNAs in the circulation change, and a blood test could detect these variations, years, maybe decades, before symptoms develop.

An international team of scientists, led by researchers at Imperial College London (UK), has identified a miRNA linked to the pancreas. The scientists reported that a particular molecule, called miR-375, is released by the very cells in the pancreas that produce insulin. These cells normally contain high levels of miR-375, which helps control cell growth. In type 1 diabetes, it is released into the bloodstream in large quantities as soon as the cells begin to die.

Adiponectin, a protein hormone produced and secreted exclusively by adipocytes, regulates the metabolism of lipids and glucose and influences the response to insulin. Higher levels of adiponectin are associated with increased insulin sensitivity, thereby reducing diabetes risk. Adiponectin also has anti-inflammatory effects on the cells lining the walls of blood vessels. Therefore, low levels of adiponectin can be indicative of insulin resistance leading to type 2 diabetes and cardiovascular disease (CVD). Low adiponectin levels have also been correlated with increased likelihood of a woman developing gestational diabetes in pregnancy.

Obesity is associated with the risk of developing type-2 diabetes, nonalcoholic fatty liver disease, cardiovascular disease and cancer. However, it has been increasingly recognized that obesity is not a homogeneous condition, and about 25 to 40 percent of obese individuals can actually maintain a healthy status with no apparent signs of health complications.

Researchers at the University of Hawaii Cancer Center have discovered a panel of markers that helps identify if a person is pre-diabetic by measuring the fatty acids in their blood. The levels of these fatty acids can change up to 10 years before the individuals are diagnosed with diabetes. This discovery, they explain, may allow physicians to warn patients years before the onset of diabetes, therefore allowing them to change their lifestyle patterns, potentially avoiding the diagnosis of a chronic disease.

Table 5-29: Selected POC Diabetes Monitoring Tests

Company	Location	Details
Gentag	US	Insudex, type 1 diabetes autoantibodies, POC cartridge
		glycosylated fibronectin, preeclampsia and gestational diabetes
Diazyme Laboratories	US	SMART Cystatin C POC test kit
Epinex Diagnostics	US	G1A Diabetes Monitoring Index, glycated albumin
NeuroMetrix	US	DPNCheck nerve conduction test for diabetic peripheral neuropathy
Nirmidas Biotech	US	pGOLD Slides with islet cell-targeting autoantibodies
XRGenomics Ltd	UK	RNA profiling for prediabetes/diabetes risk

Source: Kalorama Information, company reports

The Major POC Test Players

The market for POC tests is highly diversified and, for the most part, a different set of companies is active in each subsegment. POC testing by professionals is dominated worldwide by the vendors of glucose testing devices: Roche Diagnostics, Dexcom, Abbott Diagnostics and Ascensia.

Table 5-30: POC Test Revenues of Selected IVD Companies, 2025 ($ million)

Company	Est.	Target Markets
Abbott Diagnostics	10,891	immunoassays, critical care, cardiac, DAU, infectious diseases, DofA. diabetes
Dexcom	4,662	diabetes CGM
Exact Sciences	2,531	fecal occult testing
Roche Diagnostics	2,352	troponin T, critical care, coagulation, UA
Beckman Coulter/Danaher	1,266	cancer markers, rapid tests, fecal occult
Medtronic	1,040	diabetes CGM
Siemens Healthcare	940	cardiac markers, critical care, UA, coagulation, DofA
Ascensia	677	diabetes
Radiometer/Danaher	619	chemistries
QuidelOrtho	602	infectious diseases, cardiac markers, pregnancy/fertility
Sysmex	504	blood chemistries, electrolyte, UA
Becton Dickinson	279	infectious diseases rapid tests

Source: Kalorama Information, company reports

POC vendors Roche Diagnostics, Siemens Healthineers, Beckman Coulter, Dexcom, Exact Sciences, and Abbott hold significant positions in niched segments with at least 40 - 60 other companies offering a wide range of POC tests, worldwide.

Abbott is the clear leader in POC testing with tests and devices for cardiac markers, diabetes, HbA1c, lipids, infectious diseases, drugs of abuse, and blood and electrolyte testing.

Roche offers a number of solutions for diagnostic testing by healthcare professionals outside the central lab, including PT/INR testing and anticoagulation management tools, glucose testing, blood gas/electrolytes testing for critical care and respiratory therapy, cholesterol testing and urinalysis. These are sold under the CoaguChek, AccuChek and cobas brand names. Physicians have been using Roche's CoaguChek instruments for POC PT/INR (Prothrombin Time/International Normalized Ratio) testing since 1994.

Siemens Healthineers offers several products. The company is a major participant in POC testing for blood and electrolytes, rapid coagulation, rapid cardiac markers, drugs of abuse, and urinalysis tests. Siemens Healthineers offers a large menu of critical care options for use in ICU, NICU, operating room, emergency department, laboratory, and respiratory. The product menu includes: RAPIDLab 1200 and RAPIDLab 248/348 Systems, RAPIDPoint 400/405 Systems and RAPIDPoint 340/350 Blood Gas Systems. In addition to a broad line of blood gas instruments, the CE Marked and FDA RAPIDPoint 500 Analyzer, a cartridge-based critical care system, provides testing for lactate, blood gas, electrolytes, metabolites, and CO-oximetry.

Dexcom is a leader in the POC CGM arena. The company has been increasing revenues year on year, driven by the growing use of CGM.

Exact Sciences continues to grow its colon cancer testing. It is anticipated that the company will continue to post large gains in the future due to its product offerings.

Beckman Coulter participates in several POC testing segments and has a leading market share in POC blood and electrolytes testing, colon cancer screening/FOB testing, infectious disease and cancer testing markets.

QuidelOrtho's rapid diagnostics products test for flu, RSV, FOB, strep A, pregnancy, bacterial vaginosis, infectious mononucleosis, H. pylori, and Chlamydia. During the COVID event, Quidel offered numerous products including a 25-minute molecular test that runs on the Solana platform, QuickVue to detect SARS viral antigen, and a 15-minute MultiAntigen Respiratory Panel. The company also offers the Sofia and Solana analyzers. The merger of Quidel and Ortho Clinical provided added combined revenue in POC.

Ascensia Diabetes Care is a top provider in the glucose testing market. The company has recently entered the CGM segment, which will help to increase revenues in the coming years.

At least 20 companies are active in pregnancy and ovulation (LH) testing. The top vendors are SPD, Church & Dwight, bioMérieux, Meridian and others. Further, all major pharmacy chains sell their own home-brand test kits, manufactured by leaders and other OEMs. This test segment continues to perform at an average annual growth rate of 2%-3 %.

The hospital market for POC coagulation tests is made up of activated coagulation time (ACT) tests run on patients receiving heparin during cardiovascular and other surgeries and PT/INR tests for patients taking warfarin (Coumadin) anticoagulant. Manufacturers of commercially available analyzers for ACT testing include Array Medical, Roche Diagnostics, International Technidyne Corp., Helena Laboratories, and Medtronic. No one company dominates the market. These companies also sell PT/INR tests and devices.

More robust is the market for PT/INR testing by professionals in physician offices, clinics and community care. In fact, there is a growing trend to integrate retail clinics with pharmacists to adjust warfarin dosages as needed. The leader is Roche Diagnostics.

Point-of-care PT/INR self-testing for patients on warfarin is a well-established segment, although overall growth has slowed as newer anticoagulants reduce the need for routine monitoring. Roche Diagnostics has been a leading player in this market since the 1990s with its CoaguChek systems, which have seen strong adoption in Europe, particularly in Germany. In the United States, home PT/INR testing has expanded more gradually, supported by physician-managed programs and reimbursement policies.

Earlier systems from companies such as International Technidyne and HemoSense played a role in developing the market but are no longer widely used. Today, Roche's CoaguChek platforms remain among the most recognized options, allowing patients to perform fingerstick testing at home and share results with healthcare providers through connected data systems. While home testing offers convenience and reduces the need for venous blood draws, the overall market is now more stable than it was during periods of high growth, reflecting a broader shift in anticoagulation therapy.

New biosensor-based and microfluidic technologies continue to be explored to simplify and standardize point-of-care coagulation testing. While earlier development efforts from companies such as Microvisk highlighted the potential of these approaches, the current market remains dominated by established PT/INR systems. Ongoing innovation focuses on

improving ease of use, consistency, and connectivity rather than introducing entirely new platform technologies for routine clinical use.

Gaining acceptance are rapid tests for cholesterol and other lipids. These are used by physician offices and clinics to monitor people at risk of cardiac events. The market leaders are Roche's AccuChek and Reflotron products and Abbott's LDX system.

CholesTrak was FDA-cleared for professional use in 1991 and was introduced to the over-the-counter market for consumer use in 1994. CholesTrak was formally known as Advanced Care and originally promoted by Johnson & Johnson. AccuTech acquired cholesterol in 1999 from a failed company called ChemTrak, which had manufactured the product for Johnson & Johnson. AccuTech then reintroduced the product to the POC market in its current form, a palm-sized, non-instrumented cassette cholesterol test system called the CholesTrak.

Polymer Technology Systems offers the PTS Lipid Panel Test Strips for use with the CardioChek device. The lipid panel test strips are dry-phase strips constructed in a plastic holder that holds chemically treated membranes. The lipid panel test strips are for in vitro diagnostic use with the CardioChek reflectance photometers. Lipid measurements assess cholesterol, HDL cholesterol, and triglycerides in whole blood.

OraSure Technologies has pioneered self-testing for HIV. The company’s products include rapid tests for detecting antibodies to HIV and HCV at the point of care, and testing solutions for detecting various drugs of abuse. The company’s lead product is the OraQuick In-Home HIV Test, the first rapid HIV test approved by the U.S. Food and Drug Administration for sale to the consumer over-the-counter market in the U.S. OraSure Technologies claims to be the leading supplier of oral-fluid testing solutions for drugs of abuse and for the detection of antibodies to HIV in the professional POC market. The OraQuick HCV test is the first and only FDA-approved, CLIA-waived point-of-care test for detecting HCV infection in at-risk individuals.

OraSure Technologies received a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for its OraQuick Ebola Rapid Antigen Test for use with fingerstick and venous whole blood. This test has been authorized by FDA under an EUA for use by laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics).

As for the remainder of self-tests on the market – H. pylori, vaginitis, TSH. FSH, etc., just about any company involved in the immunoassay industry has a POC strip test for sale.

In hospitals, the trend towards more ambulatory procedures and decreased hospital days per patient means that the acuity of the patient mix has increased. Thus, critical care testing devices that previously ran only blood gases and electrolytes now have added glucose, lactate, other metabolites, hemoglobin and ACT to the menu. Abbott Diagnostics' i-STAT is the clear leader in the market for handheld critical care test systems, now offering glucose testing along with other critical care tests. Critical care tests are performed on hospitalized patients only and most decentralized critical care testing is done on small lab-type analyzers marketed by Roche Diagnostics, Siemens Healthineers, Radiometer/Danaher, Nova Biomedical and Instrumentation Laboratory (Werfen).

Cardiac markers (BNP, CK-MB, myoglobin and troponin I/T) are showing steady demand in the hospital sector. The leaders are Abbott Diagnostics' i-STAT, Biosite and Siemens Healthineers STRATUS. Cardiac markers for decentralized testing are also available from Roche Diagnostics (cobas h232) Radiometer/Danaher (AQT 90) and PHC Group (Pathfast system), There are also at least another 20 companies that sell test strips for all or one of the marker panels.

Chapter 6: The Core Lab

Scope

The core laboratory concept integrates multiple diagnostic disciplines—including clinical hematology, chemistry, immunochemistry, toxicology, and coagulation—into a single, automated, and contiguous workflow. This model has evolved significantly due to advances in instrument interconnectivity and laboratory information technology systems, enabling seamless integration of diverse testing methodologies. However, the most compelling driver behind this evolution remains the urgent need to reduce the escalating costs associated with laboratory operations.

While large institutions may still manage molecular diagnostics and specialized tests as separate entities, many smaller hospital laboratories and regional systems are shifting toward a fully integrated core lab model. These smaller labs are increasingly investing not only in multifunctional instrumentation but also in automation and informatics to enhance operational efficiency.

Core Lab Overview and Trends

The consolidation of routine testing across multiple disciplines within the core laboratory continues to expand. Over time, a broader range of analytes that were once run on specialized immunoassay systems are now run on integrated core lab platforms. These include tests such as D-dimer, vitamin D, HbA1c, BNP, hsCRP, cystatin C, procalcitonin, and a variety of infectious disease markers, with additional specialty assays increasingly incorporated where volumes support automation. As a result, traditional boundaries among chemistry, immunoassay, and certain aspects of hematology and serology have become less distinct, thereby supporting a more centralized and efficient workflow. While disciplines such as microbiology, blood banking, and pathology remain operationally separate, they are increasingly connected through shared automation, informatics, and data management systems, reinforcing the role of the core lab as a central hub in modern laboratory medicine.

Several external forces are accelerating this transformation. Economic constraints, staffing shortages, and the constant expansion of test menus are pushing laboratories to adopt more efficient models. Currently, over 80 immunoassays are available on many core lab analyzers, and with continued automation, it is increasingly feasible that most routine manual tests will become fully automated in the near future.

In response to these pressures, even smaller hospitals are embracing core lab systems that consolidate chemistry and immunoassay testing. A new generation of compact, tabletop analyzers now offers multianalyte testing capabilities previously reserved for larger platforms. These systems are being developed with seamless connectivity to laboratory information systems (LIS) and centralized lab tracks, allowing labs of all sizes to achieve higher throughput, better resource utilization, and improved turnaround times.

The core lab model is no longer just a strategy for high-volume reference centers—it is becoming the operational backbone for labs across the healthcare spectrum.

Some of the tests added to core lab instruments over the past few years are shown below.

Table 6-1: Selected Analytes for the Core Lab

Company	Location	Area	Details
SCIEX Pte Ltd.	U.S.	Vitamin D	SCIEX Vitamin D 200M kit for Topaz LC-MS
Abbott Diagnostics	U.S.	sepsis	ARCHITECT BRAHMS PCT (procalcitonin)
Beckman Coulter/Danaher	U.S.	reproductive	Access Sensitive Estradiol
Beckman Coulter/Danaher	U.S.	reproductive	Access AMH (anti-Müllerian hormone) assay
Beckman Coulter/Danaher	U.S.	cardiac	High-sensitivity troponin assay
Beckman Coulter/Danaher	U.S.	sepsis	Procalcitonin assay
Beckman Coulter/Danaher	U.S.	endocrine	Access TSH assay
Diazyme Laboratories	U.S.	sepsis	Procalcitonin assay
Diazyme Laboratories	U.S.	diabetes	Direct HbAc1 assay, enzymatic on-board lysis
Diazyme Laboratories	U.S.	Vitamin B	Vitamin B12 and Folate assays
EKF Diagnostics	UK	ketones	β-Hydroxybutyrate LiquiColor Reagent, automated analyzers
EKF Diagnostics	U.S.	diabetes	Quo-Lab and Quo-Test HbA1c analyzers
MedTest Dx	U.S.	Vitamin D	25-OH vitamin D assay for Mindray BS-480 Chemistry Analyzer
QuidelOrtho	U.S.	diabetes	VITROS C-peptide reagents & calibrators
QuidelOrtho	U.S.	diabetes	EKF's β-Hydroxybutyrate assay for ketoacidosis
QuidelOrtho	U.S.	sepsis	BRAHMS PCT for VITROS
QuidelOrtho	U.S.	diabetes	VITROS Insulin reagent & calibrators
QuidelOrtho	U.S.	kidney	VITROS NephroCheck Assay; TIMP-2 and IGFB-7
Randox Laboratories	UK	diabetes	Adiponectin biomarker assay
Randox Laboratories	UK	wellness	sLDL (small dense LDL) Cholesterol assay
Roche	Switzerland	coagulation	cobas t 411 analyzer

Company	Location	Area	Details
Roche	Switzerland	Vitamin D	Elecsys Vitamin D total II assay
Roche	Switzerland	reproductive	Elecsys AMH assay
Sekisui Diagnostics	U.S.	coagulation	Coapresta 3000 (CP3000) instrument
Siemens	Germany	cardiac	ADVIA Centaur Intact High-Sensitivity Troponin I assay
Siemens	Germany	endocrine	ADVIA Centaur iPTH (intact parathyroid hormone) assay
Siemens	Germany	endocrine	ADVIA Centaur Testosterone II assay
Sysmex Corp	Japan	coagulation	Revohem FVIII Chromogenic
Sysmex Corp	Japan	coagulation	Revohem PT reagent for prothrombin time
Tosoh Corp.	Japan	cardiac	ST AIA-PACK cTnI 3rd-Gen cardiac troponin
Tosoh Corp.	Japan	vitamin D	ST AIA-PACK 25-OH Vitamin D assay
Tosoh Corp.	Japan	cardiac	ST AIA-PACK Homocysteine
Tosoh Corp.	Japan	diabetes	HbA1c on AIA immunoanalyzers
Tosoh Corp.	Japan	diabetes	Tosoh HPLC HbA1c, diabetes diagnosis

Source, company reports, Kalorama Information

Of particular interest is the migration of advanced technologies to the core lab. With clinical market clearance for the Bruker MALDI Typer and bioMérieux's VITEK MS, it is not too far-fetched to see microbiology and other tests on mass spectrometry come to the core lab. This eventuality is supported by a preanalytical sample preparation system that can decap and process screw cap tubes used to transport cytology and microbiology samples, as well as traditional blood tubes.

Already, mass spectrometry specialist Sciex has introduced an HbA1c test, and the company also offers a mass spec kit for vitamin D. Newomics Inc. was awarded the CE Mark for its IVD-MS Kit for 25-OH-vitamin D2/D3 on a Sciex mass spec system. Other tests are bound to follow; stay tuned. A more detailed discussion of the role mass spectrometry plays in diagnostics is presented in Chapter 7 Immunoassays.

The importance of HbA1c in monitoring diabetic glucose management has been advanced with the market clearance of this test for diabetes diagnosis as well as disease monitoring. More importantly, major quality control companies offer HbA1c control products in an effort to standardize test results.

High-sensitivity troponin (hsTroponin) testing has become the method of choice for triage of acute cardiac disease in emergency room patients. In the past few years, a number of these tests have been added to the traditional cardiac marker panel: BNP, myoglobin, and troponin.

Lipid profile and cholesterol testing have gained importance, driven by growing awareness of the risks of heart attack and a greater realization among individuals of the need to control their cholesterol levels. Overall growth in the testing volumes is driven by factors such as an aging population and a growing number of people at risk of cardiovascular disease, including those with hypertension, diabetes mellitus, and abdominal obesity. Thus, lipid profile tests are becoming increasingly evident in the core lab.

Vitamin D deficiency has been linked to various diseases, including cancers, cardiovascular disease, diabetes, osteoporosis, multiple sclerosis, Alzheimer's disease, and all-cause mortality. This new understanding of the importance of vitamin D levels has driven an increase in the number of physician requests for total 25-Hydroxy vitamin D tests in the United States and worldwide.

For esoteric immunoassays, microplate-based ELISA assays are commonly used to process tests that are not available on automated platforms. With the ongoing consolidation among laboratories, however, the demand for esoteric immunoassays is reaching volumes that require automation. Therefore, ELISA system manufacturers have automated the test process, from stand-alone washers and readers to fully automated workstations and solutions, to meet a clinical laboratory’s assay and throughput requirements.

Connectivity

Adopting the new generation of connectivity standards is an opportunity that should not be missed. Laboratories owe it not only to the general public, but also to the hundreds of highly qualified volunteers who have contributed thousands of hours to define the industry's best-ever standards, all for the common good of improving patient healthcare.

The LOINC Terminology Service provides features based on the HL7 FHIR standard. The update consists of support for multiple versions of LOINC across CodeSystem, ConceptMap and ValueSet resources and inclusion of LOINC concept translations and alternate names as FHIR designations.

LOINC marketed version 2.74 includes new, edited, and newly mapped concepts across laboratory, clinical, and other domains. It features a streamlined file structure.

LOINC marketed the 2.78 version, which included 1,589 new concepts and 1,416 edits to existing LOINCs.

In February 2025, LOINC offered the 2.8 Hotfix, which was designed to correct issues with the 2.79 version and add terms accidentally omitted.

IICC members include Abbott Diagnostics, Beckman Coulter, Becton Dickinson, bioMérieux, Data Innovations, Orchard Software, QuidelOrtho, Roche Diagnostics, Siemens Healthineers, and Systelab Technologies, S.A.

Overview of Chemistry Tests

The new look of chemistry may center on the core lab, but clinical chemistry remains one of the most important areas in lab medicine. Routine clinical chemistry comprises 30 to 40 tests, including substrates, metabolites, electrolytes, blood gases, enzymes, urinalysis, and lipids, and can be divided into tests performed for routine patient investigation and rapid-response tests used to monitor unstable hospitalized patients. Esoteric tests for renal clearance, liver function and metabolic status also feature in this segment.

Some chemistries are used in the routine medical checkup. Clinical chemistries are among the classic routine tests run as a first pass to a diagnosis, along with the hematology complete blood count (CBC) and urinalysis. Thus, the chem 7 (glucose, BUN, cholesterol, electrolytes), urinalysis and the CBC are among the most common tests performed. Long eclipsed in apparent importance by molecular tests and esoteric immunoassays, several chemistries are making a mark in patient management.

A basic metabolic panel (BMP) includes 8 tests - sodium, potassium, chloride, bicarbonate, blood urea nitrogen (BUN), creatinine, glucose, and calcium. A more comprehensive metabolic panel could include 14 tests: a BMP plus total protein, albumin, alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin. They provide physicians with an overall appraisal of a patient's wellness. Abnormal values in any one of these tests would signal further investigation.

Clinical chemistries are performed using serum or plasma on analyzers with varying levels of automation, depending on the test volume at a particular test site. The market for routine clinical chemistries can be segmented into high and low-volume users. High-volume users are found in large urban and regional hospitals and private laboratories. Low-volume users are found in non-laboratory test sites within the hospital, physician office labs, small and medium-sized hospitals, and community laboratories.

This mature industry is continually seeking to reinvent itself by improving test processes and menus. Trends in clinical chemistries over the next 5-10 years include:

- new emerging tests, including markers for metabolic and cell pathways
- a reorganization of testing procedures
- emphasis on increasing whole blood analysis

- workstation consolidation
- expansion of automated solutions

Lab Automation

Laboratory automation is the use of technology to streamline or replace manual operation of equipment and processes. Automated solutions can be applied to the majority of lab procedures—from simple capping and decapping of sample bottles to high-throughput screening.

The goal is to automate or minimize manual work previously performed by medical technologists, including sorting tubes, decapping, centrifuging, loading analyzers, and prepping and sorting materials for storage, while optimizing workflow and the electronic transfer of test results to a lab information system and/or electronic medical record.

Sometimes, a core lab is highly automated, with a preanalytical sample-preparation station that sorts and prepares samples for transport to the appropriate analyzer along an automated track. Other times, preanalytical sample preparation is simply automated in a central location where samples are logged in and then are manually transported to analyzers, all located in the same room. In each case, the heart of the system is a lab information system with intelligent software that controls all activities.

Automation has long been regarded as an important means for clinical laboratories to achieve greater efficiency, accuracy, standardization, and test quality. Lab consolidation increases the number of samples processed in one facility and with increasing competition and demands for higher levels of performance, the need for automation has become more and more essential, even among smaller labs that have been resistant to automating. Meanwhile, the development of new generations of automated stand-alone and benchtop equipment has made lab automation a more and more viable option for labs of all sizes.

One of the most popular automation solutions has been the pre-analytical sample-preparation station. This is because the preanalytical phase accounts for more than half of all laboratory costs and has been shown to be a source of laboratory errors due to specimen mislabeling, misidentification, mis-sorting, improper routing, and decanting. While Beckman Colter/Danaher has been a pioneer in this area, other major IVD vendors now offer a variety

of automation preanalytical solutions, including Bio-Rad Laboratories, Abbott Diagnostics, Siemens Healthineers, Roche Diagnostics, and others.

The major automation companies that partner with IVD companies to provide customized automation solutions include: Tecan Group, Copan, Kiestra, Hitachi High Technologies, and others. The next logical step is to incorporate a variety of molecular tests in the core lab. It is likely that, with this level of amalgamation, the lineup of red-, lavender-, green-, gray-, and blue-stoppered tubes would eventually become generic, with all tubes the same color. In fact, this trend is already in progress.

Market Analysis

The remainder of this chapter discusses the market for lab-based and POC chemistries. Routine lab-based clinical chemistry testing comprises 30 to 40 tests, including substrates, metabolites, electrolytes, blood gases, enzymes, urinalysis, and lipids. Traditionally included in clinical chemistry analysis are data for rapid-response analytes that are also run on lab-based systems, including blood gases, electrolytes, glucose, urea, creatinine, lactate, and ionized calcium, which are measured using either whole blood or serum, either in a laboratory or as point-of-care tests.

The global market for clinical chemistry is estimated at $11.0 billion in 2025. Overall, this test segment is projected to grow by 3.9% per year, reaching nearly $13.3 billion by 2030.

Table 6-2: Global Lab-based Clinical Chemistry Sales, by Test Category, 2025-2030 ($ million)

[Blood Gases; General Chemistries; Urinalysis]

Clinical Chemistry	2025	% Mkt	2030	% Mkt	CAGR
General Chemistries	8,645	79%	10,650	80%	4.3%
Blood Gases	1,195	11%	1,388	10%	3.0%
Urinalysis	1,138	10%	1,270	10%	2.2%
Total	**10,978**	**100%**	**13,308**	**100%**	**3.9%**

Note: Includes all lab chemistries, electrolytes, enzymes, and lipids run on chemistry analyzers; excludes POC.

Source: Kalorama Information

Table 6-3: Global Clinical Chemistry Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	39%
Europe	33%
Asia Pacific	16%
RoW	12%
Total	**100%**

Source: Kalorama Information

Intense provider consolidation in the United States, the commoditization of most chemistry offerings, and increasing price pressures have pushed the cost per test for routine chemistries to just about the lowest possible level. The average 2%-4% annual growth in this segment is driven by new tests in lipid analysis, proteins, hormones, and enzymes used to test for diabetes, cardiovascular disease, cancer, and other acute and chronic conditions.

In developed countries (North America, Western Europe, and Japan), almost all routine electrolyte estimations are performed on automated general chemistry analyzers, while in the developing world, 70% are run on dedicated instruments. The major players for clinical chemistry analyzers and reagents are shown below.

Table 6-4: Selected Major Clinical Chemistry Companies, by Sales, 2025 ($ million, estimated)

Company	Clinical Chemistry Revenues
Beckman Coulter/Danaher	1,855
Roche Diagnostics	1,311
Werfen	970
Abbott Laboratories	911
Siemens Healthineers	758
QuidelOrtho	596
Radiometer/Danaher	429
Sysmex	304
Others	5,392
Total	**12,526**

Note: Sales include combined laboratory and POC

Source: Kalorama Information

In addition, serving European and emerging markets are local companies such as Eiken Chemical, Menarini Diagnostics (Florence, Italy), Dr. Bruno Lange GmbH (Berlin, Germany), Biochemical Systems (Arezzo, Italy), Transasia Bio-Medicals Ltd (Maharashtra, India) and Snijders Scientific (Tilburg, Netherlands) market small tabletop instruments that run a wide chemistry test menu on both serum and whole blood.

Despite intense competition and a modest growth potential, the market for chemistry systems is in constant renewal. A selection of innovations in clinical chemistry analyzers is listed below.

Table 6-5: Selected Clinical Chemistry Innovations

Company	Location	Details
Beckman Coulter/Danaher	U.S.	AU5800 automated chemistry system
Carolina Liquid Chemistries	U.S.	CLC1600 High Throughput Chemistry Analyzer
Carolina Liquid Chemistries	U.S.	CLC 800 Clinical Chemistry Analyzer Mid-Volume Labs
Diatron	Hungary	Pictus 700, fully automated chemistry analyzer
EKF Diagnostics	UK	Altair 240 clinical chemistry analyzer
ERBA Diagnostics	Germany	ERBA Automated Chemistry Analyzer XL-400
ERBA Diagnostics, Inc.	Germany	Chemistry Analyzer XL-400
Horiba Medical	Japan	Pentra C400
Mindray/MedTest Dx	China	Mindray BS-480 analyzer, chemistry & drugs of abuse reagents
QuidelOrtho	U.S.	VITROS XT 3400 reads pair of tests on one Micro Slide
Randox Laboratories	UK	RX imola, chemistry analyzer
Sekisui Diagnostics	U.S.	SK500 Chemistry System, SEKURE reagents, mid volume labs

Source: Kalorama Information

Rapid Response Systems

Systems designed for rapid-response testing are used both in central laboratories and at the point of care. Many of these systems use whole blood, which helps eliminate the need for centrifugation and speeds up turnaround time. This is especially important for time-sensitive testing, although not all rapid testing platforms rely exclusively on whole blood. The major and emerging players in whole blood analysis systems used both inside and outside the lab are outlined in the following table.

Table 6-6: Selected Major Whole Blood Chemistry Analyzers

Analyzer
AVL, Indianapolis, IN
Awareness Technologies, Inc., Palm City, FL
Diagnostics/International Technidyne/Diametrics, St Paul, MN
Instrumentation Laboratory, Lexington, MA
i-STAT/ Abbott, East Windsor, NJ
Nova Biomedical, Waltham, MA
Radiometer, Westlake, OH
Scil Diagnostics, Martinsried, Germany
Siemens Healthineers, Tarrytown, NY
Transasia Bio-Medicals, Mumbai, India

Source: Kalorama Information

Critical Care Analysis

Blood gas/electrolyte and critical care testing are among the more mature areas of the lab; however, with increased acuity of the inpatient population, these critical care systems have become increasingly important. Critical care chemistries are highly time-sensitive diagnostic tests, such as blood gas, electrolyte, and metabolite analysis. In some cases, a sample is sent to the lab for testing and increasingly portable systems are used at the bedside.

These analyzers are primarily used in the emergency room, operating room, cardiac monitoring area and any location where time-critical diagnostic testing is performed within the hospital setting. They are also used in routine laboratories for stat testing.

In 2025, rapid-response tests or POC critical-care testing accounted for $1,119 million in sales revenue. This segment is currently growing at 1.8% annually as more hospitals are

moving these time-critical tests closer to the patient. The market is expected to expand to an estimated $1,225 million in 2030.

Blood gas analysis, more specifically arterial blood gas (ABG) analysis, is a standard clinical diagnostic test that measures a patient's blood gases; oxygen and carbon dioxide levels constitute a delicate balance within the human body. Arterial blood pH is included in these measurements because dissolved carbon dioxide helps balance the acidity or alkalinity of the respiratory system. Similarly, bicarbonate balances pH in the renal system. Bicarbonate also functions as an indicator of metabolic balance.

Other parameters that can be tested in conjunction include electrolytes and metabolites. Blood gas analysis can not only assess a patient's health status but also diagnose respiratory, renal, or metabolic diseases that affect the normal balance of blood gases.

In critical care medicine, blood gas analysis is combined with other critical care analytes, including bilirubin for neonates, glucose, BUN, creatinine, calcium, ionized calcium, magnesium, lactate, pH, hemoglobin, and hematocrit. Blood gases, oximetry and a cardiac marker panel are added for patients with chest pain. The most advanced critical care test devices include various cartridge combinations of gases, electrolytes, and others, depending on the patient care situation. These may be used for POC testing in intensive care units, emergency rooms, ambulances, and other acute-care settings, as well as in laboratories.

Handheld devices include Abbott/i-STAT; Opti Medical; Medica Corp. EASY systems; LifeHealth IRMA TruPoint Blood Analysis System; and Alere Epoc (now Siemens Healthineers). The leader in this field is Abbott's i-STAT, which has gained market share through a continuous menu expansion that includes basic chemistries, blood gases, electrolytes, coagulation, hematology, and cardiac markers. Abbott has reported that more than 50,000 i-STAT handhelds are used by health care professionals in a variety of high-acuity settings worldwide–including in more than 1,800 hospitals. More than 50 million test cartridges are produced annually.

Small portable lab-style systems include: Instrumentation Laboratory's Gem Premier systems; Roche Diagnostics cobas b 123 POC System; Radiometer ABL800 FLEX Blood Gas Analyzers; Nova Biomedical StatProfile pHOx Ultra; and Siemens Healthineers RAPIDLab 1200 Blood Gas Systems and RAPIDpoint systems.

The major traditional players in blood gases are Radiometer/Danaher, Instrumentation Laboratory/Werfen, Siemens Healthineers, Roche Diagnostics and Nova Biomedical.

These companies and others are focusing on expanding the test menu to support more efficient on-site critical care diagnostics. They are also commercializing instruments with minimal or no maintenance, multi-test cassettes, remote instrument management for maintenance and quality control and automatic transfer of test results to an information system. These features are necessary for easier market penetration for POC usage, but also for use in core laboratories for stat and evening and night shifts.

Neonatal jaundice has generally been measured using non-invasive transcutaneous bilirubin measurement with transdermal devices. In the past few years, total bilirubin testing has been added to critical care analyzers. For example, Instrumentation Laboratory offers what it claims is the first-ever, rapid point-of-care, laboratory-quality blood test for measuring total bilirubin in newborns. The tBili test is performed on the company's automated GEM Premier 4000 critical care analyzer, providing on-the-spot results in 90 seconds. Similarly, Siemens Healthcare has been awarded the CE Mark for a total bilirubin test on its RAPIDPoint 405 system.

Werfen offers the GEM Premier 7000 with IQM 3 Blood gas testing system for POC. The product represents a breakthrough in blood gas testing due to its ability to detect hemolysis as the POC.

In this test segment, the division between POC and lab-based systems is blurred because the instruments can be and are used in multiple test settings. Nevertheless, Kalorama has estimated the use of critical care testing inside and outside the lab.

In 2025, the world market for blood gas, electrolyte and POC critical care instruments is $2,314 million ($1,195 million lab; $1,119 million POC). Performance in critical care POC has been slow. Expect annual growth of 2.4%, driven primarily by the lab-based sector (3.0%).

Table 6-7: Blood Gas, Electrolyte, and Critical Care Instrument Market, by End User, 2025 and 2030 ($ million)

[Lab-based; POC-based]

End User Category	2025	2030	CAGR (%)
Lab-based	1,195	1,388	3.0%
POC-based	1,119	1,225	1.8%
Total	**2,314**	**2,613**	**2.4%**

Source: Kalorama Information

The market leader for blood gas analyzers (for all critical care, not just gases, including POC) shifted slightly, bringing Siemens Healthineers' market share to 20%. Radiometer increased its market share to 19%, Abbott maintained its at 18%, Werfen at 9%, and Beckman Colter at 7%.

Table 6-8: Blood Gas, Electrolyte, and Critical Care Market Leaders, 2025 (% distribution of total sales, including POC)

Company	% Mkt
Siemens Healthineers	20%
Radiometer	19%
Abbott	18%
Werfen	9%
Beckman Coulter	7%
Others	28%
Total	**100%**

Source: Kalorama Information

Urinalysis

Urinalysis consists of two separate elements: reading a strip test for chemical analysis of the sample and a microscopic examination of cellular elements. Urine sediment analysis is an important test used in diagnosing renal disease and urinary tract disorders. Clinical laboratory technologists use microscopes to classify, and measure formed elements in the urine sediment, including red blood cells, white blood cells, and bacteria.

These procedures are usually done manually and are considered fairly low-tech and routine compared to other analysis groups. Since urinalysis samples come from a variety of collection sites: inpatient, nursing homes, physician offices, outpatient clinics, emergency departments at all times of the day and night, laboratories need a simple solution to manage high volumes as well as individual samples. In this era of cost pressures and scarce human resources, urinalysis was ripe for automation. Therefore, in the past few years, most laboratories have been upgrading to automated systems that read the urine strip and integrate the two steps.

Further, image analysis from Iris International (now part of Danaher), Sysmex and ARKRAY provides a quantitative urine sediment test result that is necessary for initial disease assessment.

Lab-based urinalysis systems are estimated at $1,138 million in 2025, reflecting steady sales. The market is expected to grow at a 2.2% annual growth rate, to reach $1,270 million in 2030. Additionally, the POC UA market is valued at $214 million for 2025. Key players include ARKRAY Inc., Beckman Coulter, Roche Diagnostics, Siemens Healthineers and Sysmex.

Table 6-9: Urinalysis Market, by End User, 2025 and 2030 ($ million)

[Lab-based, POC-based]

End User Category	2025	2030	CAGR (%)
Lab-based	1,138	1,270	2.2%
POC-based	214	247	2.9%
Total	**1,352**	**1,517**	**2.3%**

Source: Kalorama Information

The market leader in 2025 is Sysmex, with 22% of the market share. Sysmex grabbed the market-leading position due to increasing demand for reagents in Asian markets. In the Americas and EMEA, Sysmex reported enhanced promotional efforts and increased product demand. Siemens Healthineers holds approximately 20% of the market and Roche holds 18%, Beckman Coulter secured 13%, and ARKRAY held 8%. Other market vendors share the remaining 19%.

Table 6-10: Urinalysis Systems (including POC) Market Leaders, 2025 (% distribution of total sales, estimated)

Company	% Mkt
Sysmex	22%
Siemens Healthineers	20%
Roche	18%
Beckman Coulter	13%
ARKRAY	8%
Others	19%
Total	**100%**

Source: Kalorama Information

Urinalysis innovations include the addition of analytes other than traditional urinalysis parameters, automated instrumentations and apps for test management. A selection of these innovations is presented below.

Table 6-11: Selected Urinalysis Innovations

Company	Location	Area	Details
Acon Laboratories	U.S.	instrument	Mission U120 Ultra Urine Analyzer
ARKRAY	Japan	instrument	Urine Analyzer Aution Hybrid AU-4050
Beckman Coulter	US	Instrument	DXU Iris Workcell
ERBA Diagnostics	U.S.	instrument	Laura M, urine analyzer with microalbumin & creatinine
ERBA Diagnostics	U.S.	instrument	Laura XL, a fully automated urinalysis and sedimentation processor
IRIS	U.S.	Instrument	IChem line of analyzers (legacy brand)
Macherey-Nagel	Germany	Instrument	URYXXON Relax
Roche	U.S.	Instrument	Urisys 1100
Siemens Healthineers	U.S.	instrument	CLINITEK Novus Analyzer, dipstick cassette
Siemens Healthineers	U.S.	connect	CLINITEK Status Connect System, wireless
Sysmex Corp	Japan	instrument	Eiken's urinalysis strips with Sysmex's automated analyzers
Sysmex Corp	Japan	instrument	UD-10, complete analysis of urine in combination with the UF-5000/4000
Sysmex	Japan	Instrument	UN-Series Automated urinalysis solution

Source: company reports, Kalorama Information

The Commercial Outlook for Chemistry Tests

The clinical chemistry market, though mature, continues to experience moderate growth, driven by technological innovation and evolving clinical needs. Emerging tests are being rapidly integrated into modern chemistry analyzers. Examples include homocysteine, anti-CCP, tumor markers, procalcitonin, autoimmune markers (e.g., ANAs), allergy testing, B-type natriuretic peptide (BNP), high-sensitivity C-reactive protein (hsCRP), and hemoglobin A1c. These additions expand diagnostic capabilities and support broader clinical decision-making.

Instrumentation is also becoming increasingly automated. Leading vendors are investing heavily in next-generation systems designed to streamline workflow, increase throughput, and reduce labor costs, all in response to the industry's push for operational efficiency. AI is being used in analyzers to boost accuracy and efficiency.

A major contributor to market growth is the increased use of whole-blood specimens on miniaturized platforms. These compact systems are utilized in core laboratories, critical care units, and point-of-care settings, offering fast turnaround times and greater flexibility for routine and urgent testing. Analytics support multi-omics integration with genomics/proteomics in IVD, especially in oncology and chronic disease.

As hospitals consolidate testing into centralized core labs, analyzers that offer broad test menus and scalability are in high demand. This is particularly advantageous for both high- and medium-volume laboratories, which benefit from comprehensive, integrated solutions that support consolidation and improve overall lab efficiency.

Chapter 7: Immunoassays

Scope

The immunoassay IVD market covers diagnostic tests and systems that detect or quantify specific analytes such as proteins, hormones, pathogens, or antibodies based on the binding reaction between an antigen and an antibody. Included in this chapter are:

- **Thyroid function tests**
- **Therapeutic drug monitoring**
- **Vitamin D tests**
- **Anemia tests**
- **Toxicology and drugs of abuse testing**
- **Allergy testing**
- **Proteins**
- **Tumor markers**
- **Cardiac markers**
- **Rheumatoid arthritis**
- **GI testing**
- **Transplant management**
- **Women's health**
- **Alzheimer's disease**
- **Traumatic brain injury**
- **Pregnancy and fertility testing**

The market is further divided into Professional use and POC OTC use. This chapter discusses all lab based and POC immunoassay categories except those for infectious

diseases, which are covered in Chapter 12 covering Blood Banking Services, and Chapter 11 covering Microbiology/Virology.

For the purposes of this report, the following definitions apply: Drugs of abuse tests include those for: alcohol; illegal drugs such as cocaine and opiates; and prescription drugs such as barbiturates and benzodiazepines used for clinical purposes, not workplace testing. Cardiac marker tests include: CK-MB, myoglobin and troponin I/T.

Overview and Trends

Immunoassays—tests based on the specific binding of antibodies to antigens—have played a transformative role in clinical laboratory medicine since their introduction in the mid-1960s. Today, they remain indispensable for the diagnosis and monitoring of a wide array of diseases and conditions. Formats such as manual and automated enzyme immunoassays (EIAs), ELISAs, bead arrays, microarrays, and newer platforms leveraging mass spectrometry are widely used across all segments of lab medicine.

Despite earlier predictions that molecular diagnostics would eclipse immunoassays, these tests have instead experienced a significant resurgence. Their relevance has expanded well beyond infectious disease and hormone testing to include assays for metabolic pathways, autoimmune conditions, gastrointestinal disorders, diabetes, and women's health.

The publication of the human genome in 2001 catapulted in vitro diagnostics, and immunoassays in particular, into a new and revitalized track—generally referred to as post-genomic medicine. Lab medicine in this post-genomic era involves tests based on protein and nucleic acid targets derived from human genome research. Gene identification is the first step; the next step involves detecting the physiological elements—proteins, hormones, and enzymes —expressed by genes. Immunoassays are used to test all of these entities. Proteins perform many important cellular functions, serve as targets for most drugs and therapies, and are often used as biomarkers for detecting and monitoring disease.

Proteins, enzymes, coenzymes and a host of cellular elements are the major players in metabolic pathways that actually promote and predict the evolution of a disease. The combination of genes, proteins, and pathways creates a comprehensive toolbox for modern post-genomic lab medicine.

Immunoassay Technology Continues to Evolve

One aspect of proteomic research is the discovery of markers that are implicated in various disease processes. However, in many cases, the concentration of these new markers in both healthy and disease states is very low. This is especially true in the case of cancer and neurological diseases such as Alzheimer's disease and Parkinson's disease. While advanced techniques such as mass spectrometry are used in the search for new markers, they are not appropriate for routine testing in hospital laboratories.

New ultra-sensitive test methodologies are being developed to detect highly specific disease markers, many of which are present at nanomolar, picomolar, and femtomolar concentrations.

ELISA remains a well-established and widely used immunoassay technique, particularly in laboratory settings. It is a solid-phase method typically performed in microtiter plates, where an antigen or antibody is immobilized in a test well. When a sample is added, the target analyte binds through a specific antigen–antibody interaction if present. After a washing step to remove unbound material, a detection antibody linked to an enzyme is introduced, allowing the reaction to be visualized through a measurable signal, most commonly colorimetric, but also fluorescence or chemiluminescence in some formats. While the sandwich format is widely used due to its sensitivity, other ELISA formats such as competitive and indirect assays are also employed. Although ELISA is a mature technology, it continues to play an important role in detecting low concentrations of analytes, even as more automated and high-throughput immunoassay systems expand in the core laboratory.

There remains strong investment in new technologies that expand the capabilities of immunoassay-based testing. While major IVD companies are advancing next-generation systems, smaller specialized firms also play an important role in developing innovative approaches. These include multiplexing, microarrays, and biosensor-based platforms, all aimed at improving sensitivity, throughput, and ease of use. Additionally, techniques such as mass spectrometry are being used alongside immunoassays in certain applications. A key focus across these technologies is the ability to detect analytes at very low concentrations, enabling earlier and more precise disease detection.

This ability to wash away nonspecifically bound materials makes the ELISA a powerful tool for measuring specific analytes within a crude preparation. However, the process involves many steps and is not readily adapted to automated immunoanalyzers or core lab clinical workstations. So … one can see the innovation in progress to enhance the delivery of ELISA testing with random access, arrays, digital and microfluidic techniques and automation. These enhanced ELISA systems improve the technology's versatility to support more efficient immunoassay processing.

Veravas provides VeraBIND technology for ultra-sensitive assays and matrix-free sample analysis. The technology is bead-based and enables reliable biomarker detection. VeraBIND is designed for use in clinical diagnostics and research to improve workflows and enable more sensitive detection of low-abundance biomarkers. Once validated, it is compatible with

commercially available assays and can be run using any detection method, including ELISA, chemiluminescence, and mass spectrometry.

With continuous investment from both large IVD companies and agile biotech startups, immunoassays are poised to remain a key platform in diagnostic medicine, meeting the growing demand for precision, sensitivity, and speed in detecting today's most complex diseases.

Table 7-1: Selected Immunoassay Technologies

Company	Location	Area	Details
Aesku Diagnostics	Germany	ELISA	HELMED 3 in 1 platform - IFA, ELISA, and BLOT
ALPCO Diagnostics	U.S.	ELISA	Euro Diagnostica's ELISA
Bio-Techne Corp	U.S.	multiplex	Ella, new ProteinSimple Simple Plex platform
Caprion BioSciences	Canada	mass spec	CellCarta, gel-free, label-free mass spec platform
Corgenix Medical Corp	U.S.	ELISA	SkyLab 752 dual-pipette automated ELISA analyzer
Cyvek, Inc. (Bio-Techne)	U.S.	multiplex	CyPlex System multiplex test cartridge; Ella/Simple Plex
Dynex Technologies	U.S.	automation	DSX automated enzyme-linked immunosorbent assay; Agility EKLISA
Enzo Clinical Labs	U.S.	EIA	Diasorin's immunoassays, Liaison XL
Fujirebio Diagnostics	Japan	EIA	LUMIPULSE G1200, chemiluminescent EIA LUMIPULSE G B-Amyloid LUMIPULSE G B.R.A.H.M.S. PCT Assay
Gold Standard Diagnostics	U.S.	ELISA	200 ThunderBolt-Ready ELISA from 20 companies The Bolt
Gyros AB	Sweden	nano	Gyrolab immunoassays
Immunovia	Sweden	array	IMMray, antibody biomarker microarray
InDevR, Inc.	U.S.	multiplex	miPLEX translate single well ELISA to multiplexed
InDevR, Inc.	U.S.	IT	automate interpretation hemagglutination assays
Indi Molecular	U.S.	tech	protein catalyzed capture reagents (PCCs)
INOVA Diagnostics, Inc.	U.S.	EIA	BIO-FLASH, a rapid chemiluminescent analyzer
Intel Corporation	U.S.	chip array	silicon microarray chip real-time analysis in minutes
Mindray Medical	China	EIA	CL-2000i instrument and reagents
Olink Bioscience	Sweden	immunoPCR	Proseek Multiplex proteins, Fluidigm BioMark HD PCR
OTraces, Inc.	U.S.	automation	CDx Chemistry System, automated ELISA
ProteinSimple	U.S.	multiplex	Simple Plex platform with Bio-Techne proteins

Company	Location	Area	Details
Qualigen, Inc.	U.S.	EIA	FastPack IP System, chemiluminescent immunoanalyzer
Quanterix Corp	U.S.	digital ELISA	Simoa HD-1 Analyzer, SR-X Ultra-Sensitive Biomarker Detection System
Quidel Corp	U.S.	EIA	Sofia fluorescent immunoassays
Randox Laboratories	UK	multiplex	Evidence Multistat Biochip Analyzer
Response Biomedical	Canada	ELISA	with Hangzhou Joinstar Biomedical (China)
Singulex	U.S.	cell	Sgx Clarity System, single cell counting
Singulex	U.S.	automation	Sgx Clarity Tecan's Freedom EVO liquid handling
Singulex	U.S.	EIA	Erenna Immunoassay System
SISCAPA Assay Technologies	Canada	mass spec	SISCAPA SAT affinity-MS technology antibodies
Somalogic	U.S.	aptamers	SOMAmer aptamers & antibody reagent
Somalogic	U.S.	multiplex	SOMAscan assay proteomics platform
T2 Biosystems	U.S.	biosensor	T2MR miniaturized, magnetic resonance
Theradiag	France	ELISA	Theralis: xMAP, immunofluorescence, ELISA
Theradiag	France	CLIA	BioCLIA 1 200, nanoparticle chemiluminescence, automated

Source: Kalorama Information

Mass Spectrometry

Mass spectrometry makes an important contribution to protein analysis. Sequencing of the human genome has provided a picture of the human proteome as well as the genome. An important step in immunodiagnostics is the ability to screen an individual's proteome using a standardized, quantitative tool. Mass spec has been recognized as an ideal solution.

Mass spectrometry quantifies molecules in a sample and offers high specificity and sensitivity compared to traditional techniques. It can be used for a variety of specimen types, including blood spots, serum, plasma, and breath.

Mass spectrometry in clinical laboratories has traditionally been viewed as complex, time-intensive, and costly, thereby limiting its use to specialized applications. Early adoption focused on areas such as toxicology using GC-MS and later LC-MS/MS for assays where high specificity was required, and commercial immunoassays were not available.

Today, mass spectrometry is more widely established in clinical laboratories, particularly in larger hospital and reference lab settings. Improvements in automation, system design, and workflow integration have made the technology more accessible, and the range of applications has expanded significantly. In addition to toxicology, mass spectrometry is now routinely used for therapeutic drug monitoring, endocrinology testing, vitamin analysis, and other specialized assays. Ongoing advances continue to improve ease of use and throughput, supporting broader adoption across the clinical lab environment.

Compared to immunoassays, mass spec is sensitive enough to detect disease-specific proteins that have leaked into the blood flow. Proteins released into body fluids by diseased tissue are the most relevant biomarkers, but their dilution in blood means they are present at very low levels that cannot normally be detected by immunoassays.

Proprietary protein technology from Proteome Sciences plc has enabled the detection and quantification of very low-abundant disease-related proteins in body fluids that are undetectable by other methodologies. The company reported that it has detected and quantified 41 phosphorylated peptides of the tau protein (an Alzheimer's disease marker) in human cerebrospinal fluid using mass spectrometry.

SISCAPA Assay Technologies developed a mass spec process for protein quantification, enabling panels of proteins to be measured across large numbers of samples with a very short turnaround time. Samples may be collected as Dried Blood Spots (DBS) and shipped at room temperature. The initial panel consists of proteins pertinent to cardiovascular function, inflammation, and muscle distress: Alpha-1-acid Glycoprotein, Cystatin C, C-Reactive Protein, Hemoglobin, Haptoglobin, Insulin-like Growth Factor 1, LPS Binding Protein, Mannose Binding Lectin, Myeloperoxidase, and Serum Amyloid A.

Mass spec is an attractive alternative to ELISAs for clinical protein biomarker detection because of its multiplexing capabilities. Also, mass spec assays often have better specificity than immunoassays, providing greater confidence that the measured analyte is, in fact, the assay target.

VeriStrat, a multivariate serum protein test, is Biodesix's first product developed with this technology. The commercially available test provides oncologists with information to help them select between erlotinib and single-agent chemotherapy for patients with advanced lung cancer. Tests are processed in Biodesix's CLIA-certified laboratory and results are reported in less than 72 hours.

Biodesix uses the MALDI-MS platform to generate spectra containing eight proteomic peaks that comprise the VeriStrat classifier. Biodesix and Bruker are combining Biodesix's platform technology, including Biodesix's proprietary data analysis algorithms, and Bruker's instruments, which form the basis for a clinical diagnostics platform.

Even with the evolution of mass spec instrumentation for more routine analyses, it is still not as easy as running a clinical analyzer. Therefore, Sciex has invested in developing its training solutions to provide more tailored support for less-experienced clinical users.

Mass spectrometry has become an important tool in clinical laboratories, with early applications focused on toxicology and metabolic screening, including newborn screening. More recently, the adoption of MALDI-TOF systems from companies such as Bruker and bioMérieux has transformed clinical microbiology by enabling rapid identification of bacteria and fungi.

The range of applications for mass spectrometry continues to expand, particularly in therapeutic drug monitoring, endocrinology, and specialized biomarker analysis. While research efforts are exploring its use in oncology, neurodegenerative diseases, and pregnancy-related conditions, many of these applications are still emerging rather than routine.

There has also been ongoing interest in miniaturizing mass spectrometry systems to create more portable and user-friendly devices. However, most clinical use today remains centered on laboratory-based instruments, with portable systems still largely limited to research and niche applications rather than widespread clinical deployment.

The Ohio State University Badu Research Group developed a paper-based mass spectrometry immunoassay platform that uses stable and cleavable ionic probes as mass reporters. The scientists report these probes make possible sensitive, interruptible, storable, and restorable on-demand detection. In addition, a new touch paper spray method was developed for on-chip, sensitive, and cost-effective analyte detection. The paper contains

small synthetic chemical probes that carry a positive charge. It's these ionic probes that allow ultra-sensitive detection by a handheld mass spectrometer.

Another emerging area of interest is the use of mass spectrometry for imaging tissue sections. This approach provides detailed molecular information that goes beyond what is available with traditional stain-based histology, offering the potential for deeper insight into disease processes. While improvements have been made, challenges such as acquisition time, workflow integration, and standardization continue to limit widespread clinical adoption. Even so, the ability to generate high-content molecular data directly from tissue makes this a promising technology for future use in pathology and translational research.

Looking further into the future, it is expected that the trend toward increasing automation will ultimately result in the introduction of fully automated clinical analyzers using mass spectrometry-based detection, at which point mass spectrometry will become widely used by smaller clinical laboratories.

It is beyond the scope of this research to evaluate the market for clinical mass spectrometry applications with certainty; however, Kalorama Information estimates the market at $1,032 million in 2025, growing at 8.6% annually.

The major mass spectroscopy system manufacturers include: Sciex/Danaher, Agilent Technologies, Bruker Corp., PerkinElmer, Shimadzu Corp., Thermo Fisher Scientific Sigma Aldrich and Waters Corp. The technology is used primarily in pharmaceutical research, biotechnology, industrial chemistry, environmental testing, and food and beverage testing. In clinical diagnostics, many LDTs based on mass spectrometry are currently addressing a range of analytes.

For years Sciex/Danaher has been considered the top provider in this segment. The company markets kits for steroids, vitamin D and metabolites, T3/T4, homocysteine, therapeutic drug monitoring, and inborn errors of metabolism, among others. In recent years, however, competition has increased in the space, including a recent surge in approvals, some examples of which are listed below.

Waters markets the MassTrak system, which is CE Marked, for measuring the immunosuppressive drugs tacrolimus and everolimus.

Thermo Fisher Scientific markets kits for pain management, drugs of abuse analysis, and endocrine analysis.

Shimadzu offers the MALDImini-1, the first compact MALDI digital ion-trap mass spectrometer. The MALDImini-1 fits in a space the size of a piece of paper, while allowing fast high-sensitivity measurements and detailed structural and qualitative analyses over a wide mass range, even with sub-microliter sample volumes. Shimadzu also offers Fraction Collector FRC-40 for high performance liquid chromatography. The FRC-40 incorporates improved fraction simulation to ensure pure fractions. Operators simply select the peaks of interest, and the software dynamically configures parameters that will collect them.

SCIEX offers the TripleTOF 6600+ LC-MS System and Scanning SWATH Acquisition alongside data processing with OneOmnics in SCIEX Cloud. These products together enable precise large-scale quantification to drive the discovery of new biomarkers. SCIEX also offers the Micro-ESI 9030, an interface compatible with the Nexera Mikros Microflow LCMS that enables micro flowrate analysis with the LCMS-9030 Q-TOF system.

PerkinElmer offers its GC Platform, an advanced automated gas chromatography headspace sampler and GC/mass spectrometry solution to help labs operations.

Waters offers its MassTrak IVD portfolio of LC-MS systems. The system, next-generation Xevo TQ Absolute IVE mass spec, is up to five times more sensitive for quantifying clinical analytes.

Bruker offers the timsTOF Ultra Mass Spectrometer with Transformative Sensitivity. It incorporates a Captive Spray Ionization Ultra ion source. Additionally, Bruker markets the EVOQ DART-TQ+ system for chromatography-free triple-quadrupole mass spectrometry in POC analysis.

Thermo Fisher markets the Thermo Scientific Orbitrap Astral mass spectrometer, which combines fast throughput, high sensitivity and deep proteome coverage. The Astral analyzer complements Thermo Fisher's Orbitrap MS platform.

Shimadzu offers the new LCMS RX series of triple quadrupole mass spectrometry instruments. The CoreSpray improves heat distribution in the ionization source, enhancing data reliability. The IonFocus removes matrix contaminants. Shimadzu offers its MALDI EasyCare solution. The MALDI EasyCare Solution decreases downtime and makes it easier to perform routine upkeep on the MALDI-8000 Series TOF mass spectrometers

SCIEX offers the SCIEX 7500+ System, one of the newest flagship instruments in the company's mass spectrometry portfolio. The SCIEX 7500+ System is designed to deliver

exceptional sensitivity while maintaining high robustness and resilience to matrix effects, supporting reliable, high-throughput quantitative testing across demanding analytical applications.

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Table 7-2: Selected Innovation in Mass Spectrometry for Routine Analyses

Company	Location	Area	Details
Agilent Technologies	U.S.	pregnancy	mass spec for pregnancy complications
Applied Proteomics	U.S.	cancer	SimpliPro Colon
Biodesix, Inc.	U.S.	cancer	VeriStrat, a multivariate serum protein test
Biodesix, Inc.	U.S.	IT	ProTS, data analysis algorithms, and Bruker instruments
BioMark Diagnostics	Canada	cancer	acetylated form of the drug Amantadine, PGx
Caprion Proteomics	Canada	instrument	CellCarta, gel-free, label-free mass spec platform
Matrix-Bio Inc.	U.S.	cancer	VeraMarker metabolite assays pancreatic, liver, colon cancer
Microsaic Systems	UK	miniature	Microsaic 4000 MiD miniature mass spectrometer
PerkinElmer	U.S.	instrument	AxION iQT gas chromatography tandem mass spectrometer
Proteome Sciences	UK	Alzheimer's	tau peptides and phosphopeptides in CSF
Sciex	U.S.	instrument	API 3200MD and 3200MD QTRAP LC/MS/MS
Sciex	U.S.	instrument	Citrine system
Sciex	U.S.	transplant	SCIEX IVD-MS Immunosuppressants kit
Sciex	U.S.	vit D	SCIEX IVD-MS Kit for 25-OH-vitamin D2/D3
Sera Prognostics, Inc.	U.S.	pregnancy	PreTRM, risk of preterm birth, Agilent technology
Shimadzu	Japan	instrument	MALIDmini-1
SISCAPA Assay Technologies	Canada	technology	SISCAPA SAT affinity-MS technology antibodies
SISCAPA Assay Technologies	Canada	technology	SISCAPA SAT antibodies with Agilent instrumentation
Thermo Fisher Scientific	U.S.	cancer	detect and track circulating biomarkers, mass spec
University of Michigan	U.S.	cancer	Mi-Prostate Score, early markers in urine

Source Kalorama Information

Radioimmunoassays

Radioimmunoassay (RIA) remains one of the most sensitive immunoassay methodologies, utilizing radioactive isotopes to quantify antigen-antibody interactions. This groundbreaking technique, developed by Rosalyn Yalow and Solomon A. Berson, transformed hormone testing and paved the way for modern endocrinology. Their early work on blood volume and iodine metabolism was followed by the application of RIA to hormone studies, most notably insulin, leading to their discovery that type 2 diabetes results from insulin resistance rather than insulin deficiency.

Throughout the years, RIA was a cornerstone of laboratory testing for fertility, hormone levels, and endocrine disorders. However, it was time-consuming, labor-intensive, and required strict regulatory controls due to its use of radioactive materials. In a typical chemistry lab, RIAs were often run once or twice per week and took nearly a full day to complete—usually by a senior technologist. The advent and commercialization of enzyme immunoassays (EIAs) and ELISAs revolutionized lab workflows. These new methods eliminated radioactivity concerns, reduced processing time, and enabled random-access automation, with test results available in under an hour. This led many to believe RIA would become obsolete. This has not been the case. RIA has proven to be extremely precise and sensitive and thus, the technique is still used for infectious diseases, hormone analysis and oncology in some clinical labs worldwide. It is used particularly in Europe and emerging markets where EIA test kits and instrumentation are difficult to obtain.

Kalorama estimates the 2025 market for RIAs is worth roughly 11% of the 'other' immunoassay market, which is valued at $3.0 billion. Beginning in the 14th Edition and continuing for the 15th Edition and beyond, RIA's have been consolidated into the immunoassay chapter figures. Major companies that still offer RIAs include: Danaher/Beckman Coulter, Bio-Rad Laboratories, Diasorin S.p.A., DRG International, Inc., MilliporeSigma, and MP Biomedicals, LLC.

The immunoassay business of the next 5-10 years will see:

- continued automation and commoditization of routine immunoassays—thyroid, anemia, proteins, fertility, therapeutic drug monitoring and drugs of abuse;
- more new assays and test categories—infectious diseases, cardiac markers, allergy, autoimmune, coagulation, bone and tumor markers;

- menu expansion for more automatable and specialized assays, since labs want platforms that test for more tests and samples on a single platform;
- the migration of more immunoassays onto core lab workstations;
- the design of more sensitive, automated, homogeneous techniques; and
- the search for an ideal point-of-care platform.

Market Analysis

The immunoassay market as a whole demonstrated growth in 2025. The global market for immunoassays (excluding those for infectious diseases and blood unit screening) is estimated at $14.3 billion. By 2030, the market for immunoassays (excluding infectious diseases and blood screening) will reach $17.3 billion worldwide, with a CAGR of 3.9%.

Table 7-3: Global Lab-based Immunoassay Sales (excluding infectious disease and blood screening), by Analyte Type, 2025-2030 ($ million)

[Allergy; Anemia; Autoimmune; Cardiac Markers; Diabetes/HbA1c; Drug of Abuse; Fertility; Proteins; Therapeutic Drugs; Thyroid; Tumor Markers; Vitamin D; Others]

Analyte Type	2025	% Mkt	2030	% Mkt	CAGR
Cardiac Markers	1,867	13%	2,170	12%	**3.1%**
Proteins	1,862	13%	2,840	16%	**8.8%**
Tumor Markers	1,533	11%	1,685	10%	**1.9%**
Diabetes/HbA1c	1,342	9%	1,700	10%	**4.8%**
Autoimmune	955	7%	1,030	6%	**1.5%**
Therapeutic Drugs	775	5%	875	5%	**2.5%**
Thyroid	680	5%	730	4%	**1.4%**
Allergy	616	4%	652	4%	**1.1%**
Anemia	513	4%	527	3%	**0.5%**
Fertility	500	4%	525	3%	**1.0%**
Drug of Abuse	333	2%	353	2%	**1.2%**
Vitamin D	289	2%	290	2%	**0.1%**
Others	3,020	21%	3,943	23%	**5.5%**
Total	**14,285**	**100%**	**17,320**	**100%**	**3.9%**
w/o HbA1c	**12,943**	--	**15,620**	--	**3.8%**

Note: Total percent may not add up due to rounding.

Source: Kalorama Information

The largest portion of the market (~74%-78%) is held in the more mature geographic segments of the world – North America (39%), Western Europe (32%) and Japan (5%). Emerging nations with stronger economies, such as those in Latin America and Africa, contribute to overall growth through the continued expansion of the market for routine immunoassays and some more esoteric tests.

Table 7-4: Global Immunoassay (excluding infectious disease and blood screening) Sales Distribution, by Region, 2025 (%)

[Asia Pacific, Europe, Japan, North America, Rest of World]

Region	% Mkt
North America	39%
Europe	32%
Asia Pacific	8%
Japan	5%
RoW	16%
Total	**100%**

Source: Kalorama Information

Markets in the Middle East, Saudi Arabia, Turkey, in particular, and Africa, led by S. Africa and Nigeria, are sparking the interest of competitors. These regions are looking to boost their diagnostics offerings. A once-emerging market, China, faces some uncertainties in growth due to a challenging healthcare environment, facing restructuring and government restrictions in response to cost savings initiatives.

The commoditization of routine immunoassays and contractions in lab testing in the United States, Japan, and Western Europe has seen a decrease in the number of routine immunoassays performed. In addition, the centralization of non-stat immunoassays on core lab analyzers (diabetes, thyroid, fertility, proteins, anemia, most infectious diseases), which make up 60% to 70% of immunoassays, has created pressure to decrease the cost per test.

Nevertheless, immunoassay growth of about 3.9% in 2025 to 2030 derives primarily from testing in proteins due to the uptick of amyloid beta testing for Alzheimer's disease, which has exploded on the scene at 8.8% CAGR, diabetes (HbA1c) expected at 4.8% CAGR, followed by cardiac markers (3.1% CAGR).

In support of the use of immunoassays, a number of new quality control products have been commercialized. The market for IVD quality control is estimated at $1,172 million for 2025.

Table 7-5: IVD Quality Control (immunoassay/molecular) Market, 2025 ($ million, estimated)

Market	2025
IVD Quality Control Market	$1,172

Source: Kalorama Information

The leading companies in third-party validated quality control products are Bio-Rad Laboratories, Thermo Fisher, and Randox Laboratories.

Table 7-6: Selected Immunoassay Quality Control Products

Company	Location	Details
Bio-Rad Laboratories	U.S.	Lyphochek Whole Blood Immunosuppressant Control Lyphochek Anemia Control, Hypertension, Endocrine, Urine, Bone
Bio-Rad Laboratories	U.S.	Liquichek Immunoassay Plus Control/Premium Control
Bio-Rad Laboratories	U.S.	InteliQ Immunoassay Plus Control/Specialty Immunoassay Control
Quanterix Corp	U.S.	Complete D 25-OH Vitamin D Control
Randox Laboratories	Ireland	Acusera Aldolase & Ammonia Ethanol controls
Randox Laboratories	Ireland	Acusera HbA1c, whole blood
Randox Laboratories	Ireland	Acusera Immunoassay Premium Plus
Randox Laboratories	Ireland	Acusera Liquid Tumor Marker Control
Randox Laboratories	Ireland	Acusera Immunology CSF control
Thermo Fisher	U.S.	MAS Omni-Core
Thermo Fisher	U.S.	MAS Omni-IMMUNE Pro Max
Thermo Fisher	U.S.	AcroMetrix
ViveBio LLC	U.S.	Seracare QC products with ViveST sample

Source: Kalorama Information

Table 7-7: Revenues of Leading Lab-based Immunoassay Vendors, 2024-2025 ($ million)

Vendor	2024	2024 % Mkt	2025 est	2025 % est Mkt
Roche	5,904	21.7%	5,658	20.3%
Abbott	3,674	13.5%	3,757	13.5%
Siemens	2,122	7.8%	2,146	7.7%
Becton Dickinson	1,250	4.6%	1,108	4.0%
Beckman Coulter	1,704	6.3%	1,669	6.0%
Thermo Fisher	1,229	4.5%	1,096	3.9%
QuidelOrtho	1,278	4.7%	1,179	4.2%
Total	**17,161**	**63.1%**	**16,613**	**59.6%**

Source: Kalorama Information

The global market for immunoassays has been dominated by three top IVD companies, including Roche, Abbott Diagnostics, and Siemens Healthineers. For the past few years, Roche Diagnostics has been very aggressive, displacing Abbott as the immunoassay leader. Roche has excelled in infectious diseases and in tests for women's health, sepsis, vitamin D, and a number of cancer markers, all of which are higher-growth segments.

Abbott's strength lies in a broad menu of tests and assay systems and successful capture of at least 18% of the global market for infectious diseases (when combining its presence in POC infectious disease), primarily hepatitis and HIV tests, outside the United States, as compared to Roche with 9%, making Abbott the undisputed leader in microbiology immunoassays. Abbott Diagnostics has also added the Galectin-3 assay, for use in conjunction with clinical evaluation to aid in assessing the prognosis of patients diagnosed with chronic heart failure, and the HbA1c test.

The completed acquisition of Alere created a stronghold in POC and rapid testing immunoassays. The company had a substantial presence in the IVD immunoassay market before the acquisition, but Alere's top POC immunoassay position helped to strengthen Abbott's market share.

Only a few other companies can match the Roche and Abbott immunoassay test menus, including the third largest provider, Siemens Healthineers, with its Immulite products. Immulite is a dedicated immunoanalyzer, and although Siemens Healthineers has automated it, the company has focused on its chemiluminescence test menu within the ADVIA Centaur Immunoassay Systems line, originally from Bayer Diagnostics.

Beckman Coulter's Access and Synchron systems provide a wide menu that is continuously enhanced by new tests. Beckman Coulter's immunoassay menu consists of more than 60 tests for cancer detection, cardiac disease, thyroid function, reproductive endocrinology and women's health. Beckman Coulter continues to add novel and proprietary tests from different sources including tests for: inhibin A, High Mobility Group Box 1 (septic shock), erythropoietin, cPAPPA (marker of plaque instability), placental growth factor (PIGF), soluble fts-like tyrosine kinase 1(sFlt-1), soluble CD40 ligand (sCD40L), preeclampsia, fertility hormones, CVD, autoimmune, inflammatory disease/ cytokines, and prenatal screening.

bioMérieux's immunoassay product line includes more than 130 products: rapid single-dose tests, VIKIA; a high-throughput, fully automated microplate processor, DAVINCI; and automated multiparametric analyzers, VIDAS, miniVIDAS, and VIDIA. bioMérieux has been working hard to establish a stronger presence in the immunoassay market. The VIDAS product range includes 99 tests covering a wide range of assays: identification and quantification of bacteria, viruses, and parasites; antibody measurements of the immunological response to an infection; various proteins circulating in the blood; markers for selected cardiovascular diseases and certain cancers; the inflammatory response; and hormonal dysfunction.

bioMérieux offers the VIDAS C. difficile GDH, an innovative, qualitative assay for the automated detection of GDH, offering clinical laboratories a fully automated, standardized and cost-effective solution for C. difficile diagnosis and infection control.

Other players include Becton Dickinson, Thermo Fisher and QuidelOrtho. There are also strong niche players such as Fujirebio, Tosoh, and Werfen. Diasorin has made a concerted effort to expand the test menu and distribution network, primarily in the U.S., India, China and emerging markets. Diasorin offers 122 available products, of which 31 are specialty tests.

Most of the tests included in the most mature immunoassay segment, such as thyroid, therapeutic drugs, and anemia, are part of the menu on clinical workstations discussed in Chapter 6.

Mature Assay Segment

Thyroid Function

Among the most mature immunoassays are those for thyroid disorders. Thyroid tests include thyroid peroxidase autoantibodies (Anti-TPO), thyroglobulin autoantibodies (Anti-Tg), free and total triiodothyronine (T3), free and total thyroxine (T4), thyroid- stimulating hormone (TSH) and T-Uptake. TSH is the thyroid function screen test and gatekeeper for almost all other thyroid function tests and makes up 50%-70% of the $680 million thyroid function test category in 2025. With an estimated 1.4% annual growth, the market for thyroid markers will reach $730 million in 2030. Growth in this test segment comes from esoteric thyroid function tests, such as TPO-Ab (Anti-Thyroperoxidase Autoantibodies) and TSH-R Ab (TSH Receptor Autoantibodies), many of which are performed by RIA.

Genalyte markets its Thyroid Stimulating Hormone immunoassay, performed on the Maverick's silicon chip.

Therapeutic Drug Monitoring

Therapeutic drug monitoring (TDM) is the measurement of a drug's serum concentration to ensure it remains within the therapeutic range. A drug's serum therapeutic range or index is the concentration range in which the drug is known to be effective while causing little or no toxic effects to the patient. Therapeutic drug tests ($775 million in 2025) include digoxin, anti-asthmatics, anti-epileptics, anti-microbials and cyclosporine. Here, digoxin occupies 50%-60% of the test volume. TDM testing is conducted primarily in the major developed markets, where Siemens Healthineers' products and Abbott Diagnostics are the leaders. Elsewhere, this market is mostly served by local manufacturers of ELISA tests.

In recent years, therapeutic drug monitoring assays have been developed for newer anticonvulsant and related drugs. For example, ARK Diagnostics introduced the ARK Levetiracetam Assay, expanding immunoassay-based monitoring options for epilepsy management.

Vitamin D

In the U.S. vitamin D testing is not recommend for most people, citing that there merely isn't a good, practical reason to do so unless a patient in a high-risk category of people such as those with osteoporosis or other bone conditions, those with issues of fat absorption (e.g., Celiac disease, weight reduction surgery), or those who take medications that interfere with vitamin D activity (e.g., glucocorticoids, anticonvulsants). That being said, U.S. doctors do conduct the testing, and Medicare stats indicate doctors have ordered over 12 million lab vitamin D tests for Medicare patients.

Major suppliers in the vitamin D testing market include DiaSorin S.p.A., Immunodiagnostic Systems (IDS), Roche Diagnostics, and Abbott Diagnostics. Among the earliest companies to introduce automated vitamin D assays, Diasorin and IDS benefited from a rapid surge in clinical interest around 2009, when testing volumes expanded dramatically, often cited as increasing by 30%–50% year over year. Since that initial market expansion, automated vitamin D assays have become widely available and are now marketed by major IVD manufacturers, including Abbott Diagnostics, Danaher (Beckman Colter), bioMérieux, QuidelOrtho, Roche Diagnostics, Siemens Healthineers, and others.

For several years, Diasorin was the first and major supplier of Vitamin D immunoassays. Diasorin received FDA clearance for the LIAISON 25-OH Vitamin D TOTAL assay in 2012. With increased demand for Vitamin D testing, most of the major IVD vendors market a test on their automated workstations. This has eroded Diasorin's market share.

Nevertheless, Diasorin has invested in enhancing the test. According to Diasorin, the LIAISON XL 1,25 Dihydroxyvitamin D Assay is the first extraction-free, fully automated 1,25 dihydroxyvitamin D assay available with a time-to-first result of only 65 minutes.

Table 7-8: Selected Vitamin D Immunoassays

Company	Location	Technology	Details
Aesku Diagnostics	Germany	ELISA	Vitamin D ELISA
ALPCO Diagnostics	U.S.	ELISA	25-OH Vitamin D Total ELISA
bioMérieux	France	EIA	VIDAS 25 OH Vitamin D Total
Boditech Med	U.S.	EIA	Ichroma Vitamin D
Carolina Liquid Chemistries	U.S.	EIA	automated Vitamin D-direct assay
Diasorin	Italy	EIA	LIAISON XL 1,25 Dihydroxyvitamin D Assay
Diazyme Laboratories	U.S.	EIA	25-Hydroxy Vitamin D levels (D2 + D3 levels)
Diazyme Laboratories	U.S.	EIA	Vitamin D for Clinical Chemistry Analyzers
Gold Standard Diagnostics	U.S.	ELISA	Diasource's 25-OH Vitamin D, Total ELISA
Immunodiagnostic Systems	UK	ELISA	IDS-iSYS 1,25 VitDXp assay
QuidelOrtho (QuidelOrtho)	U.S.	EIA	VITROS 25-OH Vitamin D Total Assay
Qualigen, Inc.	U.S.	rapid	FastPack Vitamin D Immunoassay, 10-minute result
Quantimetrix Corp.	U.S.	QC	Complete D 25-OH Vitamin D Control
Roche Diagnostics	U.S.	EIA	Elecsys vitamin D Total
SCIEX	U.S.	ELISA	Vitamin D 200M Assay
Sekisui Diagnostic	Japan	POC	FastPack IP Vitamin D Immunoassay
Siemens Healthineers	U.S.	EIA	ADVIA Centaur Vitamin D Total Assay
Tosoh Corp.	Japan	EIA	ST AIA-PACK 25-OH Vitamin D assay
Zivak Technologies	Turkey	HPLC	automated Vitamin D2-D3 UHPLC analyzer

Source: Kalorama Information

Qualigen markets the CE Marked and FDA-cleared FastPack Vitamin D Immunoassay for use on its FastPack System for the rapid determination of vitamin D status. FastPack Vitamin D test results are available in 10 minutes.

NanoSpeed Diagnostics Inc. developed Test4D, a POCT device for the qualitative detection of 25-OH Vitamin D in human blood obtained via fingertip puncture.

Kalorama estimates that the world market for vitamin D tests performed on automated instruments is approximately $289 million in 2025 and that testing will remain steady, reflecting a mature market environment and an increasing number of vendors, resulting in price sensitivity among buyers.

Anemia

The hematology complete blood count is the primary tool for anemia testing; immunoassays are used as follow-on tests to further analyze the source of the patient's anemia. Anemia markers B12/folate and ferritin just about share the segment in 2025. The anemia marker immunoassay market estimated revenues for 2025 totaled $513 million. With an estimated 0.5% annual growth, the world market for anemia marker immunoassays will reach $527 million in 2030. These are now part of the menu on most automated systems. Other, more esoteric tests, such as erythropoietin, are run in ELISA format. There has not been a significant development in immunoassays for anemia primarily because the hematology CBC is the major test for anemia. Immunoassays are used to investigate cases where more intensive patient evaluation is required.

DIESSE offers two tests for Vitamin B12 and Folate. These tests are available on the CHORUS systems as monotests.

Toxicology/DAU

In the hospital setting, tests for toxicology and drugs of abuse are usually done as a panel on trauma patients brought into emergency and include: a screen for alcohol, acetaminophen, salicylates, tricyclic antidepressants and individual tests for amitriptyline, amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine and metabolites, antidepressants, LSD, methadone, methamphetamine, morphine, opiates and PCP. These same tests are used in the workplace screening and criminal justice markets. The market for these analytes is primarily

served by home testing services. These tests use hair and other noninvasive samples. The market for toxicology and drugs of abuse tests for clinical medical purposes is estimated at $333 million in 2025. This reflects a slight increase from the 2024 market. Excluding COVID-19 impact, the segment's maturity does not give credit to the growing market opportunity. The recent attention of drug addiction and increased hiring trends in major markets has increased the opportunity and growth potential.

The abuse of and addiction to opioids such as heroin, morphine, and prescription pain relievers such as Percocet (oxycodone) and Fentanyl is a serious global problem that affects the health, social, and economic welfare of all societies. It is estimated that 68 million people abused opioids worldwide in 2025

While much attention has focused on deaths from the overdose of these drugs, there is a growing problem associated with substance abuse by pregnant women and the subsequent addiction of newborns.

There is no single standardized national protocol in the United States for drug screening in pregnant women, and practices vary across states and healthcare institutions. While clinical guidelines exist, hospitals and providers differ in how they implement screening, including whether to use targeted risk-based approaches or broader screening strategies for mothers and newborns. As a result, testing methods, consent practices, and referral pathways are not fully uniform across the healthcare system.

Positive testing rates for prescription painkillers have risen dramatically over the past decade. The rates more than doubled for hydrocodone and hydromorphone and are up more than 70% for oxycodone. Pain is one of the most common reasons why people visit the doctor's office. Recently, overdose deaths from painkillers surpassed those from heroin and cocaine combined, according to U.S. federal data. U.S. physicians who prescribe medication for chronic pain are often caught in a conundrum. More and more patients are presenting with chronic pain, and at the same time, the black market for pain medicines such as oxycodone is increasing with alarm. Patients are also mixing a number of non-prescribed medicines. So, some physicians fear they will be held responsible for painkiller-overdose-related deaths and accidents.

In the past few years, there has been a growing shift from instrumented screening for DAU to testing with disposable devices, with Abbott as the market leader. The leader in

instrumented tests is Siemens Healthineers EMIT products. However just about every major immunoassay company offers tests for the basic drugs of abuse.

Thermo Fisher announced the availability of the Thermo Scientific CEDIA Mitragynine (Kratom) Assay, its newest drugs of abuse test that includes supporting calibrators and controls. The CEDIA Mitragynine (Kratom) Assay can be run on commonly used clinical chemistry analyzers. This test is for criminal justice and forensic use only. Kratom is not currently classified as a controlled substance, but it is listed by the Drug Enforcement Agency (DEA) as a "drug of concern," since it can result in severe health effects or even death.

Siemens Healthineers added fentanyl assay to its Atellica menu. The ARK Fentanyl Assay extends the detection window to provide the information clinicians need to triage their patients more appropriately. This is important because fentanyl absorption occurs at different rates depending upon the type of exposure, and during this time, a patient will typically face suppressed respiratory function and should be closely monitored.

Many of BTNX's rapid tests are lateral flow tests. The company distributes its products under the Rapid Response brand. The company provides single drug test strips for testing the presence of fentanyl and other drugs. The company also offers Xylazine Test Strips.

Hangzhou AllTest Biotech markets the AllTest Xylazine and Fentanyl Rapid Test. These are lateral-flow rapid screening tests that can be performed at the POC. The test uses monoclonal antibodies to selectively detect specific drugs.

Allergy

Allergies represent the fifth leading chronic disease in the United States, with an estimated 85 million Americans suffering from one or more allergy types. Moreover, it is estimated that 30%- 40% of the world's population is now affected by one or more allergic conditions. This will increase demand for allergy and autoimmune testing. Additionally, fewer specialists are graduating in this area. Early diagnosis and treatment of allergy have been shown to modify the course of the disease and help prevent subsequent development of other more serious conditions.

However, most allergists in the U.S test using the skin test that is not part of this market assessment. Serological allergy tests measure IgE and/or IgG immunoglobulin response to allergens. More patients are seen by family physicians that have little experience with skin

tests. The market is expected to increase by roughly 1.1% annually from $616 million in 2025 to $652 million in 2030. At least half of the market for blood-based allergy tests is held in Western Europe.

Allergy blood testing is recognized by the National Institutes of Health for managing patients with asthma. IgG reactions to food have been implicated in a number of chronic diseases, including arthritis, irritable bowel syndrome, bronchitis, and depression.

Allergies are often thought of as nothing more than a seasonal inconvenience; this is not always the case. Researchers have demonstrated a link between allergic diseases such as eczema, food allergy, otitis media, allergic rhinitis, and asthma. More importantly, these diseases are recognized as steps in the Allergy March that generally start with eczema and end in asthma. Allergy remains among the most common, yet often overlooked, chronic diseases according to the Asthma and Allergy Foundation of America.

Statistics from the Global Allergy and Asthma European Network indicate that over 80 million people are affected by some form of allergic disease in Europe. Allergy affects more than 87 million Americans and is now the third most common chronic disease among children under 18 years old.

Phadia (now part of Thermo Fisher), pioneered in vitro allergy testing and claims that seven out of ten allergy laboratory tests worldwide use Phadia's ImmunoCap products.

Food allergies are a serious condition, and peanut-free places and foods are now advertised with great frequency. Phadia has partnered with Quest diagnostics to increase the penetration of blood-based allergy testing in the U.S., where the skin test still occupies the major portion of the market.

The major allergy IVD suppliers include Thermo Fisher Scientific's Phadia ImmunoCAP platform, Siemens Healthineers' 3gAllergy specific IgE assays, and Werfen's HY·TEC allergy testing system (formerly Hycor). In addition, allergy immunoassays are available from a range of other manufacturers, including ALPCO, BioCheck, Biomerica, BMD France, DiaSys, and EUROIMMUN, which primarily serve regional and niche segments of the allergy diagnostics market.

Immunodiagnostic Systems (IDS) offers a set of allergy tests on its IDS-iSYS immunoanalyzer. PRO-LAB Inc. (Miami, FL) offers a test service to analyze allergens in vacuum cleaner dust.

HOB Biotech (Beijing, China) has established itself as a leading Chinese manufacturer of allergy immunoassays for Asian markets (Middle East, Southeast Asia, and South Asia), ranging from Line Immuno Assay (LIA) to Enzyme-linked immunosorbent assay (ELISA).

Biomerica offers the Food Intolerance 14G Food Additives Test is a food allergen-specific ELISA kit intended for in vitro quantitative analysis of IgG antibodies to 14 unique food additive allergens in human serum.

Others involved include AIBioTech and Omega Diagnostics, which offer Allergodip India, Allergodip LF IgE adapted for India. Additionally, DST offers Fast CheckPOC.

Thermo Fisher received FDA clearance to market the ImmunoCAP Specific IgE blood test for Ara h 6, part of a line of assays for detecting specific peanut allergen components. Thermo Fisher reported that results from Ara h 6 ImmunoCAP testing can aid specialists and other clinicians in better understanding patients' risk factors as part of tailored allergy treatment or management plans.

Thermo Fisher markets its ImmunoCAP test, the ImmunoCAP IgE test, which is available to more patients in the U.S., and is available to patients at all Kroger Health The Little Clinic locations.

Kenota Health offers its POC allergy test system. This is the first CLIA-waived IgE test available to allergy specialists in the office.

Growth Immunoassays

The growth categories of immunoassays include tumor markers, cardiac markers, diabetes, autoimmune disease tests and tests for sepsis.

Proteins

Most protein testing for a wide class of entities, including complement components, transport proteins, and plasma proteins, generally falls under the heading of esoteric tests and is done by nephelometric methods or RIA. These tests are used to diagnose a large number of metabolic, coagulation and malabsorption conditions. Siemens Healthineers, Bio-Rad Laboratories and Beckman Coulter are the world leaders in this segment. Roughly half of the market for these tests is in Europe, where there is a long tradition of in-depth protein analyses.

The increased use of mass spectrometry to discover more precise biomarkers for the world's major diseases, such as diabetes, cancer, and cardiovascular diseases, has placed greater emphasis on protein analysis. As part of the body's immune response to cancer, antibodies are produced to fight cancer cells. These antibodies are generated in the earliest stages of cancer. Mass spectroscopy is one of the tools used to detect these early antibodies. At this point in the research, protein patterns are emerging as a diagnostic tool. As these proteins are better defined, they will, once validated, become part of the toolbox for specific diseases.

One area of protein immunoassays includes amyloid beta testing, which is used to guide treatment of Alzheimer's disease. Alzheimer's disease protein immunoassays are highlighted in the growth immunoassay section.

Thus, there is great expectation that, in the near future, protein analysis will emerge from the esoteric realm into that of the more routine. The market for protein tests is estimated at $1,862 million in 2025 and, with an annual growth rate of 8.8%, will reach $2,840 million in 2030. This market will be driven by amyloid beta testing for Alzheimer's disease and dementia during the forecast period.

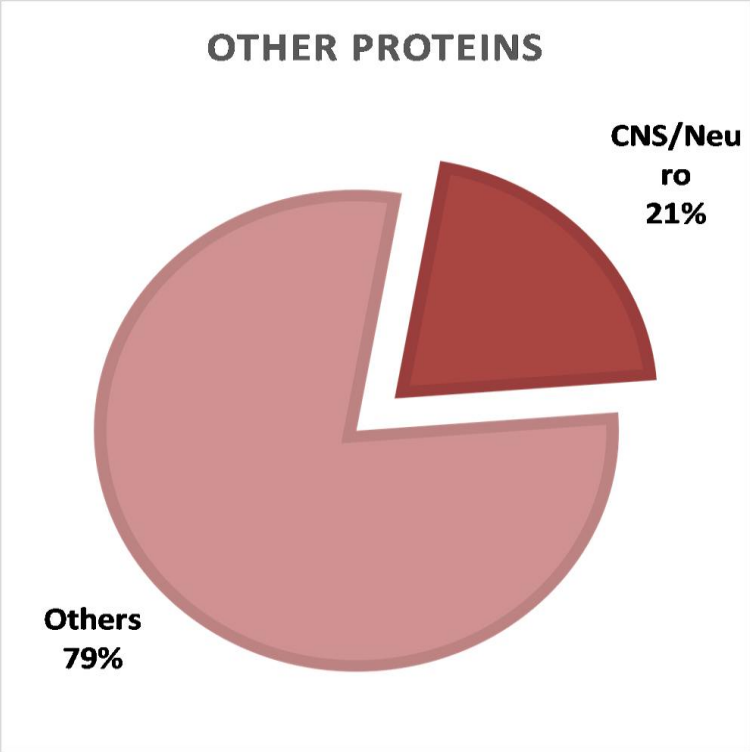
Roche markets its Elecsys pTau217 assay. This blood-based test is intended to help identify amyloid pathology in individuals with cognitive impairment or dementia, offering a less invasive approach to Alzheimer's disease evaluation than PET imaging or cerebrospinal fluid

testing. Roche is collaborating with Eli Lilly to support broader access to earlier Alzheimer's diagnosis and to align diagnostic development with emerging disease-modifying therapies.

CNS/neurological proteins total 21% of the total protein immunoassay market, reaching an estimated $400 million. Most of this is from the advancements in Alzheimer's disease testing. There have been several approvals, and lab-developed tests are also growing in this arena. The main contributor is Roche followed by Fujirebio.

It is anticipated that this area of protein immunoassays will continue to grow as more discoveries are made and technology advances.

Figure 7-1: Other Proteins, by Percent of Total, 2025 (%)



Source: Kalorama Information

Tumor Markers

Immunoassays measure antibodies produced by the body in response to cancer cells, which help prevent their growth. This early warning system has value in stratifying cancer types

and in monitoring disease progression and the effects of therapy. However, most antibodies do not provide sufficient specificity.

One cancer immunoassay continues to preoccupy science and medicine: PSA, prostate-specific antigen, a protein made by the prostate. For decades, the PSA test has been used as a marker for the presence of prostate cancer in men. High levels of PSA in the blood may indicate the presence of a prostate tumor. However, the PSA test is a nonspecific test for prostate cancer. That is, non-cancerous conditions such as an enlarged or inflamed prostate can cause elevations in PSA levels. And even when PSA levels rise above what has routinely been considered a trigger level (4.1 ng/ml in the blood), indicating the need for a needle biopsy to check prostate tissue for signs of cancer, less than half of those biopsies find cancerous cells. In addition, up to 44% of PSA-triggered biopsies find non-lethal, indolent prostate cancer cells. Indolent prostate cancer is highly unlikely to shorten the lifespan of a man. However, treatment with surgery or radiation can carry a significant risk of side effects such as incontinence or sexual dysfunction.

Immunoassays continue to play an essential role in cancer diagnostics. The 2025 market for blood-based immunoassay cancer tests is estimated at $1,533 million and, with an annual growth of 1.9%, will reach $1,685 million in 2030. This segment represents the third-largest immunoassay segment in this report.

The major innovator in cancer immunoassays is Fujirebio, which has licensed its technology to other companies in order to make its tests readily available. The company's existing CA125 biomarker is the current gold standard for monitoring ovarian cancer. Fujirebio reported that a combination of biomarkers offers clinicians a diagnostic tool with higher sensitivity and specificity than CA125 or HE4 alone.

Fujirebio’s lead test is an FDA-cleared and CE-marked test that combines HE4 and CA125 with the Risk of Ovarian Malignancy Algorithm (ROMA). The test is offered as a test service by Labcorp and other labs and is available on integrated analyzers from Abbott Diagnostics. Companies, including Abcodia (UK), and Roche Diagnostics (U.S.), market improvements for ovarian cancer diagnosis.

Just about every major IVD company and ELISA system vendor offers the standard tumor marker tests. Some 80% of the market for tumor markers is held in the U.S., Europe and Japan.

Alongside advances in molecular diagnostics and liquid biopsy, there is continued interest in developing new approaches to cancer testing. Mass spectrometry is being explored as a complementary tool, particularly in proteomic analysis and biomarker discovery, with some applications available through specialized testing services and others still in development. At the same time, there is a growing focus on assessing immune response to therapy, especially in immuno-oncology. This includes measuring T-cell activity and related biomarkers using a combination of immunoassays and other advanced techniques, supporting efforts to better understand treatment response and guiding patient management.

The MasSpec Pen is a tool that rapidly and accurately identifies cancerous tissue during surgery. It is a handheld instrument that provides surgeons with information on which tissue to preserve or cut. This device is in development by scientists at the University of Texas at Austin.

Scienion entered into a collaboration with IPA to develop UROfast, a rapid bladder cancer diagnostic platform. The collaboration is ongoing and designed to detect multiple biomarkers at the point of care.

INEX Innovate, a Singapore-based diagnostic company, offers its lead ovarian cancer product, OvaCis Rapid Test. OvaCis is a POC test that differentiates benign from malignant ovarian cysts in the operating room. The test works by identifying a protein biomarker present in ovarian cysts to determine whether the cyst is benign or malignant within five minutes. The entire test provides results within 15 minutes. The test allows surgeons to make fast, informed decisions about the patient's status.

Promis Diagnostics offers EarlyTect BCD as a non-invasive, urine-based diagnostic for bladder cancer in patients with hematuria.

Anbio offers its Anbio Lateral Flow Assay, which utilizes the immunochromatography principle to visually detect a specific biomarker in a sample. It can generate results in about 20 minutes.

Table 7-9: Selected Tumor Marker Innovations

Company	Location	Area	Details
Arrayit/Avant Diagnostics	U.S.	immune resp	OvaDx cancer immune response
Barts Cancer Institute	UK	pancreas	LYVE1, REG1A, TFF1 early pancreatic cancer
Binding Site (Thermo Fisher)	UK	immunoglobulin	Freelite in 2017 Chinese Myeloma Guidelines
Binding Site(Thermo Fisher)	UK	immunoglobulin	Hevylite IgA, SPAPLUS Multiple Myeloma
Biocare Medical	U.S.	p63	AsymmetRx's (Acton, MA) p63 antibody, prostate
BioLight Life Sciences	Israel	bladder	CellDetect bladder cancer in urine, colorimetric cells
BioNTech Diagnostics	Germany	immune resp	PCRTyper, to monitor T cells immune response
Euro Diagnostica AB	Sweden	endocrine	NEOLISA CgA, ELISA neuroendocrine tumors
Genalyte Inc.	U.S.	immune resp	tumor antigen-associated autoantibodies, immune response
Immunovia	Sweden	immune resp	IMMray PanCan-d pancreatic cancer
Integrated Diagnostics	U.S.	pan cancer	multiple protein expression classifier
Labcorp	U.S.	ovarian	ROMA, Risk of Ovarian Malignancy Algorithm
Minomic International	Australia	prostate	MiStat MIL-38 marker prostate cancer in urine
QuidelOrtho	U.S.	prostate	VITROS Total PSA Assay II
OTraces, Inc.	U.S.	prostate	BC Sera Dx panel for breast, prostate
Provista Diagnostics, Inc.	U.S.	breast	proteomic breast cancer assay
Quansys Biosciences	U.S.	EIA	Q-Plex Array, chemiluminescent assays
Quanterix Corp	U.S.	digital ELISA	digital Elisa cancer proteins
Quest Diagnostics	U.S.	TDM	tamoxifen drug metabolites in a blood specimen
Randox Laboratories	UK	bowel	bowel cancer antibodies, biochip array
Roche Diagnostics	U.S.	ovarian	Elecsys HE4 assay, ovarian cancer
ScheBo-Biotech AG	Germany	FOB	ScheBo · 2in1 Quick test, screen, M2-PK & iFOBT

Company	Location	Area	Details
Sequenta, Inc.	U.S.	T/B cells	ClonoSIGHT MRD minimal residual disease, leukemia, lymphoma
Siemens Healthineers	U.S.	liver	ADVIA Centaur enhanced liver fibrosis (ELF) panel
Sphingotec GmbH	Germany	breast	sphingotest pro-NT, neurotensin breast cancer screen service
Theranostics Health Inc.	U.S.	breast	TheraLink HER Family Assay, signal transduction pathway, breast
Tosoh	Japan	liver	ST AIA-Pack PIVKA II, liver cancer marker
Vigilant Biosciences	U.S.	oral fluid	OncAlert Oral Cancer CD44/Total Protein
VolitionRx	Belgium	nucleosomes	NuQ Nucleosomics ELISA colon, prostate & ovarian cancer
XEMA Corporate Group	Russia	ovarian	XEMAtest Ovascreen, test strip, CA125 and HE4
University of Texas	US	tissue	MasSpec Pen to detect cancer by touch

Source: Kalorama Information

Cardiac Markers

The World Health Organization estimates that cardiovascular diseases, including those of the blood vessels supplying the heart muscle and the brain, are the leading cause of death globally.

With the incidence of cardiovascular disease going through the roof, cardiac markers are in huge demand and a constant subject of research for improvement. Cardiac biomarkers are substances that are released into the bloodstream when the heart is damaged or stressed. In patients with chronic heart failure, measurement of these biomarkers is used to help risk-stratify, to assess treatment options, monitor progress, and guide in-hospital and post-discharge care.

Physicians use cardiac markers in two ways: to diagnose a cardiac event in a hospital emergency room or to evaluate the risk of a cardiovascular event. The traditional markers, such as BNP, troponin, and myoglobin, are used in acute care, and tests such as cholesterol are used to evaluate risk.

The menu of biomarkers for cardiac risk is multidisciplinary and includes troponins (cTnI and cTnT), BNP, NT-proBNP, GFAP, H-FABP, LDH isoenzymes, IMA, MPO, myoglobin, and sCD40L. Recent studies suggest that new biomarkers show promise for enhancing traditional methods of diagnosing and managing heart failure (HF). These biomarkers include cardiac troponin, Galectin-3, Copeptin, ST2 and MR-proADM.

Recognizing the multifaceted nature of cardiac disease, a cardiac risk work-up generally includes a mix of lipid and inflammatory markers: cholesterol, HDL and LDL, homocysteine, fibrinogen, C-reactive protein, lipoprotein fractions, and D-Dimer Test.

The lead acute care cardiac markers are troponin, BNP, and myoglobin. Together, these tests account for about 75% of the segment, which is worth $1,867 million in 2025. The market is expected to increase to $2,170 in 2030, representing 3.1% CAGR.

An aging population, combined with technological advancements, is fueling this growth as health care providers seek ways to meet demand for high levels of service more cost-effectively.

Approximately 2.6 million people die of CVD each year in the seven leading countries: France, Germany, Italy, Japan, Spain, the UK, and the U.S. Thus, the market for CVD tests is concentrated in the developed world. One can therefore expect that these countries account for roughly 80% of product sales, with the ROW accounting for the remaining 20%. The U.S. and Canada make up 45%, EU countries 27% and Japan 8%.

Table 7-10: Regional Cardiac Marker Immunoassay Market Share, by Country, 2025 (%)

[EU Countries; Japan; Latin America; Middle East; North America; Rest of Asia Pacific; Rest of Europe; Rest of World]

Region	2025
North America	45%
EU Countries	27%
Japan	8%
Rest of Asia Pacific	7%
Latin America	4%
Middle East	4%
Rest of Europe	3%
ROW	2%
Total	**100%**

Source: Kalorama Information

A number of new and developing markers are in the works. It is possible that new cardiac panels will emerge, which combine markers of inflammation, ischemia, plaque instability and necrosis.

At this time, troponin is attracting considerable attention. Not too long ago, the debate was quite simple: troponin I or troponin T. But the limitation of conventional troponin assays is their low sensitivity, so cardiac troponin (cTn) has been developed. The process of necrosis is not immediate in response to ischemia, and once necrosis occurs, it usually takes 1–4 hours for cTn to increase in the circulation before becoming detectable in the blood. This timing varies due to differences in the analytical sensitivity of cTn assays. Physicians from the Department of Cardiology at University Hospital Basel (Basel, Switzerland) pioneered rapid diagnostic algorithms for acute myocardial infarction (AMI), most notably the 0/1-hour rule-out and rule-in protocol using high-sensitivity cardiac troponin (hs-cTn). Their work demonstrated that measuring the absolute change in hs-cTn concentrations over one hour, rather than relying solely on a single cutoff value, allows clinicians to safely rule out AMI in

a substantial proportion of emergency department patients while rapidly identifying others who require immediate intervention.

These findings fundamentally changed emergency cardiac care and have been incorporated into ESC and international clinical guidelines, significantly reducing time to diagnosis, length of stay in the emergency department, and unnecessary hospital admissions.

High-sensitivity troponin assays are compatible with existing core laboratory immunoassay platforms, enabling laboratories to adopt the technology without major workflow disruption. In response to the clinical evidence, IVD manufacturers have commercialized multiple high-sensitivity troponin assays that are now widely used in routine care.

Currently available high-sensitivity troponin assays include:

- Abbott Laboratories – ARCHITECT and Alinity hs-Troponin I, CE-marked and FDA-cleared, supporting 0/1-hour and 0/2-hour AMI algorithms
- Roche Diagnostics – High-Sensitivity Troponin T, CE-marked and FDA-cleared, extensively validated in ESC rapid triage protocols
- Siemens Healthineers – Atellica IM and ADVIA Centaur hs-Troponin I, CE-marked and FDA-cleared

Earlier-generation assays such as Troponin I Ultra have largely been supplanted by true high-sensitivity assays, which offer superior analytical precision at very low troponin concentrations and enable reliable detection of small dynamic changes over short time intervals. differences in patients' physiology.

Cardiac markers have been expanded with tests such as myeloperoxidase, brain natriuretic peptide (BNP), proBNP, becoming part of the acute care test menu and tests such as highly sensitive C-reactive protein, homocysteine, Fatty Acid Binding Protein, Glycogen Phosphorylase isoenzyme BB (GPBB), urinary albumin, S-100 protein and hemoglobin A1c are now part of the risk evaluation toolbox.

Thus, the cardiac test toolbox may include C-reactive protein and N-terminal pro-B-type natriuretic peptide, which have been extensively studied in cardiovascular disease, and four analytes that have recently been identified as related to cardiovascular risk, including Cystatin C, Lp-PLA2, MR-proADM, and MR-proANP.

Biomarkers, MR-proADM, MR-proANP, and CT-proET1 measure inactive stable precursors of their respective peptide hormones. Adrenomedullin (ADM) is a hemodynamically active vasodilatory hormone. Its precursor, MR-proADM, is elevated in chronic heart failure. Atrial Natriuretic Peptide (ANP) is a diuretic, natriuretic and vasodilatory peptide hormone produced in the upper chambers (atria) of the heart. MR-proANP could potentially be used for disease prognosis. Endothelin-1 is a potent vasoconstrictor produced by vascular endothelial cells. Thermo Fisher Scientific is developing a test for MR-proADM, MR-proANP, and CT-proET1.

There have been incremental improvements in heart disease detection. Novel markers such as ST2, galectin, PAPP-A and PGF, may improve the risk stratification and prognostic assessment. Heart-type fatty acid-binding protein(h-FABP) was first noted as a marker of myocardial infarction in 1988. Over the years, numerous studies have been relatively inconclusive in h-FABP's ability to predict long-term mortality after acute coronary syndrome and to identify high-risk patients. The marker faces an uphill battle in proving itself as a valuable addition to the acute care test menu that includes Troponin, BNP and myoglobin.

Surfactant Protein-B (SP-B) is a lung-specific protein and a key functional component of the alveolus. SP-B is present at very low concentrations in the serum of healthy people. It is released into the bloodstream following lung injury and is significantly elevated in primary and secondary lung disorders that mainly affect the lung parenchyma. This includes the alveolocapillary system, such as chronic obstructive pulmonary disease, acute respiratory distress syndrome and heart failure. Changes of lung disorders can be monitored by measuring levels of SP-B in the blood. Roche Diagnostics acquired a license to develop tests for SP-B and suggests that, together with BNP or NT-proBNP) tests, SP-B helps to discriminate between cardiac and non-cardiac causes of dyspnea.

The soluble β-galactoside-binding lectin, galectin-3, is elevated in a substantial portion of patients with heart failure, especially those with more severe disease and renal dysfunction. Increased levels of circulating galectin-3 may reflect the severity of active myocardial remodeling and adverse outcome as galectin-3 regulates fibrogenesis, inflammation, tissue repair, and cell proliferation.

Galectin-3 has been implicated in a variety of biological processes important to the development and progression of heart failure. Higher levels of galectin-3 are associated with a more aggressive form of heart failure, which may make identification of high-risk patients

using galectin-3 testing an important part of patient care. Galectin-3 testing may help physicians identify patients at higher risk of death, hospitalization, or 30-day readmission.

Critical Diagnostics markets the Presage ST2 Assay. It is the only commercially available ST2 biomarker that has been CE Marked and cleared by the U.S. FDA for use in risk stratification of patients with chronic heart failure. ST2 is a member of the interleukin -1 receptor family, whose expression in heart cells is upregulated in response to stress. Large amounts of soluble sST2 result in adverse cardiac remodeling, heart failure, and premature death. Clinical studies have further shown that sST2 prognostic information is independent of, and adds value to, that of commonly used cardiac biomarkers.

Coronary artery disease results when plaque grows in the arteries until blood flow to the heart is constricted and if enough plaque builds up, a piece could break off and block blood flow to the heart, which results in a heart attack or stroke. Researchers at the University of Nebraska, while seeking clues to understand inflammatory conditions such as arthritis and alcoholic liver disease, focused on a molecule that is a strong indicator of inflammation. The molecule, known as malondialdehyde–acetaldehyde (MAA), also appeared to indicate the presence of coronary artery disease. The University of Nebraska Medical Center's technology transfer office, UNeMed Corporation, is collaborating with several companies to translate the results into products that better account for a patient's risk of heart attack. The scientists hope the test could be used to definitively inform younger patients in their forties, thirties, or even their twenties, whether or not they will develop potentially fatal heart disease. The physicians suggest that even patients who are still teenagers could receive early warnings and begin taking preventive measures.

Originally thought of as "a cholesterol-fueled, plumbing problem", atherosclerosis is now understood as a chronic inflammatory disease. This shift has prompted a search for new biomarkers of inflammation that predict cardiovascular event risk.

Radiometer's POC AQT90 FLEX can simultaneously measure cardiac markers, coagulation markers, infection markers, and pregnancy markers, including troponin I, CKMB, myoglobin, NT-proBNP, CRP, βhCG, D-dimer, and troponin T. In 2016, Radiometer added procalcitonin and creatinine to the test menu.

The AQT90 FLEX PCT assay offers laboratory-quality, quantitative determination of procalcitonin in whole blood or plasma at the point of patient care. Prehandling of whole blood samples is not required and results are available in less than 21 minutes.

Ani Biotech Oy offers the Biocard Troponin I test, which is a one-step immunochromatographic assay for the rapid detection of cardiac specific troponin I from patient whole blood samples. The company also offers myoglobin, MPO, hsCRP, quantitative reader, and CRP cardiac marker tests.

Siemens Healthineers offers the Stratus CS analyzer for near-patient care quantitative cardiac marker testing from a whole blood sample in 14 minutes. The company also offers myoglobulin, CK-MB, and cardiac troponin I tests

Table 7-11: Selected Cardiac Marker Innovations

Company	Location	Area	Details
Abbott Diagnostics	U.S.	galectin	Architect galectin-3 on analyzers
ALPCO Diagnostics	U.S.	RIA	Cisbio Bioassays, Renin RIA, hypertension
Beckman Coulter/Danaher	U.S.	troponin	Access AccuTnI+3 troponin I
Beckman Coulter/Danaher	U.S.	PAPP	plasma protein-A (PAPP-A)
Diasorin S.P.A	Italy	aldosterone	Liaison Aldosterone, hypertension
Diazyme Laboratories	U.S.	myoglobin	Myoglobin latex-enhanced immunoturbidimetric
DRG International	U.S.	renin	DRG Renin
GD Biosciences	U.S.	risk	Cardiac PLUs early cardiac risk, asymptomatic
HealthMed Holdings	Qatar	inflammation	Myocardial Assessment Profile, inflammation
Immunodiagnostic Systems	UK	renin	IDS-iSYS Direct Renin
Nanomix Inc.	U.S.	panel	Omega-3 Cardiac Panel, cTnI, myoglobin, H-FABP
Olink Bioscience	Sweden	panel	Proseek Multiplex CVD II and CVD III panel, protein markers
R&D Systems	U.S.	corin	Quantikine Human Corin Immunoassay, atrial fib
Randox Laboratories	Ireland	sPLA2	Aterovax's Phospholipase A2 (sPLA2), cardiac risk
Randox Laboratories	UK	aspirin PGx	automated urine 11dhTxB2
Randox Laboratories	UK	H-FABP	H-FABP assay, Heart-type Fatty Acid Binding Protein
Singulex	U.S.	panel	Sgx Clarity troponin, BNP, endothelin
Sphingotek GmbH	Germany	panel	sphingotest penKid and sphingotest bio-ADM

Source: Kalorama Information

Cardiac biomarkers are substances that are released into the bloodstream when the heart is damaged or stressed. In patients with chronic heart failure, measurement of these biomarkers is used to help risk-stratify, assess treatment options, monitor progress, and guide in-hospital and post-discharge care.

But the goal is to detect heart disease risk before events occur. Screening comprised a standard examination of blood pressure, an electrocardiogram, an oral glucose tolerance test, a lung function assessment, and measurements of height, weight, waist, and hip circumference.

Several research studies have shown that this systematic screening and repeated lifestyle intervention do not reduce the 10-year incidence of cardiovascular disease in the general population. There is a large unmet clinical need for biomarkers that can identify patients along the spectrum of heart failure progression from disease risk in apparently healthy individuals to symptomatic heart failure.

Beckman Coulter markets the Access NT-proBNP assay for the assessment of heart failure in less than 11 minutes. The test is run on the Dxl 9000 Immunoassay Analyzer. The Access NT-proBNP assay helps to identify patients with acute heart failure.

Autoimmune

Autoimmune diseases occur when the immune system mistakenly recognizes the body's own proteins as foreign invaders and produces antibodies that attack healthy cells and tissues, leading to a variety of diseases.

There are at least 80 clinically distinct autoimmune diseases, including insulin-dependent diabetes mellitus (type 1 diabetes), multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis, inflammatory bowel disease, psoriasis, uveitis, and autoimmune thyroid disease. Autoimmune diseases collectively affect approximately 5% to 10% of the population of the developed world.

NIH estimates up to 23.5 million Americans have an autoimmune disease. And in fact, of the 50 million Americans living and coping with autoimmune disease (AD), more than 75 percent of them are women. In Europe, some 20 million people are thought to have an autoimmune disease.

Autoimmune diseases were perceived as a relatively small and esoteric segment of the in vitro diagnostic market. Recent scientific discoveries, however, are finding autoimmune characteristics in many of the more common diseases, such as arthritis, liver disease, atherosclerosis, celiac disease, diabetes, antiphospholipid syndrome, and vasculitis, among others.

There are more than 80 different types of autoimmune disorders and diagnosis is a complex process. Focusing on the allergy and autoimmune markets provides important synergies as the diagnostics for these disease categories share commonalities such as platform, assay development and manufacturing, and also target the same end user and areas of the laboratory.

In 2025, the market for immunoassay-based autoimmune disease marker test kits is estimated at $955 million worldwide and is projected to reach $1,030 million by 2030. The leading companies are Werfen, Bio-Rad Laboratories and Thermo Fisher Scientific.

But as common as autoimmune disease may seem, scientists face many diagnostic challenges. The NIH (National Institutes of Health) reports that autoimmune disease medicine is not well defined, in spite of the fact that many people are affected.

Autoimmune diseases include:

- multiple sclerosis
- juvenile diabetes
- rheumatoid arthritis
- scleroderma, lupus
- Sjogren's disease
- Graves' disease.

This is a growing field of medicine that involves the use of many different analytes. A positive ANA test is a screen for an autoimmune condition. Because manifestations of autoimmune disease can be very nonspecific, the diagnosis is often difficult. Several different laboratory tests are used to identify autoimmune disease, including antinuclear antibodies, rheumatoid factors, erythrocyte sedimentation rates, or C-reactive protein and anticytoplasmic nuclear antibodies.

The ANA assay is the first test typically run if an autoimmune disease is suspected. The immunofluorescence assay is the gold standard for ANA testing. However, IFA, as it is currently practiced in many laboratories, is time- and labor-intensive and subject to interpretation, since ANA screening by IFA requires visual interpretation of the stained pattern under a microscope. The test is performed by a specifically trained technician. Therefore, laboratories have increasingly been shifting to ELISA because it automates and standardizes the ANA test.

Werfen has been an important contributor to the modernization of ANA testing using indirect immunofluorescence (IFA). Through its NOVA View automated IFA microscopy platform, the company has helped move ANA testing from a fully manual, reader-dependent process toward a semi-automated digital workflow. The system integrates slide scanning, image capture, pattern recognition support, and result archiving, improving throughput, consistency, and traceability while reducing inter-observer variability. As a result, automated IFA systems are increasingly used to support IFA's role as the reference method for ANA testing and to help laboratories address ongoing staffing and efficiency challenges.

At the same time, the market continues to see rapid growth in decentralized, automated autoimmune testing formats, particularly in rheumatology and plasma cell disorder assessment. Orgentec Diagnostika offers lateral flow assays for anti-mutated citrullinated vimentin and rheumatoid factor, supporting faster turnaround times and expanded testing outside high-complexity core laboratories. These assays complement automated laboratory testing by enabling quicker initial screening or follow-up in specific clinical settings.

Similarly, Abingdon Health addresses unmet needs in plasma cell dyscrasia testing with Seralite-FLC, a rapid serum assay for free light chains (kappa and lambda). The test provides quantitative ratios in a shorter timeframe than traditional immunonephelometric methods, aligning with market demand for faster results, simplified workflows, and near-patient testing capability.

The next step in automation is multiplex systems for the simultaneous measurement of autoantibodies based on microspheres beads coated with specific antigens and flow cytometry detection. These tests have been available since early 2000s. Multiplex ANA tests usually detect the most common autoantibodies including: dsDNA, Chromatin, Ribosomal protein, SS-A (52 and 60), SS-B, Sm, Sm/RNP, RNP (A and 68), Scl-70, Jo-1 and Centromere B antibodies. With this method ANA screen reports show the actual levels of individual analytes. Here too, further confirmation can be made using the IFA method.

These multiplexed tests are closed system tests run on a company's test kits run on a proprietary flow cytometer such as the Luminex xMAP system. Inova Diagnostics (Werfen), Zeus Scientific, Bio-Rad Laboratories and Biomedical Diagnostics market the leading bead-based multiplexed autoimmune tests.

Thermo Fisher Scientific offers the ImmunoCAP IgE test, a widely used laboratory-based assay for allergy diagnostics. The company has expanded access to this testing in the United States through collaborations with retail health providers, including Kroger Health's The Little Clinic, which offers allergy testing in select locations. These efforts aim to improve patient access to diagnostic testing outside traditional laboratory settings.

Augurex Life Sciences markets SPINEstat, a blood test that detects auto-antibodies to the 14-3-3eta protein. This blood test will assist in the diagnosis of axial spondyloarthritis, which is a chronic inflammatory disease that causes persistent back pain.

Table 7-12: Selected Autoimmune Test Innovations

Company	Location	Technology	Details
AliveDx	US	IFA	LumiQ IFA
Binding Site (Thermo Fisher)	UK	automation	Optilite, automation for Freelite & Hevylite
Binding Site	UK	EIA	Optilite IgG, IgA, IgM, albumin, CSF & CSF/serum
Biomerica	U.S.	PGx	Thiopurine methyltransferase PGx, thiopurine drugs
EUROIMMUN AG	Germany	IFA	EUROPattern system ANA IFA IT
Genalyte Inc.	U.S.	EIA	Maverick diabetes & autoimmune assays
HUMAN Diagnostics	Germany	ELISA	HUMAN IMTEC, Phospholipid Screen ELISA
Inova Diagnostics (Werfen)	U.S.	ELISA	QUANTA Lite Calprotectin, fecal ELISA
Inova Diagnostics (Werfen)	U.S.	EIA	Quanta Flash extractable nuclear antigen tests
Inova Diagnostics	U.S.	EIA	Quanta Flash Beta-2 Glycoprotein1
Inova Diagnostics	U.S.	digital IFA	NOVA View, automated digital IFA microscope
Inova Diagnostics	U.S.	automation	NOVA Lite DAPI ANA Kit, automated
Kronus Inc.	U.S.	ELISA	Glutamic Acid Decarboxylase Autoantibody
Miraca Life Sciences	U.S.	PGx	Theradiag's (France) LISA TRACKER assays
Orgentec Diagnostika (Sebia)	Germany	ELISA	ELISA tests autoimmune liver diseases, automated
Protagen Diagnostics	Germany	EIA	SeroTag markers for autoimmune diseases
Protagen Diagnostics	Germany	EIA	SeroTag Multilisa BICD2, systemic sclerosis
Protagen Diagnostics	Germany	EIA	with Qiagen SeroTag autoimmune tests
Theradiag	France	PGx	10 LiSA TRACKER autoimmune CDX

Source: Kalorama Information

Rheumatoid Arthritis

The most prevalent autoimmune disease is rheumatoid arthritis (RA). Rheumatoid arthritis occurs when, during inflammation, certain proteins are altered through a process known as citrullination. These modified proteins can induce an immune response in the body, whose antibodies can turn on themselves. Multiple studies have demonstrated that patients with rheumatoid arthritis are positive for rheumatoid factor and/or antibodies to citrullinated protein antigens from 2 to 10 years before symptoms appear.

Approximately 350 million people worldwide have arthritis. Over 40 million people in the United States are affected by arthritis, including over a quarter of a million children. More than half of those with arthritis are under 65 years of age.

Arthritis is a systemic disease and can significantly damage other parts of the body as well, resulting in infection, osteoporosis and cardiovascular disease, a leading cause of death for arthritis patients. Rheumatoid arthritis is a particularly debilitative form of arthritis that, if left untreated, results in 70% of patients developing irreversible joint damage within 2 years of symptom onset.

RA patients may experience difficulties with everyday tasks and restricted work options. Thus, RA has significant health economic implications. Early intervention gives immediate patient benefit and reduces healthcare costs. There are many obstacles in the diagnosis and monitoring of arthritis, including an incomplete understanding of disease pathogenesis, changes in physician behavior, and acceptance of costs by health insurers.

The consensus in the medical community is that early and accurate stratification of patients with arthritis, followed by frequent monitoring and responsive therapeutic adjustments, is critical to improving clinical outcomes. However, it can be difficult for a primary care physician to diagnose because the joint pain symptoms are common to other conditions. The U.S. Centers for Disease Control and Prevention stated that, while the cause of RA remains unknown, it may result from a combination of genetic and environmental factors. Age and sex, genetics, smoking, oral contraception, and lack of exercise are some risk factors.

Despite significant progress in the treatment of rheumatoid arthritis over the last 10 years, many patients remain partial responders and true remission is rarely achieved. A major goal is to develop precision tests for arthritis that can predict treatment response prior to initiating arthritis therapy.

Initiatives are underway, led by the American College of Rheumatology and the European League Against Rheumatism, to establish quantitative objective indicators of disease activity to assist in routine clinical practice and for outcome measures in clinical trials.

By studying biological samples from RA patients, RA-MAP (www.ra-map.com) aims to develop an immunological toolkit to measure the immune status of healthy individuals and patients.

The MATURA consortium is a UK-based stratified medicine research initiative focused on improving treatment selection for people with rheumatoid arthritis (RA). MATURA aims to identify biological and molecular predictors of treatment response, enabling patients to be allocated early in the disease course to therapies they are most likely to benefit from.

The consortium is funded primarily by the Medical Research Council (MRC) and Versus Arthritis (formerly Arthritis Research UK). MATURA brings together a large collaborative network of academic research groups and industry partners, coordinated through Queen Mary University of London, with clinical and translational research activity spanning multiple UK centers.

MATURA investigates genetic, transcriptomic, cellular, and protein biomarkers in blood and synovial tissue to understand why individual patients respond differently to disease-modifying antirheumatic drugs, biologics, and targeted therapies. By linking molecular signatures to clinical outcomes, the consortium seeks to reduce trial-and-error prescribing, shorten time to disease control, and improve long-term outcomes in inflammatory arthritis.

Overall, MATURA represents a major UK initiative in precision and stratified medicine for rheumatoid arthritis, providing a framework for biomarker-guided therapy selection and accelerating the translation of discovery science into clinically actionable diagnostics.

A number of targeted drugs are used in the most severe cases, including anti-TNF-α agents (infliximab, etanercept, and adalimumab), treatments directed against IL1 (anakinra), a CTLA4-directed T-cell modulator (abatacept), and a monoclonal antibody against CD20 that serves as a B-cell modulator (rituximab).

These emerging therapies offer great promise as well as challenges. They will likely be expensive and not uniformly effective. The need to identify biomarkers of treatment response and toxicity specific to the various agents will greatly enhance the ability to tailor treatment to individual RA patients.

Early diagnosis is a key to effective treatment options. Tests that detect antibodies to citrullinated proteins are already being used to diagnose RA.

Physicians commonly use a combination of clinical assessment, X-rays, and laboratory tests to help determine the risk of progression of structural damage. Serologic factors, including rheumatoid factor (RF), anti-CCP antibodies, and an elevated baseline erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, are associated with disease course. None of these tests provides patient-specific information.

The diagnosis of arthritis today is based on a scoring system for affected joints, symptom duration, general markers of inflammation, and the two specific markers, RF and anti-CCP. Research has shown that approximately one-third of RA patients are negative for the two serological markers that are predominantly used in the diagnosis of RA: rheumatoid factor (RF) and anti-cyclic citrullinated peptides (CCP). While third-generation CCP assays (CCP 3.0 and CCP 3.1) have increased sensitivity in early disease, some RA patients remain seronegative.

Researchers at Hasselt University conducted a study to identify novel autoantibody markers to improve the diagnosis of seronegative and early-stage rheumatoid arthritis. The research addressed a key unmet need in RA diagnostics, as approximately one-third of RA patients test negative for established serological markers, including rheumatoid factor (RF) and anti-citrullinated protein antibodies (anti-CCP).

Investigators have identified several novel autoantibody biomarkers that may have diagnostic value in early rheumatoid arthritis, including in patients who are seronegative by conventional testing. In research settings, combining these emerging markers with established tests such as rheumatoid factor and anti-CCP has shown potential to improve overall diagnostic sensitivity compared with standard serology alone.

Further work is underway to validate these findings in larger patient populations and to assess whether these biomarkers could also help predict disease progression or response to therapy. While these markers are still in the research and early translational stage, they highlight the potential of expanded autoantibody panels to address diagnostic gaps and support earlier identification of rheumatoid arthritis.

A novel biomarker for rheumatoid arthritis has significant potential to help physicians better identify early-stage disease when treatment can often arrest further disease progression and disability. Researchers found that elevated levels of the 14-3-3eta protein outperformed

conventional antibody testing, including rheumatoid factor alone and anti-citrullinated peptide antibodies alone, in identifying RA. A test for 14-3-3eta protein is offered as a lab-developed test by Quest diagnostics under a license from Augurex Life Sciences Corporation.

Table 7-13: Selected Arthritis Immunoassay Innovations

Company	Location	Details
Aesku Diagnostics	Germany	AESKULISA MMP-3, marker for RA
Augurex Life Sciences	Canada	14-3-3eta biomarkers for rheumatoid arthritis
Exagen Diagnostics, Inc.	U.S.	Avise MTX, methotrexate resistance
Gold Standard Diagnostics	U.S.	Axis-Shield's Anti-CCP2
Orgentec Diagnostika (Sebia)	Germany	Anti-MCV ELISA, autoantibodies mutated citrullinated vimentin
Oxford University	UK	protein tenascin-C arthritis risk marker
Quest Diagnostics	U.S.	RA panel: Augurex's 14-3-3eta, RF, anti CCP
Siemens Healthineers	U.S.	Immulite anti-CCP IgG, arthritis
Werfen	U.S.	rheumatoid arthritis autoantibodies

Source: Kalorama Information

The RA diagnostics market is evolving from single-analyte serology toward expanded autoantibody and biomarker panels that support earlier diagnosis, risk stratification, and therapy selection, particularly in seronegative and early RA populations.

Gastrointestinal Disorders

Inflammatory bowel diseases (IBD), including Crohn's disease, celiac disease, and ulcerative colitis, are chronic inflammatory conditions of the intestinal tract. The conditions can be difficult to diagnose and manage clinically while consuming a substantial amount of healthcare resources in terms of physician time, procedures and medications.

Inflammatory bowel diseases (IBD) affect approximately 1.6 million Americans, or 1 in 200 people, with the incidence evenly split between ulcerative colitis and Crohn's disease. An

estimated 2.5–3 million people in Europe are affected by IBD, with a direct healthcare cost of 4.6–5.6 billion Euros/year. IBD affects men and women equally and can strike at any age. While both inflammatory bowel diseases have similar symptoms, including diarrhea, abdominal pain, weight loss, and fatigue, Crohn's disease can affect any part of the GI tract, whereas ulcerative colitis is limited to the colon. Although considerable progress has been made in IBD research, investigators do not yet know what causes IBD. There is currently no medical cure for ulcerative colitis or Crohn's disease.

Current methods for the initial clinical diagnosis of colitis and Crohn's remain challenging. Healthcare providers primarily rely on colonoscopies and biopsies. The development of a stool-based diagnostic test for IBD provides a non-invasive, cost-effective alternative.

Researchers have found that high levels of serologic markers of inflammation are present in the circulation of patients who go on to develop inflammatory bowel disease many years before symptoms appear.

Calprotectin is released in large quantities by granulocytes during inflammatory processes and fecal calprotectin is an established marker of intestinal inflammation. The determination of calprotectin in stool is, therefore, ideal for the differentiation of inflammatory and functional gastrointestinal diseases. Monitoring fecal calprotectin concentrations in patients with inflammatory bowel syndrome is also a reliable tool for assessing the efficacy of TNFα blocker therapy. Elevated levels are an early and reliable indicator of a relapse in IBD patients.

Prometheus Laboratories suggests that a Calprotectin test, together with a TNFα blocker monitoring test, is a powerful toolbox for diagnostics and therapeutic control in IBD patients. This research was unable to quantify the market for GI tests with certainty.

DiaSorin offers a range of gastrointestinal assays on its LIAISON platform, including tests for Helicobacter pylori and Clostridioides difficile GDH and toxins A/B, with additional assays supporting the detection of enteric pathogens such as enterohemorrhagic Escherichia coli. These tests are performed on fully automated immunoassay systems designed to support routine laboratory workflows. However, fully automated platforms for infectious disease and gastrointestinal testing are widely available across the industry, and similar capabilities are offered by multiple diagnostic companies.

Table 7-14: Selected Inflammatory Bowel Disease Test Innovations

Company	Location	Details
ALPCO Diagnostics	U.S.	Portfolio of stool-based gastroenterology assays
Biohit Oyj	Finland	GastroPanel on Dynex ELISA systems
Biomerica	U.S.	Transglutaminase IgA ELISA, celiac disease
Biomerica	U.S.	Antigliadin IgA/IgG ELISA, celiac disease
Euro Diagnostica AB (Svar Life Science)	Sweden	Wieslab Celiac hs Screen, gliadin, celiac disease
Preventis GmbH	Germany	PreventID CalScreen, calprotectin in stool, IBD
Prometheus Biosciences	U.S.	Anser IFX test, infliximab drug antibody
Quanterix Corp	U.S.	TNF- and IL-6 concentration, Crohn's disease
Randox Laboratories	Ireland	Biohit's GastroPanel, gastric disorders
Theradiag	France	LIS TRACKER Certolizumab and Vedolizumab, IBD

Source: Kalorama Information

The GI and IBD diagnostics market continues to evolve toward non-invasive stool biomarkers, multiparametric serologic panels, and therapeutic drug monitoring to support precision management of chronic gastrointestinal disease, particularly IBD and celiac disease.

Transplant Management

Organ transplants have saved more than 2 million years of life in the United States over 25 years. However, less than half of the people who needed a transplant in that time period got one, because of a shortage of donors.

Nearly 48,149 organ transplants were performed in the United States in 2024. They routinely extend lives, but the success of these procedures remains limited by complications, including rejection of the new organ by the recipient’s immune system.

A major role for immunoassays in transplant medicine is to adjust anti-rejection drug dosage. More and more transplant patients are being treated with multi-drug regimens that include mycophenolic acid (MPA), and studies suggest that therapeutic drug monitoring of MPA levels is helpful in-patient management. Therefore, having the ability to efficiently monitor any combination of MPA, cyclosporine, tacrolimus and sirolimus therapy on one integrated instrument can help to ensure patients receive the optimal balance of therapy. This may not only save the transplanted organ but also the patient's life.

Siemens Healthineers has offered an assay to monitor the dosage of immunosuppressant drugs given to transplant patients. Siemens offered Mycophenolic Acid assay (MPAT) on the Dimension Integrated Chemistry Systems in the U.S. According to Siemens, with this addition, the company became the first company to offer the consolidation of four fully automated immunosuppressant drug (ISD) assays on a single integrated chemistry system. The four ISD tests—mycophenolic acid, cyclosporine, tacrolimus and sirolimus—are the most commonly prescribed immunosuppressants used by physicians to prevent organ rejection.

Elecsys Tacrolimus assay is intended to be used as an aid in the management of liver and kidney allograft patients receiving tacrolimus therapy. Tacrolimus (TAC) is a post-transplantation immunosuppressant drug used in patients for whom careful monitoring of TAC concentration is essential.

Roche announced the availability of its CE-marked Elecsys Sirolimus and Everolimus immunosuppressive drug assays. These two assays complement the currently available Elecsys Tacrolimus and Cyclosporine assays, and with the mycophenolic acid (MPA) assay complete the Roche Diagnostics immunosuppressive drug monitoring portfolio.

QIAGEN announced the commercial launch of the CE-marked QuantiFERON Monitor (QFM), a diagnostic for monitoring immune function in solid-organ transplant recipients. In North America and other markets, QFM is available for research use as a marker of immune function in studies of immunosuppressive conditions, immune-modulating therapies, and recovery following transplantation. The test is used to assess patients' risk of both organ rejection and infections to determine the appropriate dosage of immunosuppressive drugs.

QFM uses a combination of stimulants that specifically target different cell types involved in both the innate and adaptive immune systems to detect cell-mediated immune response, thereby providing qualitative and quantitative measurement of cell-mediated immune

function. Clinical studies are underway to investigate QFM's utility in transplantation for multiple organs (heart, lung, liver and kidney).

This research was not able to quantify the market for the transplant immunoassays with certainty.

Table 7-15: Selected Immunoassays for Transplant Medicine

Company	Location	Details
One Lambda (Thermo Fisher)	U.S.	LABScreen Multi antibody screening, HLA/HNA
Oxford Immutec	UK	T-SPOT.PRT T reactive cells
Plexision	U.S.	Pleximmune test liver transplant rejection
Siemens Healthineers	U.S.	Mycophenolic Acid on Dimension Systems
Thermo Fisher Scientific	U.S.	Thermo Scientific QMS Everolimus Assay Kit
ViveBio LLC	U.S.	Renovar's markers rejection kidney transplant, urine

Source: Kalorama Information

Transplant diagnostics are increasingly moving beyond drug level monitoring and HLA antibody screening toward functional immune assays and noninvasive biomarkers, particularly urine- and cell-based tests aimed at earlier detection and risk stratification of rejection.

Women's Health

Of particular interest is immunoassays related to women's health and preeclampsia in particular. According to the Preeclampsia Foundation (www.preeclampsia.org) thousands of women and babies die or get very sick each year from preeclampsia, a disorder that occurs only during pregnancy and the postpartum period. Preeclampsia is a cardiovascular disorder of late pregnancy. Preeclampsia and related disorders such as HELLP syndrome and eclampsia are most often characterized by a rapid rise in blood pressure that can lead to seizure, stroke, multiple organ failure and death of the mother and/or baby.

Preeclampsia affects 10 million mothers worldwide every year and is associated with premature births and infant illness, including cerebral palsy, blindness, epilepsy, deafness, and lung conditions. It is estimated that preeclampsia costs the global health care system $3 billion per year. Preeclampsia is estimated to affect 2%-8% of all pregnancies.

Metabolomic Diagnostics offers PrePsia, a screening test that identifies women at increased risk of developing preeclampsia.

In recognition of this important condition, several companies have taken up the challenge to provide diagnostic solutions. This research was unable to quantify the market for preeclampsia and preterm birth tests with certainty.

Revvity was awarded the CE Mark for the DELFIA Xpress PlGF Assay.

The Anti-Müllerian Hormone (AMH) blood test has become a widely accepted biomarker of ovarian reserve, used by reproductive endocrinologists to estimate the remaining pool of recruitable follicles in the ovaries. AMH levels correlate with the quantity of ovarian follicles, providing clinically useful information about a woman's potential response to ovarian stimulation.

Unlike follicle-stimulating hormone (FSH) and estradiol, AMH levels are relatively stable throughout the menstrual cycle, allowing blood collection on any day. As a result, AMH is increasingly regarded as a more reliable and convenient indicator of ovarian reserve than traditional day-3 FSH or estradiol testing. Standardized automated AMH assays have further enabled routine clinical adoption, supporting consistent interpretation across laboratories and fertility clinics.

Beyond assessing ovarian reserve, AMH testing is used to predict ovarian response to gonadotropin stimulation and to help guide treatment planning in assisted reproductive technologies (ART). AMH is therefore an important tool not only in fertility assessment but also in optimizing infertility treatment protocols.

AMH assays are commonly used in conjunction with recombinant follicle-stimulating hormone (rFSH) therapies, including products marketed by Ferring Pharmaceuticals. AMH-guided approaches enable individualized rFSH dosing, aiming to improve ovarian stimulation outcomes while reducing the risks of poor response or ovarian hyperstimulation syndrome (OHSS) in vitro fertilization (IVF) cycles.

Separately, in the area of maternal–fetal medicine, Thermo Fisher markets its B·R·A·H·M·S PlGF plus KRYPTOR and B·R·A·H·M·S sFlt-1 KRYPTOR immunoassays. These assays are used for the risk assessment and management of preeclampsia, representing the first FDA-cleared immunoassays for this indication in the U.S. Importantly, these biomarkers are distinct from AMH and address a different clinical need: placental dysfunction and hypertensive disorders of pregnancy, rather than fertility assessment.

Circero Diagnostics offers its MyReceptiva endometriosis detection test. The test detects the presence of the BCL6 protein. The sample needs to be collected at the right time in the luteal phase of the menstrual cycle.

For a more in-depth report see Kalorama Information's *Women's Health Diagnostics Markets: Global Outlook and Forecast to 2030.*

Table 7-16: Selected Women's Health Innovations

Company	Location	Details
Abbott	U.S.	Endoglin marker, preeclampsia
Kellbenx Inc.	U.S.	fetal fibronectin, preterm birth
Kellbenx Inc.	U.S.	interleukin panel, preterm birth screen
Metabolomic Dx	UK	metabolite panel preeclampsia
Revvity	U.S.	PreeclampsiaScreen | T1 screen panel
Revvity	U.S.	DELFIA /AutoDELFIA PlGF Assay, preeclampsia
Pronota NV	Belgium	mid-gestation preeclampsia screening test
Roche Diagnostics	U.S.	preeclampsia panel
Sera Prognostics	U.S.	PreTRM, Proteomic Assessment of Preterm Risk
Siemens Healthineers	U.S.	endometriosis panel
Wistar Institute, The	U.S.	Adam 12 protein blood marker for ectopic pregnancy

Source: Kalorama Information

AMH has evolved from a niche fertility marker into a routine component of modern reproductive medicine, supporting ovarian reserve assessment and more individualized treatment planning. At the same time, advances in placental biomarkers, such as PlGF and sFlt-1, are expanding the role of biomarker-guided decision-making in women's health, particularly in the management of conditions like preeclampsia.

Alzheimer's Disease and Multiple Sclerosis

According to the Alzheimer's Association, it is estimated that over 6.5 million people in the United States suffer from Alzheimer's disease. Over 500,000 patients are diagnosed annually, with nearly one-in-nine older Americans affected by the disease. Alzheimer's disease is the third leading cause of death in the United States. The cost of unpaid care in the United States is estimated at over $400 billion annually. Alzheimer's expenditures in the United States are expected to exceed $1.5 trillion by 2050. There is no cure or effective treatment for Alzheimer's disease.

An estimated 59 million people worldwide had dementia in 2023, compared with 35 million in 2009, according to a report released by Alzheimer's Disease International. This is expected to increase to 152 million in 2050, a 204% increase. The group said if there are no major medical advances, the number of people with dementia will likely double every 20 years.

About 60% of people with dementia live in developing nations and by 2050, nearly half of all those with the disease will live in Asia, according to Alzheimer's Disease International.

Alzheimer Europe (www.alzheimer-europe.org) reports that some 10 million people are afflicted with some form of dementia, including Alzheimer's disease. Worldwide, about 59 million individuals have the disease, and according to the World Health Organization, the number will double every 20 years to 116.4 million people with Alzheimer's by 2050.

Age-related diseases, such as dementia and Alzheimer's, could bankrupt Western medicine by 2050. Therefore, the search for new solutions, such as earlier and more specific diagnosis, is required to help deliver care more effectively and efficiently.

Definitive confirmation of Alzheimer's disease has traditionally relied on neuropathological examination of brain tissue, which is typically performed after death. As a result, the disease has often gone unrecognized until it has progressed. More recently, advances in biomarkers—including blood-based tests, cerebrospinal fluid analysis, and imaging—are

making it possible to identify Alzheimer's pathology earlier in the disease course. Researchers continue to focus on developing noninvasive, cost-effective markers that can support early detection and improve patient selection for prevention and treatment studies.

Early detection of Alzheimer's symptoms is critically important for people with the disease and for clinical studies seeking to slow or stop its progression. However, many diagnostic techniques can be costly or invasive. Saliva is simple to obtain and easy to transport and has been successfully used to help identify a variety of diseases and conditions. In addition, because multiple samples can be readily obtained, saliva testing is particularly useful for performing repeated assessments that span days, weeks, months or longer.

There is a consensus that Alzheimer's disease begins with changes in the brain that are happening while people are still cognitively normal, decades before memory and thinking problems begin, which then accelerate as the disease progresses. There is no known cure for the disease. The search for early markers has been expanded in light of the recent commercialization of therapeutics that appear to slow down the cognitive impairment of people with dementia and Alzheimer's.

Studies have revealed several potential protein biomarkers in cerebrospinal fluid (CSF). Tau and Aβ are among the most promising. Meanwhile, most research on proteins and other types of biomarkers in the blood and saliva are easier and cheaper to collect than CSF. It is beyond the scope of this research to evaluate the market for markers of Alzheimer's disease other than traditional CSF-based markers with certainty.

Roche is establishing the presence of degenerative diseases of the central nervous system, which is important when it comes to distinguishing age-related memory disorders from early-stage dementia. Deposits of β-amyloid peptides (1-42) and neurofibrillary tangles in the brain are the two earliest changes associated with the development of Alzheimer's disease and can be detected by different methods. Biomarkers in the cerebrospinal fluid help clinicians detect Alzheimer's disease, the most common form of dementia, from an earlier stage.

Roche has established a leading position in cerebrospinal fluid–based testing for Alzheimer's disease through its Elecsys immunoassay portfolio. The Elecsys β-Amyloid (1-42) CSF II, Phospho-Tau (181P) CSF, and Total-Tau CSF assays quantitatively measure hallmark proteins associated with amyloid plaque formation and tau pathology. These biomarkers can be evaluated individually or combined as ratios to improve the biological characterization of

Alzheimer's disease in adults undergoing assessment for cognitive impairment. The assays use electrochemiluminescence technology and are performed on Roche's Elecsys and cobas e immunoassay systems, enabling standardized, automated testing in clinical laboratories.

Roche's CSF assays have progressed from a breakthrough designation to full U.S. regulatory clearance, reflecting their clinical role in supporting the evaluation of Alzheimer's disease and other dementias in symptomatic patients. When used together as biomarker ratios, these tests help clinicians assess the likelihood of underlying amyloid pathology and the risk of disease progression, rather than serving as standalone diagnostic or screening tools.

Beyond CSF testing, the Alzheimer's diagnostics market is rapidly expanding toward blood-based biomarkers that offer less invasive assessment options. Fujirebio has advanced both CSF- and plasma-based assays targeting beta-amyloid peptides and phosphorylated tau, supporting earlier detection of amyloid pathology and facilitating broader clinical adoption of biomarker-guided evaluation. These assays are designed to identify disease-related changes earlier in the clinical course, when therapeutic intervention may be more effective.

C2N Diagnostics has taken a laboratory-developed test approach with its PrecivityAD blood test, which assesses circulating biomarkers associated with brain amyloid status. This test is offered through a centralized clinical laboratory and reflects growing interest in proteomic and ratio-based blood assays as complements to imaging and CSF testing.

Sysmex has focused on plasma amyloid beta measurement using its automated immunoassay platforms, positioning its assay as a tool to support the identification of amyloid accumulation in the brain. This approach aligns with industry efforts to transition Alzheimer's testing from specialized procedures to high-throughput laboratory workflows.

Quanterix has introduced a highly sensitive blood-based test that measures phosphorylated tau isoforms in plasma. Leveraging ultra-sensitive digital immunoassay technology, the test is intended to aid clinical evaluation of Alzheimer's disease by detecting low-abundance biomarkers associated with neurodegeneration.

At the same time, companies such as Revvity and Thermo Fisher Scientific remain primarily active in the discovery and translational research side of Alzheimer's biomarker development, supplying antibodies, reagents, and platforms for exploring beta-amyloid and tau targets. These tools support biomarker discovery and validation rather than serving as fully regulated clinical diagnostics.

Overall, Alzheimer's disease diagnostics are moving toward a multi-modal, biomarker-driven model that integrates CSF assays, blood-based testing, and imaging. This evolution reflects the broader trend toward earlier, less invasive, and more scalable assessment of neurodegenerative disease biology in both clinical practice and drug development.

The product helps identify the level of Aβ accumulation in the brain by measuring the ratio of Aβ peptides (1-42 and 1-40) in the blood using Sysmex's HISCL-Series, which employs chemiluminescence enzyme immunoassay (CLEIA) as its measurement principle. Unlike conventional testing methods, the Product enables testing using blood, thereby reducing the physical, emotional, and financial burden on patients with suspected Aβ accumulation in the brain. Furthermore, the product is expected to contribute to early diagnosis and early determination of optimal treatment plans for patients. In addition, automated assays using the HISCL-Series—which require only 10 to 30 µL of blood (plasma) and have a measurement time of just 17 minutes—will also help improve the efficiency and standardization of testing, according to Sysmex executives.

Sysmex offers an assay kit to detect amyloid-beta accumulation in the brain. The assays measure the level of Aβ accumulation to determine whether there is supporting evidence for a diagnosis of Alzheimer's disease.

LifeLabs markets three blood-based Alzheimer's disease biomarker tests to assess the risk of dementia or Alzheimer's disease. The portfolio consists of:

- APOE Test – a blood test for genetic factors
- P-tau317 Test – a blood marker for diagnosing Alzheimer's disease
- Beta-Amyloid 42/40 Ratio Plasma Test – a blood test that detects early signs of Alzheimer's disease.

In Europe, Roche offers its Elecsys pTau181 test to measure the phosphorylated Tau181 protein. The test can be used to rule out Alzheimer's disease.

Multiple sclerosis affects more than 2.9 million people worldwide. Roche's Elecsys Neurofilament Light Chain (NfL) test is a blood test designed to detect neuroaxonal damage associated with neuroinflammation. It is a quantitative immunoassay that measures neurofilament light chain protein concentrations in plasma. The test is CE marked and is performed on the cobas instruments. The test aims to deliver reliable insights into relapsing-remitting multiple sclerosis.

Table 7-17: Selected Innovations for Alzheimer's Disease Immunoassays

Company	Location	Details
Amprion	U.S.	cerebrospinal fluid, blood or urine
Analytik Jena	Germany	hTAU total ELISA kit tau protein, Alzheimer's, CSF
Araclon Biotech SL	Spain	ABtest40 & ABtest42, early Alz markers, blood
Fujirebio	Japan	Lumipulse G β-Amyloid Ratio (1-42/1/40) test
Innovative Health Diagnostics	France	IHD-Amy blood test, Alzheimer's disease
NanoSomiX	U.S.	blood assay, p-tau
Quanterix Corp	U.S.	Amyloid-beta 42 levels in blood, Alzheimer
Roche	Switzerland	Elecsys β-Amyloid (1-42) CSF, Elecsys Phospho-Tau (181p) CSF and Elecsys(R) Total-Tau CSF immunoassays
Spear Bio	U.S.	SPEAR UltraDetect BD-Tau 217
Sysmex	Japan	Measurement using Automated Immunoassay System HISCL-5000/HISCL-800

Source: Kalorama Information

Across Alzheimer's diagnostics, the market is clearly stratified between established CSF-based clinical assays, emerging blood-based laboratory tests, and research-stage biomarker technologies, with industry momentum shifting steadily toward scalable, minimally invasive blood testing while CSF biomarkers remain the biological reference standard.

Traumatic Brain Injury

Traumatic brain injuries (TBI), including concussions, are responsible for over 4.8 million emergency room visits per year. Most of these (40%) are concussions caused by a slip and fall. Traumatic brain injuries are seen in the sports world. Worldwide, there are approximately 10 million people affected by TBI. The primary goal of testing is to detect changes in the brain that could help determine if the brain was injured.

Abbott offers its iSTAT TBI plasma test, the first rapid, handheld TBI blood test. Results are available in 15 minutes. The company is also working on a whole blood test, which would eliminate the need to separate plasma.

A study was conducted at the UC San Francisco using the i-STAT Alinity portable blood analyzer with the ARCHITECT assay series to analyze the brain injuries on the day it happened. Results revealed that day-of-injury blood tests measuring the concentrations of the biomarkers glial fibrillary acidic protein (GFAP), which originates in glial cells, and ubiquitin C-terminal hydrolase L1 (UCH-L1), which originates in neurons, can predict the outcome of TBIs. Abbott is pursuing FDA clearance under Breakthrough Designation for the TBI test on its Alinity and ARCHITECT core laboratory instruments.

Bio-Techne offers the Simplex Assays that are run on the fully automated Ella platform. The test evaluates multiple biomarkers using the Simple Plex, which is a quantitative, multianalyte immunoassay platform. The results provide a potential profile for TBI.

A Swiss startup, ABCDx, is developing biomarker panels, including TBICheck, for traumatic brain injuries. The device is small and lightweight, producing results in less than 30 minutes.

BRAINbox is developing the first AI-enabled, multi-modality system for mild TBI. The BRAINbox test is a POC system that uses a multiplex fluorescent immunoassay for biomarkers, together with a tablet-based neurocognitive test, to diagnose mild TBIs.

Abbott markets its rapid i-STAT TBI Plasma test, which runs on the Alinity I laboratory instrument. The test provides clinicians with a way to assess individuals with mild TBI, and yields results in about 18 minutes.

Abbott also markets its i-STAT TBI test for use with whole blood. This will enable testing in a variety of healthcare settings, including on the sidelines of sporting events.

bioMérieux offers its VIDAS TBI assay. The assay is a serum-based test to aid in the assessment of patients with mild traumatic brain injury, including concussion. The test measures the biomarkers GFAP and UCH-1, which enter the circulation following cellular injury.

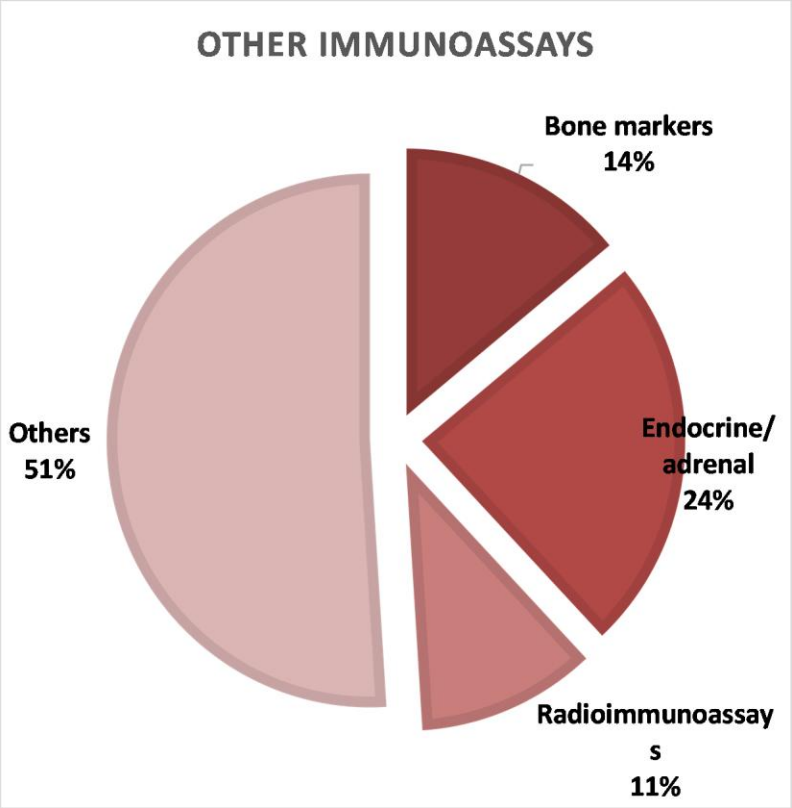
Other Immunoassays

This part of the chapter presents a list of selected immunoassay innovations. The list presented here is a testament to the breadth and significance of immunoassays in diagnostics. In the past few years, emphasis on molecular assays has somewhat overshadowed the value of immunoassays, but this lab segment is extremely vibrant and dynamic.

The other immunoassay segment is growing, posting revenues of $3,020 million in 2025. A beginning breakout of the segment features bone markers at 14% of the total, endocrine/adrenal immunoassays at 24%, and radioimmunoassays at 11%. The remaining other immunoassays are a variety of important immunoassays that are on or entering the market.

Figure 7-2: Other Select Immunoassays, by Percent of Total Immunoassays, 2025 (%)

[Bone Marker; Endocrine/Adrenal; Radioimmunoassays; Others]



Source: Kalorama Information

Table 7-18: Selected Immunoassay Innovations

Company	Location	Area	Details
Abbott Diagnostics	U.S.	asthma	periostin and DPP4 asthma markers
Abbott Diagnostics	U.S.	fertility	ARCHITECT 2nd Generation Testosterone
ALPCO Diagnostics	U.S.	cytokine	STELLUX Chemi Human IL-6 ELISA
ALPCO Diagnostics	U.S.	kidney	PPR Diagnostics, N-Acetyl-ß-D-Glucosaminidase, kidney disease
ArcticDx, Inc.	Canada	mac deg	Vita Risk pharmacogenetic analysis, macular degeneration treatment
Astute Medical, Inc.	U.S.	kidney	NephroCheck Test, acute kidney injury, IGFBP7 & TIMP-2
Bio-Rad Laboratories	U.S.	IT	automated link VARIANT II TURBO hemoglobin & BioPlex 2200
Biomerica	U.S.	kidney	Fortel Microalbumin Screening
Calbiotech	U.S.	iron met	Hepcidin immunoassays are widely used in research/translational iron studies.
Caprion Proteomics	Canada	Parkinson	CNS ProteoCarta, 142 cerebrospinal fluid proteins
Cisbio Bioassays	France	fertility	Estradiol, Cortisol and Testosterone radioimmunoassays
Clinical Research	U.S.	metabolic	Mercodia AB's metabolic disorder antibodies
Diazyme Laboratories	U.S.	ferritin	Ferritin Latex-Enhanced Immunoturbidimetric
DRG International	U.S.	iron met	DRG Hepcidin 25
EKF Diagnostics	UK	kidney	Soluble Tumor Necrosis Factor receptor 1
EUROIMMUN AG	Germany	kidney	Anti- PLA2R IFA blood test kidney disease
Exagen Diagnostics, Inc.	U.S.	lupus	Avise SLE panel, Lupus
Immuno Concepts	U.S.	SLE	IgG Anti-nDNA Fluorescent Test System
Immunodiagnostic Systems	UK	endocrine	IDS-iSYS Aldosterone
Immunodiagnostic Systems	UK	endocrine	Diametra manual immunoassays

Company	Location	Area	Details
Mercodia AB	Sweden	metabolic	ELISA and antibodies for metabolic disorders
Rowan University School	U.S.	psych	neurodegenerative disease markers
ScheBo-Biotech AG	Germany	pancreas	ScheBo • Pancreas Elastase 1 Quick stool test
Siemens Healthineers	U.S.	liver	Enhanced Liver Fibrosis test
Singulex	U.S.	inh dis	Erenna mutant Huntington protein
Thermo Fisher	Germany	Down's	Free sshCG and PAPP-A Down's markers
Tosoh	Japan	hormone	ST AIA-PACK SHBG assay, sex binding hormone
Venaxis, Inc. (Bioptix)	U.S.	appendicitis	APPY1 Test and APPYReader, appendicitis

Source: Kalorama Information

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Innovating POC

There has been renewed interest in POC immunoassays related to miniaturization and digital technologies that allow the devices to provide lab quality quantitative test results. These advances have been applied primarily to tests for infectious diseases. This has been reinforced by the number of POC COVID-19 immunoassays that have become available during the pandemic. The products for POC professional use are responding to the demand for fast and reliable solutions to screen and monitor patients for the most pressing medical conditions.

Table 7-19: Selected POC Test Innovations

Company	Location	Target	Details
Abbott Diagnostics	U.S.	concussion	i-STAT concussion test
Abbott Diagnostics	U.S.	hCG	i-STAT Total β-hCG, blood
Abingdon Health	UK	autoimmune	Seralite–FLC serum, kappa/lambda light chains
BBInternational	UK	ngal	Recombinant Human NGAL
Becton Dickinson	U.S.	women	Diabetomics preeclampsia on Veritor
Biohit Oyj	Finland	celiac	Celiac Quick Test
Boditech Med	Korea	vit D	ichromα Vitamin D
Critical Diagnostics	U.S.	cardiac	Aspect-LF ST2 test, heart failure risk
Diazyme Laboratories	U.S.	cardiac	SMART Point of Care chemistry system
Diazyme Laboratories	U.S.	kidney	SMART Cystatin C POC Test Kit
Epinex Diagnostics	U.S.	kidney	Epinex ACR, quantitative microalbumin, LF
NanoSpeed Diagnostics	Canada	vit D	Test4D, rapid vitamin D
Neogen Corp	U.S.	DAU	UltaSal, oral fluid drugs of abuse collection and test
NOWDiagnostics	U.S.	hCG	ADEXUSDx hCG rapid blood test
Oasis Diagnostics	U.S.	cortisol	cortisol in saliva rapid test
Oasis Diagnostics	U.S.	Parkinson's	saliva-based, rapid test Parkinson’s disease
Omega Diagnostics	UK	allergy	Allergodip India, Allergodip LF IgE adapted for India
OPKO Diagnostics	U.S.	cancer	Claros PSA and 4KScore Prostate Cancer, kallikrein
OPKO Diagnostics	U.S.	Vit D	Claros Vitamin D test
Orgentek Diagnostika	Germany	arthritis	lateral flow anti-MCV and rheumatoid factor
Progenika Biopharma	Spain	endocrine	AlphaKit QuickScreen, Alpha-1-Antitrypsin Deficiency
PTS Diagnostics	U.S.	cotinine	PTS Detect systems, cotinine tobacco detection
Royal Philips	Netherlands	troponin	Minicare I-20 system, biosensor

Company	Location	Target	Details
Sekisui Diagnostics	U.S.	FOB	OSOM iFOB
Sekisui Diagnostics	U.S.	hCG	OSOM Ultra hCG Comb, serum or urine
Trinity Biotech	UK	BNP	Meritas point-of-care BNP (B-type natriuretic peptide)
Trinity Biotech	UK	D-dimer	Meritas D-dimer
Trinity Biotech	UK	troponin	Meritas, high sensitivity Troponin I (hsTnI)
True Diagnostics	U.S.	PSA	TrueDX PSA, finger stick blood
True Diagnostics	U.S.	TSH	TrueDX TSH test

Source: Kalorama Information

Tests are only one aspect of POC testing with immunoassays. New platforms, many of which are still in development, illustrate the creativity underway to make POC testing easier and more efficient. Included are saliva, digital and paper-based test platforms. Manufacturers are also investing in critical connectivity tooled platforms.

Table 7-20: Selected POC Immunoassay Test Platforms

Company	Location	Details
BBInternational	UK	Novarum DX smartphone-based Reader
Boditech Med	Korea	Ichromα II
Cambridge Consultants	UK	XylemDx, paper-based tests with 3D printed microfluidics
Fio Corporation	Canada	Deki Reader with Fionet connectivity, LF immunoassays
LamdaGen	U.S.	LAuRA plasmonic ELISA, 20-minute multiplexed panels
Nanomix Inc.	U.S.	Nanomix eLab diagnostic platform
Oasis Diagnostics	U.S.	VerOFy point-of-care testing platform
Oasis Diagnostics	U.S.	VerOFy Point-of-Care Testing platform, saliva
OPKO Diagnostics	U.S.	Claros 1 in-office analyzer, Sangia microfluidic cassette
Sekisui Diagnostics	U.S.	Qualigen' s FastPack IP System, POC immunoassays
Silicon BioDevices	U.S.	instrument free chip with wireless connectivity
Skannex AS	Norway	SkanFlexi and SkanSmart, LF test readers
Trinity Biotech/Stago	UK	Meritas POC Analyzer, laser diode to detect immunofluorescence
True Diagnostics	U.S.	TrueDX reader, tests, wireless & USB connection

Source: Kalorama Information

The Commercial Outlook for Immunoassays

The global immunoassay market continues on a steady growth trajectory. While many immunoassay tests, such as ELISA and lateral flow assays, are mature and well-established, the market remains highly competitive and dynamic. The COVID-19 pandemic underscored the value of immunoassays, particularly for rapid point-of-care (POC) and at-home testing using lateral flow formats, highlighting their critical role in public health response.

Prospects for growth in the immunoassay market are good in certain geographic regions worldwide (developing countries). Several factors are driving the growth of diagnostic testing, including lateral flow testing, in these markets. One major factor is economics. There is a growing middle-class population that is increasingly insured in many countries in Southeast Asia and Latin America, and these patients are better able to pay for services. These and other factors will make these regions promising segments of the immunoassay market. Many companies are targeting these markets, including major worldwide diagnostic companies and smaller companies established in those countries. Much of the growth in testing in these markets in the near future will be driven by existing technologies (including ELISA and lateral flow tests).

However, all immunoassays will have to pass the test of medical research to prove their contribution to improved patient outcomes. Increased knowledge of disease physiology from molecular biology and human genome studies will enhance the role of analytes in chronic conditions such as cardiovascular disease, autoimmune disorders, and diabetes. The function of genes is measured by the presence of tangible products—proteins of every size and molecular structure. Thus, immunoassays combined with DNA probe studies will have an important place in post-genomic medicine.

For the point-of-care sector, the news is good and bad. Since the early 1990s, patient self-testing has grown in popularity. Kits are available for pregnancy, blood pressure, drugs of abuse, H. pylori, blood glucose, cholesterol, cancer, and HI. More are in development for heart attack monitors, and sexually transmitted disease tests, among others. Predictions are that patient self-testing will skyrocket due to rising consumer expectations, technological innovations, and a surge in consumer activism in healthcare, especially with the growing acceptance of POC immunoassay testing. Further, pharmacies, retail outlets, and the physician's office are establishing their position for patient wellness screening. The expectation is that under these conditions, POC testing, both self and professional, will grow.

The current set of tests and technologies can't accommodate all the needs of the consumer and professional markets. For consumers, many of the tests are blood-based, not a user-friendly sample type. Further, many times, people just don't want to know what is really wrong with them. There is also a barrier in consumer perception of costs - the thought that new tests and technologies are just too expensive. Faster, more sensitive, more user-friendly, and less expensive tests may produce better market penetration.

Again, in the development of COVID-19 immunoassays, there was a push to provide saliva-based tests, which has spilled over into other areas, increasing acceptance, including cortisol analysis.

After many years of little growth, the professional POC test market is picking up steam. In the past few years, demand for quicker test turnaround time has spurred the launch of nearly 100 new POC tests and devices.

As the cost of POC devices becomes more affordable and healthcare organizations have constructed data management infrastructures, point-of-care testing has also become an attractive operational and economical alternative to traditional laboratory-based testing in a variety of situations, including physician office testing, home care and in-hospital care.

The other significant opportunity for growth in the immunoassay market lies in innovations that create new opportunities. This includes both innovative new platforms, innovative technology and development of novel biomarkers.

With the continued emphasis on earlier detection, personalized medicine and remote care, immunoassays will remain a relevant and foundational tool for diagnostics.

Chapter 8: Molecular Assays

Scope

The molecular assays market consists of all IVD diagnostic products and technologies that detect and/or quantify nucleic acids (RNA, DNA) to identify pathogens, genetic mutations, and other molecular targets. It encompasses oncology, inherited disease and thrombosis, depression and psychiatric disorders, prenatal and newborn testing, transplant diagnostics, and women's health.

The molecular diagnostics field has evolved into one of the fastest-growing and most transformative segments of the in vitro diagnostics (IVD) industry. Since the discovery of the DNA double helix in 1953, the journey from basic scientific understanding to practical clinical tools has spanned decades, culminating in today's highly sophisticated molecular testing platforms.

Focus on infectious diseases was maintained even in the early years of the last decade by companies that ventured into the molecular diagnostics sector, and commercial molecular assays were introduced for hepatitis and respiratory diseases, as covered in Chapter 11. The blood banking sector became one of the key application areas during this period, as the high sensitivity offered by molecular diagnostics brought significant value to donor blood screening for pathogens of great concern, a topic covered in Chapter 12. Currently, the use of molecular diagnostics methods is not limited to infectious diseases. Other disease segments where molecular assays have high demand include inherited diseases, coagulation, transplant medicine, prenatal and postnatal screening and cancer.

Overview

Over the last 30 years, molecular tests have been used in just about every facet of laboratory medicine: infectious diseases, inherited diseases, coagulation, transplant medicine, prenatal and postnatal screening, and, of course in cancer. Their contribution to patient care is quite remarkable. The first generation of molecular testing tools includes basic, time-consuming, and labor-intensive techniques such as Southern blotting, DNA probes, pulsed-field gel electrophoresis, and capillary electrophoresis. These techniques are still used; however, their influence in the evolution of molecular testing has been overshadowed by the power of PCR and other amplification techniques, sequencing, mass spectroscopy, microarrays, and biochips.

Molecular diagnostics is a fast-evolving, dynamic field and one of the fastest-growing segments within the IVD market. It has become an indispensable tool in clinical medicine that touches all aspects of healthcare including treatment decisions in terms of identifying antimicrobial resistant (AMR) infections at the earliest, companion diagnostics assisting in the evaluation of suitability of various cancer treatment options, pharmacokinetics or patient metabolism of drugs for HIV, psychiatric conditions or blood thinners; cancer prognosis and therapy, organ matching, blood safety, and the diagnosis of latent and neonatal conditions. Rather than replacing other major IVD modalities such as immunodiagnostics, the molecular diagnostics market has expanded by meeting clinical needs that were unmet or never envisioned by other major testing disciplines. As they become more affordable, the displacement of other diagnostics, such as immunodiagnostics, has also occurred owing to the high sensitivity and unique insights that molecular diagnostic methods offer. Certain IVD segments have been, or are in the process of being, remade worldwide through the application of molecular methods, including blood screening, POC diagnostics, cytogenetics, and tissue typing.

The primary growth drivers in the molecular diagnostics market overall are the continued discovery of genetic markers with proven clinical utility, the increasing adoption of genetically based diagnostic tests, and the expansion of reimbursement programs to include more approved diagnostic tests. The most attractive growth areas are molecular tests for histological analyses, women's health, infectious diseases, organ transplant testing and oncology.

On the technology side, one of the major drivers in this market is technological advancements that lead to new tests and innovations. Although PCR is one of the standard techniques for

amplification, the method is quite complex due to the need for repeated thermocycling and cooling, and it consumes more energy. As an alternative to PCR, isothermal nucleic acid amplification circumvents the need for repeated denaturation and cooling, as the amplification occurs under isothermal conditions. This greatly aids in the design of microfluidic chips for conducting molecular diagnostics. It is expected that the miniaturization of nucleic acid-based diagnostics will boost market growth.

The key isothermal vendors are Eiken, Becton, Dickinson and Co., bioMérieux, and QuidelOrtho.

The molecular diagnostics industry is also experiencing a rapid shift toward greater process automation and the integration of sample analysis into single miniaturized devices. Miniaturization enables reducing sample volume, allowing the end-user to automate and analyze the sample.

Advancements in automation and information technology (IT) have created a new level of optimism in the molecular diagnostics market, as evidenced by research investments, university spin-offs, mergers, and acquisitions in the segment. The holy GRAIL for molecular testing is the ability to load an untreated sample onto a cartridge or cassette, push start, and then come back when the test is complete. The 'sample-to-result' table-top systems, which are fast entering the market, represent an important milestone towards achieving this goal. Some of the leading global companies offering such tabletop systems include Cepheid, QIAGEN, Hologic, and Roche. The investments by such leading companies and government agencies that partner with them are pushing the existing limits of automation and IT, facilitating fast advancement towards near-patient and point-of-care diagnostics solutions.

Table-top systems are considered the prerequisite technological advancement to providing molecular testing in small laboratories and resource-limited test sites anywhere in the world. The market is moving beyond these systems and the next generation of sample-to-result molecular test instruments is focusing on bringing genetic medicine to a much broader audience. The commercialization of these platforms and tests are the next major development towards democratization of molecular diagnostics as they have the potential to improve the quality of healthcare by improving the affordability and accessibility to advanced diagnostic solutions even in remote areas where challenges of skilled manpower and infrastructure are acute. Government investments into academic research and initiatives to support startup companies in the field are also driving the growth of molecular diagnostics sector.

Significant changes in healthcare delivery herald a new era in diagnostic testing needs. This new era requires on one hand very sophisticated, sensitive assays for disease detection, disease management and drug treatment decisions. On the other hand, these tests should be user-friendly and very cost effective. This bodes well for automated and user-friendly molecular test platforms.

However, the contribution these tests can make to patient outcomes is hindered by significant barriers, including reimbursement issues, a lack of standardization across test platforms, and limited quality-control products and programs. Also, molecular tests, especially for inherited diseases and some FISH analyses, are extremely complex. The tests provide raw data, the interpretation of which sometimes baffles even the most experienced molecular biologists.

The technologies used in the Human Genome Project have become tools that molecular pathologists routinely use to diagnose diseases in patients whose conditions had long remained a mystery. This is good for patient care, but the evolution of sequencing and next-generation sequencing-based tests has been so rapid that government agencies and payers are scrambling to address the regulatory, reimbursement, and ethical issues that accompany this new generation of tests.

Only five years ago, it would have been almost inconceivable that hospital- and government-funded programs would provide whole-genome and whole-exome sequencing for thousands, and even millions, of people. The contribution that these programs are making to patient care is beyond measure at this time. The potential is enormous. New sequencing technologies are expanding the number of genes known to cause genetic disorders. Gene identification is a first step toward the future development of targeted therapies, especially for cancer and rare diseases.

But the market potential of a diagnostic is measured by its clinical utility - the ability of the test to lead to an improved patient outcome. According to the American College of Medical Genetics and Genomics (www.acmg.net), there is great clinical value in genomic test information. The data can help physicians determine a precise medical diagnosis, a disorder's cause and prognosis, and inform preventive and treatment options.

Coverage by Medicare and other payers for a molecular diagnostics product or test can be obtained by demonstrating its clinical utility, particularly how the test can improve patient outcomes. This involves generating clinical data that demonstrates the test's utility. This is in addition to tests that evaluate analytical validity or the accuracy, precision and reproducibility

of test results and clinical validity or how well test can determine the presence, absence or risk of disease. Definitive clinical utility is becoming a criterion for the market success of new molecular diagnostics, particularly in the case of high-priced advanced tests without comparable products on the market.

Important factors considered by payers when determining the clinical utility of molecular diagnostics and associated testing services include impact on therapy, improved patient survival, and added life expectancy. This scope of clinical utility has benefited prognostic assays that provide therapeutic guidance and companion assays that identify patients eligible for co-labeled targeted therapies. Reimbursement eligibility is important for the growth of the molecular cancer diagnostics market, as evidenced by the rapid growth of the non-invasive prenatal testing (NIPT) segment of the molecular diagnostics market, which saw rapid growth after one of its tests received coverage in 2016.

Table 8-1: Common Next Generation Molecular Test Traits

Traits
Reduced test time to minutes versus hours
More test data leads to a better understanding of disease processes
Easier to use and thus found in more clinical labs
Automated sample to answer test procedures
A variety instrument choice – from high throughput systems to tabletop low volume options
Data analysis algorithms incorporated in testing system for sample to answer testing

Source: Kalorama Information

One of the major challenges facing molecular testing is getting stakeholders, including payers, physicians, researchers, and regulators, to work together to close the gap between research and clinical applicability. Physician education is another area that could advance the use of molecular assays.

The ensemble of these elements creates a dynamic, energetic, and fast-moving environment for new tests and companies, requiring vendors to adapt quickly to the changing market. This

chapter provides an overview of the market for molecular tests across the key market segments.

Molecular medicine transformed the entire spectrum of disease management, from assuring the early detection of disease, to defining the prognosis of disease evolution, and to predicting a patient's response to specific therapies. This applies to a number of chronic conditions cardiovascular diseases, diabetes, cancer, psychiatric disorders and drug therapy.

Sample Preparation and Quality Control

The generation of high-quality genomic data depends on starting material that contains adequate quantity and integrity of genomic DNA. To achieve the accuracy and reproducibility required for clinical-grade sequencing, laboratories follow established best practices in sample collection, stabilization, nucleic acid extraction, and library preparation. Each step in this workflow directly influences downstream sequencing performance, data quality, and interpretability.

Nucleic acid extraction from solid tissue samples is a relatively mature and well-standardized segment of the genomics workflow. Established vendors such as QIAGEN, Macherey-Nagel, PreAnalytiX, and Greiner Bio-One offer broad portfolios of extraction kits, collection devices, and automation-compatible consumables. In tissue-based workflows, cells are lysed and genomic DNA is purified through established chemical and mechanical processes that efficiently separate nucleic acids from proteins, lipids, and cellular debris.

In contrast, nucleic acid extraction from blood-based samples presents additional technical challenges. Many clinically relevant next-generation sequencing targets in blood are present at very low concentrations, including circulating tumor cells (CTCs), circulating fetal cells, and cell-free DNA (cfDNA) such as circulating tumor DNA (ctDNA) or circulating fetal DNA. These analytes are often fragmented, diluted by background genomic DNA, and susceptible to degradation during collection and processing.

As a result, blood-based genomic testing places greater emphasis on pre-analytical controls, including specialized blood-collection tubes, rapid plasma separation, and extraction chemistries optimized for short, low-abundance DNA fragments. These requirements have driven continued innovation in liquid biopsy workflows, distinguishing them from more traditional tissue-based extraction methods despite sharing common downstream sequencing and bioinformatics pipelines.

For blood samples, centrifugation is used to create a plasma sample from whole blood, though white blood cells remain and contamination with gDNA remains possible without proper sample collection. Formaldehyde is a common stabilizing agent for blood samples that preserves blood cells and reduces gDNA in plasma but can damage nucleic acids. Streck Cell-Free DNA blood collection tubes (BCTs) are increasingly used as a formaldehyde-free option for preserving cell-free DNA in blood samples. The product also removes the need for immediate centrifugation to plasma and remains stable for plasma preparation for up to

14 days and for CTC isolation for up to 4 days at ambient conditions. Common methods for extracting cfDNA from plasma include spin columns, silica- or magnetic-bead-based methods, phenol/chloroform extraction, and alkaline salts. However, recovery rates for these methods are low due to losses from binding, washing, and elution. Without improvements in extraction efficiency from plasma, serum or urine, larger blood draws will be necessary or clinical NGS will have to compensate through enrichment and library preparation from recovered content and improved sequencing sensitivity.

Challenges in library preparation can limit the adoption of NGS in clinical labs, especially in POC settings. In the case of targeted sequencing, libraries or templates are limited to a group of genes or only one locus to identify key variants for clinical decision-making, which is relatively easier compared to broader genome or exome sequencing for clinical purposes, which tends to be much more complex and needs to be handled by specialty labs experienced in more complex library preparation procedures. The following product developments are expected to assist more routine clinical performance of library preparation for targeted sequencing: customized and packaged probe sets for targeted enrichment; automation and engineering improvements to sequencers and other workflow instruments that reduce hands-on requirements; and single-molecule sequencing methods.

Direct detection or single-molecule sequencing platforms can simplify sequencing runs by eliminating the need for amplification with tissue samples. Pacific Biosciences' SMRT sequencing technology is complemented by automatable SMRTbell Template Prep Kits. SMRTbell templates use hairpin adapters that serve as common primer-binding sites between fragments. The template design further reduces sequencing bias that is already mitigated by the removal of amplification in SMRT workflows. Similarly, nanopore sequencing technologies, such as those marketed by Oxford Nanopore Technologies, eliminate the need for amplification in library preparation.

Automation is an important trend as it can offer better precision and reproducibility. Illumina has standardized NGS assay workflows that couple TruSight panels with library preparation kits automated under a sequencer platform such as the MiSeqDx. Illumina's automated microfluidic library preparation assays are available only for research use, but, together with panels potentially developed from TruSight research assays, they could form a reliable, hands-off solution for routine clinical sequencing.

Microfluidic and liquid-handling systems are also being employed to automate library preparation. The Illumina NeoPrep system and the DNA Electronics developmental

Pathogen Capture System (PCS) are examples of automated microfluidics systems for automated target capture and library preparation. Liquid handling systems that can be used for NGS target capture and library preparation include Agilent Technologies NGS Workstations, Takara Bio Apollo 324, Revvity Sciclone G3 Workstation, and Tecan Freedom EVO. Automated or robotic liquid-handling systems are appropriate for larger labs and will lead to clinical adoption of sequencing. Benchtop liquid-handling systems or microfluidic sample-preparation systems are suitable for clinical sequencing in hospitals and smaller labs.

Microarrays and in situ hybridization (ISH) segments are shifting toward nucleic acid amplification (NAATs) and NGS platforms in developed markets, while growth for these platforms is mainly in emerging markets. Another emerging platform within the molecular diagnostics market is isothermal nucleic acid amplification (iNAAT) technologies; the demand for which is mainly in the developed markets. Even though the POC potentials of the platform are promising for emerging markets, costs are still considered high to promote large-scale adoption in emerging markets

QIAGEN launched the QIAseq cfDNA All-in-One Kit, the first dedicated solution for liquid biopsy analysis that combines cell-free DNA extraction and library preparation on any NGS platform. The kit integrates with QIAGEN's PAXgene Blood cfDNA Tube for the collection and stabilization of blood samples, as well as with QIAGEN's bioinformatics workflow for cfDNA, creating a streamlined testing solution that enables faster, more convenient, and more reliable analysis of cfDNA from sample collection to result.

AcroMetrix, offered by Thermo Fisher Scientific, was one of the first offerings in molecular QC products. QIAGEN was the first company to routinize nucleic acid extraction and preparation in the 1990s. The company claims to still dominate the market but as seen in Table 8-2 below, there are more and more companies entering this market. Some have specialized products; others are for general use. Unfortunately for clinical labs, the majority of these products are for research use only. Market-cleared kits, reagents, and instruments are still largely lacking, and filling this gap is essential for the routine use of molecular testing.

In the same vein, appropriate sample collection and transport tools are essential to maintain nucleic acid integrity and contamination control while a sample is in route from the sampling site to the testing lab. The travel route may involve very short distances (even to the same building) to thousands of miles and days.

PreAnalytiX is a joint venture of QIAGEN and blood tube manufacturer Becton Dickinson. The products are marketed by QIAGEN. It is beyond the scope of this research to report the revenues generated from the sale of sample transport and nucleic acid extraction (preparation) with certainty.

Streck offers its Cell-Free DNA BCT, which recently received FDA De Novo clearance by the U.S. Food and Drug Administration. When paired with the Guardant360 CDx, it has quickly become the industry standard for maintaining cell-free DNA samples and limiting pre-analytical variation.

Table 8-2: Selected Molecular Test Sample Preparation and QC Innovations

Company	Location	Area	Target	Details
10X Genomics	U.S.	smpl prep	sequencing	Chromium System
Agena Bioscience	U.S.	QC	mass spec	iPLEX reference standards
Asuragen	U.S.	smpl integrity	FFPE	SuraSeq DNA Quantitative Functional Index, DNA QC
Becton Dickinson	U.S.	smpl prep	sequencing	CLiC System
Biotype Diagnostic	Germany	smpl enrich	micro	Sampletype DNA extraction from sperm, skin, swabs, blood
CareDx (Revvity)	U.S.	QC	cfDNA	Horizon's cell-free DNA QC - organ transplant
CareDx (Revvity)	U.S.	QC	transplant	Horizon Diagnostics standards, transplant, sequencing
Diasorin	Italy	smpl prep	DNA	ELITe STAR, PCR ready elutes
DxTerity Diagnostics	U.S.	smpl transport	RNA	DxCollect MCD RNA stabilized in blood
Fluidigm(Standard BioTools)	U.S.	smpl prep	sequencing	Library Prep IFCs, mRNA
IncellDx	U.S.	smpl prep	liquid biopsy	IncellPrep Liquid Biopsy cell suspension: FFPE
Seegene	Korea	smpl prep	DNA	Diasorin's DNA extraction technology
SeraCare Life Sciences	U.S.	QC	ctDNA	cell-free circulating tumor DNA (ctDNA), NGS
SeraCare Life Sciences	U.S.	QC	coag	ACCURUN 611oagulation gene markers
SeraCare Life Sciences	U.S.	QC	HPV	ACCURUN HPV mRNA positive
SeraCare Life Sciences	U.S.	QC	micro	AccuSpan viral molecular linearity panels
SeraCare Life Sciences	U.S.	QC	prenate	Non-Invasive Prenatal Testing reference materials
SeraCare Life Sciences	U.S.	QC	STD	ACCURUN 841 CT/GC Negative

Company	Location	Area	Target	Details
Thermo Fisher Scientific	U.S.	QC	cancer	AcroMetrix Oncology Hotspot Control, oncology NGS

Source: Kalorama Information

Next-generation sequencing for hereditary genetic diseases and oncology is rapidly growing. At present, there are no widely accepted genomic standards or quantitative performance metrics for confidence in variant calling. These are needed to achieve the confidence in measurement results expected for sound, reproducible research and regulated applications in the clinic.

The promise of DNA sequencing via NGS alone has already attracted many companies, researchers, and investors. Recent significant efforts in automation and miniaturization have led to a further uptick in the adoption of automated systems across the range of sample-preparation areas.

Quality control products for genomic molecular tests are a complicated matter. Many regions of the genome cannot be confidently sequenced and accurately variant called with current whole-genome and exome sequencing methods. Groups, including the NIST (National Institute of Standards and Technology, an agency of the U.S. Department of Commerce), are working on NGS quality control. This is vital for ensuring successful and accurate NGS test results take their place in routine testing. Further, external quality assurance (EQA), as is available in all other IVD test segments, will play an important role in enabling labs to benchmark this new technology, assess data accuracy, and facilitate high-quality reporting.

Molecular Evolution

The way molecular testing has evolved is interesting. Testing for infectious diseases is growing by leaps and bounds with a continuous stream of new market cleared tests and technologies. This is evident amid the recent COVID-19 pandemic. Other molecular tests, such as those discussed in this chapter, have had difficulty with market clearance and reimbursement. The result, most tests in this segment are offered by lab services or through company-sponsored accredited labs. At the same time, a number of technologies are poised to make their mark in genomic diagnostics.

Digital PCR is a new approach to nucleic acid detection and quantification that uses molecular counting. It offers an alternative to conventional real-time quantitative PCR for absolute quantification and rare-allele detection. Digital PCR works by partitioning a sample of DNA or cDNA into many individual, parallel PCR reactions; some of these reactions contain the target molecule (positive) while others do not (negative). A single molecule can be amplified a million-fold or more. During amplification, dye-labeled probes are used to detect sequence-specific targets. The strength of color generated is proportional to the amount of DNA present.

The market for digital PCR is poised for growth over the next several years, led by established life science tool vendors such as Standard BioTools, Thermo Fisher Scientific (Ion Torrent), and Bio-Rad Laboratories.

Exosome Sequencing

Exosomes are messengers released by all cells into biofluids, such as plasma/serum, urine, cerebrospinal fluid and saliva. Exosomes contain RNA, including mRNA, microRNA, lncRNA and other RNA species, as well as DNA and proteins, from their cell of origin. They can serve as rich sources of proteomic and genomic markers of tissue dysfunction. Biofluid exosomes are particularly useful for differential molecular profiling because they are present not only in primary and metastatic cancer but also in inflammatory, metabolic, cardiovascular, neurodegenerative and other disease processes.

The information in these particles is extremely stable and the focus of intense interest in the scientific community for the diagnosis and treatment of cancer, immunological disorders, newborn diseases of metabolism, preterm birth, diseases of the central nervous system,

Alzheimer's disease, autoimmune disorders and other medical conditions. The aim is to identify the genetic changes that trigger the disease's onset; however, the mutations found to date do not adequately explain the origin or recurrence of the disease.

Exosomes carry nucleic acids and proteins from their host cells and are widely considered to be essential for biomarker discovery for precision healthcare diagnostics. Tumor cells, for instance, release exosomes which contain tumor-specific RNAs that can be isolated more easily from biofluids such as blood and urine than from biopsies.

It is expected that exosome-based tests in routine genomic diagnostics will provide an alternative to tissue biopsies and create new opportunities in molecular testing, especially for cancer liquid biopsy analysis.

Exosome Diagnostics (ExoDx) is widely recognized as one of the most advanced commercial players in exosome-based diagnostics. Its technology platform uses urine and other biofluids as a liquid biopsy source and is designed to isolate and analyze exosomal RNA (exoRNA), with complementary workflows that can also incorporate cell-free DNA (cfDNA) analysis. ExoDx's approach enables interrogation of tumor- and tissue-derived molecular signals without the need for invasive sampling, positioning exosomes as a distinct, information-rich class of analytes within liquid biopsy.

ExoDx has established collaborations with academic medical centers, research consortia, advocacy organizations, and government-supported research initiatives to explore both the biological relevance and clinical utility of exosome-derived biomarkers across oncology and other disease areas. Its most visible commercial application to date has been in noninvasive cancer risk stratification, reflecting the company's focus on translating exosome biology into clinically actionable tests rather than remaining purely research-facing.

More broadly, a growing ecosystem of companies is developing exosome-related tools, assays, and services, including Aethlon Medical, Caris Life Sciences, Cell Guidance Systems, Bio-Techne, QIAGEN, and specialized exosome reagent and service providers such as Exosome Sciences. In addition, most major molecular diagnostics and life science companies are actively investigating the diagnostic and monitoring potential of extracellular vesicles as part of longer-term R&D strategies.

Despite this activity, exosome-based diagnostics remain at an early stage of market development. Outside a limited number of clinically deployed tests, most offerings today are delivered as laboratory-developed tests or research services, with significant work still underway to standardize isolation methods, analytical workflows, and clinical validation frameworks.

Separately, iGene Laboratory offers FetalExome, a whole exome sequencing–based laboratory test intended for use in pregnancies with suspected genetic complexity, such as unexplained fetal anomalies. The test analyzes fetal genetic material to support diagnosis in high-risk prenatal cases and is delivered as a specialized clinical sequencing service rather than a kit-based IVD.

Table 8-3: Selected Exosome Test Innovations

Company	Location	Area	Details
Agilent Technologies	U.S.	sample prep	SureSelectQXT Reagent Kit, sample prep for exosome sequencing
Agilent Technologies	U.S.	cancer	exome sequencing oral cancer patients
Ambry Genetics	U.S.	newborn	ExomeNext: neonatal, pediatric and adult onset
Athena Diagnostics/Quest	U.S.	psych	Personalis' proprietary ACE Exome, neurological in children
Caris Life Sciences	U.S.	cancer	Carisome TOP platform, blood-based exosomes
ExoDx	U.S.	cancer	plasma/urine-based liquid biopsies, exosomal RNA
ExoDx	U.S.	cancer	exosome RNA in CSF for brain cancer
ExoDx	U.S.	general	multiplexed sequencing, mRNA, blood and urine exosome
Labcorp	U.S.	pediatric	ExomeReveal, whole exome seq pediatric diseases
Labcorp	U.S.	sequencing	ExomeReveal, a whole exome sequencing
Thermo Fisher Scientific	U.S.	general	Ion AmpliSeq Exome Kit, CNVs on Ion Proton
Thermo Fisher Scientific	U.S.	general	Ion AmpliSeq Exome Kit
QIAGEN	Netherlands	sample prep	Exosome-based clinical tests, sample prep

Source: Kalorama Information

Exosome diagnostics represent a high-potential yet emerging segment of liquid biopsy, with early commercial traction driven by service-based models and targeted clinical use cases, while broader adoption will depend on continued standardization, regulatory clarity, and demonstration of incremental clinical value beyond cfDNA alone.

Liquid Biopsy

The topic of liquid biopsy as a complement to tumor histology and circulating tumor cells is discussed in Chapter 13; here, Kalorama provides a brief discussion highlighting the importance of this emerging technology in patient care and the role of molecular tools. Minimally invasive 'liquid biopsies' of tumor cells and tumor DNA from the bloodstream can enable earlier primary and secondary diagnosis compared to solid tumor biopsies, as well as the detection of metastasis and/or residual disease, and real-time monitoring of treatment effectiveness that is not practical with solid tumor biopsy methods.

Circulating tumor DNA is a small piece of mutated DNA that tumor cells release into the bloodstream.

Cell-free DNA can be applied more broadly than ctDNA. cfDNA will determine the standard of care in oncology, transplant medicine and cardiovascular disease. This field is emerging as one of the most promising and exciting areas of medicine and has already made a huge impact on prenatal care.

It's been known for many years that dying cells, including tumor cells, shed DNA into the bloodstream. Since the mid-1990s, Dr. Dennis Lo and his team at the Chinese University of Hong Kong have been researching the detection of circulating nucleic acids in plasma and serum. He explained the future of this new technology at a plenary session of the American Association for Clinical Chemistry's annual meeting in July 2005.

In the 1960s and 1970s, circulating DNA was found in cancer patients, but until the advent of PCR, the technology for further study was limited. More recently, next-generation sequencing technology made it possible to detect and quantify cell free and cancer-specific DNA in plasma by the identification and chromosomal location of billions of specific DNA fragments present in blood.

Researchers of circulating free nucleic acids have extended the reach of this technology beyond DNA to RNA, miRNA and exomes. Although just emerging, it is anticipated that

circulating nucleic acids may emerge as a prominent technology in future molecular diagnostics, and so it has – first in prenatal fetal testing for genetic abnormalities and now as the basis of the liquid biopsy in cancer.

Cell free DNA has already brought advances to prenatal diagnostics that allows physicians to screen for gene mutations noninvasively and avoid amniocentesis. More importantly, NIPT (noninvasive prenatal testing) using NGS can detect these mutations in the first trimester of pregnancy. NIPT has provided the proof of principle that is being applied to cancer management.

Most currently available cfDNA assays are LDTs. Asymptomatic detection and initial profiling of tumors could be achieved through more cost-effective ctDNA detection, potentially followed by CTC testing to better determine cancer stage. Either cfDNA or CTCs could be used for tumor profiling, with CTCs offering a more comprehensive analytical resource for determining intracellular cancer mechanisms. CtDNA could be used for routine patient monitoring, with its relative level monitored to determine disease progression or remission. Halted remission or cancer recurrence could prompt CTC analyses to inform the selection of new therapies. Liquid biopsies may ultimately become the standard sample type for custom panels that incorporate both CTCs and ctDNA.

A variation of sorts on CTCs is circulating tumor DNA. Circulating tumor DNA is a promising biomarker with applications for many cancers. An international team of researchers used digital PCR-based technologies to analyze blood samples from 640 patients with various cancers and detected ctDNA in the blood of more than 75% of patients with advanced cancers (including pancreatic, ovarian, colorectal, bladder, and breast). They also found that ctDNA was often present in patients without detectable circulating tumor cells. They found that ctDNA was detected in 73%, 57%, 48%, and 50% of patients with colorectal cancer, gastroesophageal cancer, pancreatic cancer, and breast adenocarcinoma, respectively.

Studies of ctDNA are also especially important in lung cancer. In response to the increasing availability of targeted therapies for non-small-cell-lung cancer (NSCLC), clinical guidelines recommend molecular testing of relevant genes to identify candidates for targeted therapy. However, an estimated one-third of NSCLC patients lack adequate tissue samples for molecular testing and therefore cannot be considered for the new targeted treatments. Noninvasive ctDNA testing has become popular as an alternative.

These technologies complement each other and once fully validated, they are poised to revolutionize cancer diagnosis, drug choice, and recurrence testing. This approach is still in the early stages of development but is the subject of much research. Researchers at the University of Cambridge and the Cancer Research UK Cambridge Institute published a proof-of-principle study in the New England Journal of Medicine suggesting that circulating cell-free DNA can serve as a blood-based marker for monitoring metastatic breast cancer in women undergoing treatment. They used targeted and/or whole-genome sequencing to find characteristic somatic mutations in metastatic breast tumors. They then tested for the presence or absence of these alterations in cell-free DNA in each woman's blood over the course of her treatment, assessing how well this technique detected metastatic disease and tracked treatment response and progression. They found that the technique compared favorably with conventional imaging-based tests for metastatic breast cancer and with other blood-based methods for detecting the disease, such as cancer antigen testing and analyses aimed at capturing intact tumor cells in blood samples.

Special blood tubes for cfDNA analyses are: Cell-Free DNA BCT tubes manufactured by Streck, Inc., and the K3EDTA tubes from BD Vacutainer. They prevent increases in background gDNA levels caused by temperature fluctuations or agitation that can occur during blood sample storage, shipping and processing. These special blood-collection tubes provide a method for obtaining high-quality stabilized samples for rare DNA target detection and determining accurate cfDNA concentrations.

There are a number of novel applications for genomic testing. Eleven percent of Americans age 12 and over are reported to be taking an antidepressant drug in the CDC's National Health and Nutrition Examination Survey (NHANES). Research shows that antidepressant drugs in the U.S., Canada and a number of European countries carry the highest-level warning for risk of suicide, but doctors have not been able to determine which patients may be at risk for suicide.

Genetic factors are known to influence susceptibility to nicotine dependence, affecting both the intensity of addiction and an individual’s response to smoking cessation interventions. Variants in genes involved in nicotine metabolism, neurotransmitter signaling, and reward pathways have been associated with differences in smoking behavior, quit success, and response to pharmacologic therapies such as nicotine replacement, bupropion, or varenicline.

BioRealm has been developing the SmokeScreen genotyping array, a research-use platform designed to support studies examining the genetic architecture of nicotine dependence and

tobacco use behaviors. The array is intended for population and translational research, enabling investigators to explore genetic variants associated with addiction risk, smoking intensity, and treatment response, rather than serving as a direct-to-consumer or clinical diagnostic test.

In a related area of addiction research, the National Institutes of Health is actively studying the genetic and biological underpinnings of alcohol use disorder. Through large-scale genomics initiatives and longitudinal cohort studies, NIH-supported researchers aim to better understand how genetic variation contributes to alcohol dependence, disease progression, and treatment outcomes. While this work may eventually inform risk stratification and personalized intervention strategies, it is important to note that these efforts are currently focused on research and discovery, rather than the near-term development of a standalone clinical genetic test for alcoholism risk.

The diagnostics industry has rallied to support CTCs, ctDNA, and cell-free DNA testing by providing sample-preparation reagents and quality-control materials. When one considers that just a few years ago Veridex was practically alone in this space, the speed with which and the depth of product development have grown is a testament to the unmet need for noninvasive diagnostics in cancer, particularly, but in all facets of medicine

Nucleix offers its real-time PCR-based Bladder EpiCheck test for qualitative detection of 15 DNA methylation patterns associated with transitional cell carcinoma.

Table 8-4: Selected Liquid Biopsy Innovations

Company	Location	Area	Details
Angle plc	UK	capture	Parsortix cell separation
Angle plc	UK	analysis	cancer detection: ovarian, c, br
ApoCell	U.S.	capture	ApoStream technology
CareDx (Revvity)	U.S.	QC	cell-free DNA QC - organ transplant
Caris Life Sciences	U.S.	Analysis	Caris Assure Molecular profiling assay
Clearbridge BioMedics	Singapore	capture	ClearCell FX System, automated CTChip
Cure Forward	U.S.	IT	patient access to CTC test from Cynvenio Biosystems
Cynvenio Biosystems (LungLife AI)	U.S.	analysis	Liquid Biopsy DNA in CTC & ctDNA
Cynvenio Biosystems (LungLife AI)	U.S.	analysis	ClearID Breast Cancer recurrence monitoring, CTC
Cynvenio Biosystems (LungLife AI)	U.S.	capture	ClearID SCORE, CTC
Epic Sciences	U.S.	analysis	metastatic bladder cancers, CTC
Epic Sciences	U.S.	analysis	high-definition CTC microscopy
Exosome Diagnostics	U.S.	analysis	prostate cancer predictive score, ExoDx Prostate
Fluxion Biosciences	U.S.	cell enrich	IsoFlux NGS assay kits
Fluxion Biosciences	U.S.	cell enrich	IsoFlux System NGS sample prep
Fluxion Biosciences	U.S.	cell enrich	IsoFlux EMT, epithelial
Genomic Health (Exact Sciences)	U.S.	analysis	line of liquid biopsy tests
Guardant Health	U.S.	analysis	Guardant360 biopsy-free cancer, CTC
Horizon Discovery (Revvity)	UK	QC	standards for circulating DNA tests
IncellDx	U.S.	smpl prep	IncellPrep Liquid Biopsy cell suspension: FFPE
Inivata (NeoGenomic Health)	UK	analysis	with Biodesix, Tam-Seq lung cancer, cfDNA

Company	Location	Area	Details
Inivata	UK	analysis	TAm-Seq, cell free DNA: sequencing
Kindstar Global	China	analysis	Advanced Cell CTCscope, ISH
Life Technologies/ Thermo Fisher	U.S.	smpl prep	Cynvenio's LiquidBiopsy with Ion Chef & AmpliSeq Cancer Hotspot
MDxHealth	Belgium	analysis	DNA methylation markers, liquid biopsy test for bladder cancer
Menarini Diagnostics	Italy	cancer	GluCyte, liquid biopsy processing & analysis
ProKyma Technologies	UK	capture	KymaSep POC CTC isolation
QIAGEN	Netherlands	smpl enrich	AdnaGen's enrichment and molecular analysis
QIAGEN	Netherlands	analysis	AdnaTest Breast Cancer/ Prostate Cancer relapse monitor
QIAGEN	Netherlands	analysis	therascreen EGFR RGQ Plasma PCR, cfDNA
QIAGEN Hanover	Germany	analysis	AdnaTest Cancer kits, RNA PCR
Rarecells Diagnostics	France	analysis	ISET test, cell sizing
RareCyte	U.S.	analysis	AccuCyteSystem, CTC microscopy
Roche Diagnostics	U.S.	analysis	cell-free DNA (cfDNA) technology
ScreenCell	France	capture	ScreenCell MB, DNA or RNA extraction from CTCs
SeraCare Life Sciences	U.S.	QC	cell-free circulating tumor DNA (ctDNA), NGS
Silicon Biosystems	Italy	analysis	DEPArray, CTC molecular characterization
SRI International	U.S.	capture	FASTcell, cancer specific cell markers, CTC cytometry
Streck	U.S.	QC	Cell-Free DNA BCT
Swift Biosciences (IDT)	U.S.	analysis	Accel-Amplicon panel with Fluxion IsoFlux
Sysmex Inostics	Germany	analysis	BEAMing: digital PCR and flow cytometry for CTCs
Sysmex Inostics	Germany	analysis	OncoBEAM companion tests, CTC
Veridex	U.S.	cell enrich	Cellsearch with Asuragen's SuraSeq panels
Veridex	U.S.	analysis	PD-L1 immune marker

Source: Kalorama Information

Caris Life Sciences offers its Caris Assure Liquid Biopsy Assay. The assay is a blood-based molecular profiling assay that uses circulating nucleic acids sequencing to analyze the cfDNA (Whole Exome) and cfRNA (Whole Transcriptome) of 22,000 genes.

Bio-Rad markets its Celselect Slides which offer an improved method of enumeration of CTCs in liquid biopsies. The Celselect Slides are designed to be used with Bio-Rad's Genesis Cell Isolation System for use in genomics, digital PCR or stained on-slide for immunofluorescent applications.

Metabolomic Profiling

The Human Metabolome Database (HMDB, www.hmdb.ca) is a free electronic database containing detailed information on small-molecule metabolites found in the human body. The database is designed to contain or link three kinds of data: 1) chemical data, 2) clinical data, and 3) molecular biology/biochemistry data. The database contains 220,945 metabolite entries, including both water-soluble and lipid-soluble metabolites, as well as metabolites that are considered abundant and relatively rare. Additionally, 8,610 protein sequences are linked to these metabolite entries.

Research into the human metabolome is uncovering important linkages between genes, metabolites and diseases. Further, researchers are gaining a better understanding of the genetic underpinnings of complex diseases and drug responses through metabolic pathways.

For example, scientists at the Wellcome Trust Sanger Institute (WTSI) have linked over 145 genetic regions with more than 400 molecules involved in metabolism in human blood. The goal was to create an Atlas of the Metabolome that could be used to target the development of drugs and clinical laboratory tests. The Atlas is an open-access database that allows researchers to easily search through the findings.

The WTSI researchers identified 90 new genetic associations, tripling the number of known genetic associations with metabolites. In the case of the already-known metabolites, they were able to link the molecule to gene function. Additionally, the researchers were able to map genes to their likely substrates or products. This allowed them to further link these metabolites to conditions, such as hypertension, cardiovascular disease, and diabetes.

The leading company in this area is Metabolon, Inc. The company is dedicated to metabolic pathway analysis for biomarker discovery and the development of follow-on diagnostic tests.

Metabolon reported that its metabolytics business has conducted more than 5,400 collaborative studies with over 1,300 clients to identify diseases, discover biomarkers, and better understand complex biological processes. Tests are run in Metabolon's in-house CLIA laboratory.

Metabolon's biomarker discovery platform has already been used to identify biomarkers for a number of diseases. These biomarkers are being incorporated into clinical diagnostic tests in the following areas: prostate cancer, bladder cancer, kidney cancer, nephrotoxicity of chemotherapy drugs and diabetes/insulin resistance.

Metabolon offers its new SmartPanel portfolio. Metabolon states that its Microbiome SmartPanel demystifies the gut microbiome by zeroing in on biologically relevant microbial and host-derived metabolites, as well as xenobiotic molecules, to reveal deep insights into microbiome function and its impact on host health. The proprietary Heliogram visualization tool allows users to explore 13 microbiome pathways to rapidly assess the impact of therapeutic interventions on the host microbiome. In addition, the on-demand access to Metabolon's comprehensive pathway knowledge base gives seamless access to expertly curated, microbiome-relevant disease associations and biological themes.

Metabolon markets its Bile Acids and Short Chain Fatty Acids Targeted Panels, which measure microbially derived metabolites of biological significance to identify biomarkers. The Bile Acids Panel measures 21 metabolites and the Short Chain Fatty Acids Panel measures nine metabolites

Other major players in the metabolomics market include Thermo Fisher Scientific, Danaher Corporation, Shimadzu Corporation, Waters Corporation, Agilent Technologies, and Bruker Corporation.

Researchers from the Norwegian University of Science and Technology have found that pregnant women with preeclampsia have a metabolic profile that is distinct from that of healthy pregnant women and women who are not pregnant. By comparing the serum and urine metabolomes of pregnant women with and without preeclampsia, they identified 9 urine metabolites that distinguished women with preeclampsia from those without.

Information Technology

As a result of intensive studies following the Human Genome Project, much of the human genome, transcriptome, and proteome have been mapped, although interpretation remains incomplete and continues to evolve. Rapid technological advances have made sequencing faster and significantly more affordable, enabling broader clinical and research use. This represents the foundational step in applying genomic analysis across technologies, but the industry is still progressing from data generation to routine clinical implementation.

Information technology plays a central role in this transition, supporting three essential functions: sharing genomic data to build well-curated variant databases, interpreting gene variants to establish clinically relevant guidelines, and disseminating actionable insights to clinicians for patient care. The scale of global genomic research continues to expand, with large population studies and biobank initiatives generating vast datasets. IT infrastructure enables aggregation and analysis of these data, improving understanding of variant-disease relationships. Data-sharing has become a cornerstone of the field, with both public and private consortia facilitating collaboration, particularly in rare diseases and precision oncology.

As gene targets are validated and incorporated into targeted assays and multiplex panels, the challenge has shifted toward interpretation and clinical integration. Laboratories and clinicians increasingly require tools that can manage and interpret continuous streams of genomic data. In response, IVD and life sciences companies are investing heavily in bioinformatics, decision-support tools, and integrated software platforms, often through partnerships and acquisitions. These tools are delivered both as standalone solutions and as components embedded within diagnostic workflows.

Companies such as QIAGEN have expanded their offerings to include custom business solutions and clinical decision-support platforms that integrate molecular data into laboratory and clinical workflows. Technology companies are also playing a growing role. Apple Inc. continues to advance health data integration through platforms such as Apple Watch, ResearchKit, and HealthKit, supporting large-scale data collection and patient engagement. Cloud-based genomics platforms like DNAnexus provide secure environments for storing, analyzing, and sharing genomic data at scale, supporting both research and clinical applications. Collaborative efforts with organizations such as Intel Corporation have focused on improving data-processing efficiency in large-scale sequencing workflows.

Regulatory and collaborative initiatives have also advanced. Platforms such as precisionFDA, developed with input from the U.S. Food and Drug Administration, support the evaluation and standardization of bioinformatics pipelines for next-generation sequencing. Large-scale data initiatives from companies like Google have evolved into broader life sciences efforts, such as Verily, that focus on integrating genomic and clinical data for research and healthcare applications.

QIAGEN's acquisition of N-of-One strengthened its position in clinical interpretation, providing oncology-focused decision support that has been incorporated into diagnostic workflows globally. These types of platforms highlight the growing importance of combining genomic data with expert interpretation to deliver clinically actionable insights.

Technological and research advances have brought routine genomic medicine closer to clinical reality, but widespread adoption depends on effective integration into healthcare systems. The next critical step is developing scalable systems that deliver clear, actionable genomic information to clinicians and patients, enabling informed decisions in precision medicine.

Next-generation sequencing has made it possible to generate detailed individual genomic profiles, but the value of this information depends on interpretation. The complexity and volume of genomic data require sophisticated bioinformatics tools and expert analysis to translate results into meaningful clinical guidance. IT and diagnostics companies continue to respond to this need, driving the convergence of genomics, data science, and clinical decision-making

Table 8-5: Selected IT Innovations in Molecular Diagnostics

Company	Location	Area	Details
Advaita Bioinformatics	U.S.	multi-omic	iPathwayGuide, multi-omic data integration and analysis
Advanced Biological Lab	Luxembourg	NGS	with Tute Genomics, OncoChek, NGS data analysis platform
Advanced Biological Lab	Luxembourg	HIV	DeepChek-HIV NGS with Illumina's BaseSpace Apps
Advanced Biological Lab	Luxembourg	micro	IT decision support for viral genome analysis
Advanced Cell Diagnostics	U.S.	CTC	RNAscope/ISH image analysis software
Agilent	U.S.	sequencing	MedGenome's OncoMD Cancer knowledge base in Bench Lab NGS
Agilent	U.S.	sequencing	CollabRx's Genetic Variant Annotation in Lab Bench NGS
Ambry Genetics (owned by Tempus AI)	U.S.	prenate	Progeny Genetics Software for prenatal analysis, service
Apple	U.S.	app	ResearchKit, open-source IT to create research apps
Apple	U.S.	app	HealthKit IT to create consumer health apps
BGI	China	sequencing	QIAGEN's Ingenuity Variant Analysis with BGI's sequencing services
BioView	Israel	CTC	BioView imaging IT for Screen Cell's cyto kit
Data4Cure	U.S.	exome	IT analyze genomes, exomes and targeted gene panels
Deep Genomics	Canada	general	Splice AI
Definiens (MedImmune)	Germany	histo	IT for Clarient's Scope IA Platform
Definiens (MedImmune)	Germany	big data	Tissue Phenomics big data analysis tissue tests
Definiens (MedImmune)	Germany	histo	Biomarker Datafication Services tissue biomarkers, service
Dell Healthcare	U.S.	histo	link for Chinese labs to Leica's histology, cloud network

Company	Location	Area	Details
Deloitte/ConvergeHEALTH	U.S.	cancer	with Moffitt's M2GEN biomarker data, personalized cancer
DNAnexus	U.S.	sequencing	with Intel, elPrep, IT to prepare genomic data, sequence analysis
DNAnexus	U.S.	whole genome	supports HgV framework, precision medicine
Fabric Genomics	U.S.	cancer	Phevor (Phenotype Driven Variant Ontological Re-ranking tool)
Genalice	Netherlands	big data	GENALICE MAP, NGS big data
Genalice	Netherlands	sequencing	with Knome turn-key IT, NGS data interpretation
Genologics (Illumina)	U.S.	LIS	Clarity LIMS X, LIS Illumina SeqLab
Genome Diagnostics	Netherlands	HLA	SBTengine is a software package for HLA-typing
GenomeNext	U.S.	general	cloud, software-as-a-service, hospital genomic analysis
GenomOncology	U.S.	sequencing	GenomAnalytics, NGS gene variants database
Golden Helix	U.S.	CTC	VarSeq information platform for CTC sequencing
Google Genomics	U.S.	autism	Autism Speaks MSSNG portal on the Google Cloud Platform
Google Genomics	U.S.	big data	Verily Baseline Study
Google Genomics	U.S.	cloud	Cancer Genomics Cloud, cancer genomic database
Illumina	U.S.	sequencing	DRAGEN Bio-IT Processor sequencing analysis IT
Illumina	U.S.	sequencing	Intel's Xeon processors for NGS data analysis
Illumina	U.S.	general	GeneInsight-Illumina Network, variant analysis IT
Illumina	U.S.	cloud	BaseSpace OnSite genomic test analysis, cloud
IntegraGen	France	cancer	data interpretation of next-generation sequencing of cancer
Intel Corporation	U.S.	genome	with DataDirect HPC infrastructure for genomic data analysis

Company	Location	Area	Details
Intel Corporation	U.S.	genome	with DNADirect HPC infrastructure, genomic data analysis
Lab7 Systems	U.S.	sequencing	sample-to-answer data management LIS for NGS
Labcorp	U.S.	genome	Enlighten Health Genomics genomic test interpretation, service
Labcorp	U.S.	genome	Omicia's Opal Clinical, Software-as-a-Service genomic interpretation
Labcorp	U.S.	prenate	Edico Genome's DRAGEN Bio-IT, genomic analysis, service
Life Technologies/Thermo Fisher	U.S.	all mol	Select Dx, database developments in molecular diagnostics
Life Technologies/Thermo Fisher	U.S.	exome	Ion Reporter Software for exome CNVs, SNPs, and indels
Life Technologies/Thermo Fisher	U.S.	micro	Ridom GmbH, SeqSphere+ whole genome bacterial typing, Ion Torrent
Massive Bio	U.S.	cancer	oncology decision support platforms
Maverix Biomics	U.S.	sequencing	Analysis Kits variants in whole genome, exome, NGS
Mayo Medical Lab	U.S.	general	Optum Labs with UnitedHealth data-mining venture, service
Mayo Medical Lab	U.S.	IT	Oneome, genomics interpretation prescription drugs, service
NantOmics	U.S.	cancer	IT and database for variation interpretation, treatment choice
Omicia (now Fabric Genomics)	U.S.	genome	Opal Clinical, Software-as-a-Service genomic interpretation
Omixon (now Fabric Genomics)	Hungary	HLA	Global Genomics IT, validate HLA sequencing datasets
PierianDx	U.S.	PGx	Clinical Genomicist Workstation NGS management IT
PierianDx	U.S.	PGx	PDx Score algorithm for PGx therapy report
QIAGEN	U.S.	sequencing	NGS analysis for CeGaT GmbH (Tubigen, Germany) panels

Company	Location	Area	Details
QIAGEN	U.S.	cancer	CNV interpretation for Affymetrix OncoScan assay
QIAGEN	U.S.	cancer	IT for NeoGenomics solid tumor NGS tests
QIAGEN	U.S.	cancer	interpretation for BloodCenter of Wisconsin's HemeOnc cancer NGS
QIAGEN	U.S.	cancer	clinical interpretation for CeGaT's cancer NGS
QIAGEN	U.S.	cancer	clinical interpretation for OncoDNA's cancer NGS (EU, Asia, Middle East)
QIAGEN	U.S.	app	Variant Interpreter app on Illumina's BaseSpace Apps
QIAGEN	U.S.	sequencing	N-of-One's services from within the Cartagenia Bench Lab NGS
QIAGEN	Netherlands	sequencing	QIAGEN Clinical Insight, DNA variants in NGS
QIAGEN	Netherlands	sequencing	Ingenuity Pathway Analysis IT with Maverix's interpretation RNA-seq data
QIAGEN	Netherlands	genome	FastQ-to-insight solution, CLC Workbench with Ingenuity Variant Analysis
QIAGEN	Netherlands	genome	numerous ingenuity collaborations
QIAGEN Bioinformatics	U.S.	microbiome	CLC Microbial Genomics Module, microbiome analysis
QIAGEN/Biobase Wolfenbuttel	Netherlands	genome	annotated gene mutation databases
Revvity	U.S.	multi-omic	Integromics' OmicsOffice, variant analysis IT
Seegene	Korea	multi-omic	SySDx big data multi-omic analytics with assays
Selventa	U.S.	multi-omic	SySDx big data multi-omic analytics
Sunquest Information	U.S.	histo	with GeneInsight, IT analysis pathology gene data
Thermo Fisher Scientific	U.S.	cfDNA	QuantStudio 3D Rare Mutation Analysis Solution, cfDNA
Thermo Fisher Scientific	U.S.	micro	MicrobeBridge IT, Sanger sequencing on CDC MicrobeNet database

Company	Location	Area	Details
Thermo Fisher Scientific	U.S.	general	Ingenuity iReport with Affymetrix expression microarray products
Thermo Fisher Scientific	U.S.	histo	Biodiscovery's Nexus for OncoScan FFPE Software

Source: Kalorama Information

Artificial Intelligence (AI)

Dozens of new AI and machine learning products have been added to the FDA list of approved clinical applications. Artificial intelligence has been getting a lot of attention in recent years. As technology advances, laboratory scientists are making great strides in AI's capabilities and sophistication. While some people may worry about patient confidentiality and other concerns, much of the AI in use today can actually help humanity. Artificial intelligence has been heavily promoted as the next big thing in healthcare for nearly a decade. AI was expected to revolutionize how doctors treat patients.

Some AI-based FDA approvals in 2024-2026 include:

- NeoBeat, NeoBeat Mini – Laerdal Medical -cardiovascular
- eCART v5 Clinical Deterioration Suite – AgileMD – cardiovascular
- Corvair and Impala– AliveCor – cardiovascular
- ASSURE Wearable ECG -Kestra Medical -cardiovascular
- AUTION EYE AI-4520 Urine Particle Analysis System – Hematology
- GI Genius ColonPro – Cosmo AI- GI and urology
- Galen Second Read – Ibex Medical – Pathology
- Tempus ECG-Low EF – Tempus Ai - Cardiovascular
- HeartFlow Analysis – HeartFlow - Cardiovascular
- US2.ca- Us2.ai – Cardiovascular
- Withings ECG App- Withings - Cardiovascular
- Volta AF-Xplorer – Volta Medical – Cardiovascular

- X100/X100HT with Full Field Peripheral Blood Smear – Scopio Labs- Hematology
- TriVerity- Inflammatix – Microbiology
- MagentiQ-Colo – Magentiq Eye- GI
- Maestro System – Moon Surgical – GI

The most notable AI use is currently in radiology; several new applications for clinical use are entering the market and are in development.

Forensic Studies – An Emerging Opportunity

Every year, investigators collect tens of thousands of biological samples from crime scenes that may hold valuable clues to solving criminal cases. Genetic research since the completion of the Human Genome Project in 2003 has uncovered thousands of biomarkers that can be applied to DNA-based forensics and human identification testing.

The U.S. Federal Bureau of Investigation (FBI) updated its current DNA databasing standards to include an Addendum to the Quality Assurance Standards (QAS) for DNA Databasing Laboratories performing Rapid DNA analysis and Modified Rapid DNA Analysis Using a Rapid DNA Instrument

The revision of the QAS enables the use of rapid DNA analysis in ways that are actionable for law enforcement in local communities. The Addendum describes the requirements that accredited laboratories performing Rapid DNA analysis or modified Rapid DNA analysis must meet for their results to be considered for inclusion in the Combined DNA Index System (CODIS).

Several IVD companies already had arrangements with law enforcement agencies for the genetic analysis of crime scene samples in centralized laboratories. This created a backlog of samples for analysis that was thought to be a barrier to the quick resolution of some crimes. Rapid DNA analysis generates DNA profiles in less than two hours for use in local and regional law enforcement to potentially fight violent crime with speedy results. This technology may also be used to prevent human trafficking and fraudulent asylum requests. Further, the act clears the way for decentralization of DNA technology, enabling state and local law enforcement jurisdictions to perform rapid DNA analysis on subjects with tests and technologies that meet the new guidelines.

Always in search of new uses for their products, IVD companies have entered the market for rapid forensic DNA testing. The total available market is very large and includes agencies at every level of government, from cities to the country. It is estimated that there are approximately 400 accredited forensic crime laboratories analyzing more than four million casework and reference samples per year in the U.S. alone.

The following companies are active in forensic and human identification DNA testing. Most offerings in this segment are delivered as laboratory-based systems or services, although a small number of vendors are advancing portable or near-field DNA analysis concepts. For example, NEC Corporation has developed a portable rapid DNA analyzer concept intended for use outside traditional laboratories, including disaster victim identification and field applications, although deployment remains limited and use cases are specialized.

IntegenX, now part of Thermo Fisher Scientific, is widely regarded as a pioneer in rapid human DNA identification. The RapidHIT system family integrates microfluidics, optics, and validated biochemistry to deliver sample-to-answer DNA profiling for law enforcement and forensic workflows. When used with GlobalFiler Express STR chemistry, RapidHIT profiles can be generated in hours and are compatible with upload to the FBI's CODIS system, supporting booking-station and investigative use cases.

Illumina established an early leadership position in forensic genomics with the MiSeq FGx Forensic Genomics System, which enabled next-generation sequencing–based analysis of a broader range of forensic markers than capillary electrophoresis-based methods. The system combined the MiSeq FGx sequencer with ForenSeq DNA Signature Prep Kits and dedicated analysis software. While Illumina has since refocused its strategic priorities, the MiSeq FGx platform remains relevant through its installed base and validated forensic workflows, particularly in advanced forensic laboratories.

QIAGEN is a major supplier of forensic reagents through its Investigator STR assay kits, which are used for DNA evidence analysis in forensic laboratories worldwide. These kits enable simultaneous analysis of multiple STR loci for human identification and include quality-assessment tools that help laboratories determine sample suitability early in the workflow. The Investigator STR portfolio aligns with current FBI CODIS core locus requirements and is also compliant with European and INTERPOL standards, facilitating international data exchange.

For more than two decades, Thermo Fisher Scientific, through its Applied Biosystems brand, has been a dominant supplier to forensic laboratories. Thermo Fisher offers a fully integrated HID testing ecosystem, spanning sample preparation, STR amplification, capillary electrophoresis instruments, and data analysis software. Its GlobalFiler and GlobalFiler Express chemistries incorporate all CODIS core loci along with additional markers commonly used in Europe, reducing the probability of adventitious matches and enabling more robust cross-border forensic comparisons.

Table 8-6: Selected Innovations in Forensic DNA Testing

Company	Location	Details
Genomica	Spain	Forensic medicine DNA analysis
Illumina	San Diego, CA	MiSeq FGx Forensic Genomics System
IntegenX	Pleasanton, CA	RapidHIT 200 Human Identification System
IntegenX	Pleasanton, CA	Life Technologies global filler on RapidHIT, automated DNA
Labcorp	Burlington, NC	Cellmark Forensics and Bode Technology forensic services
Life Technologies/Thermo Fisher	Carlsbad, CA	Applied Biosystems' GlobalFiler Express, DNA
NEC Corporation	Japan	Portable P-DNA Analyzer
QIAGEN	Netherlands	Investigator STR assay kits DNA evidence analysis in U.S.

Source: Kalorama Information

PCR opened up many doors in genetic research, including DNA analysis and identification of different genes based on their DNA sequences, and sequencing builds on many of the same underlying principles. Innovation in these core molecular techniques has largely depended on scientists refining and adapting them to make testing faster, more sensitive and specific, easier to use, and more cost-effective. Molecular tests generally consist of three key components: once genetic material is isolated from a sample such as blood, urine, stool, buccal cells, or tissue, probes bind to specific target sequences to provide test specificity; amplification processes then increase the amount of target material so it can be measured and, in sequencing, so the order of base pairs can be determined, although some newer methods can bypass amplification; finally, the nucleic acid, whether amplified or not, is labeled with colorimetric, fluorescent, or chemiluminescent markers to generate a

measurable signal, contributing to overall test sensitivity. These elements can be combined in many ways across different platforms. PCR, qPCR, and digital PCR rely on thermal cycling and require external heating through a thermal cycler to drive amplification, while isothermal technologies such as LAMP, TMA, bDNA, and NASBA operate at a constant temperature using simpler heating systems, eliminating the need for thermal cycling and making them well-suited for point-of-care and decentralized testing environments.

Test Platforms

Table 8-7: Key Molecular Technologies and Major Players

Technology	Major Players
bDNA	Grifols, Siemens Healthineers
Bead Array	Luminex, Illumina, BD
digital PCR	Standard BioTools, Thermo Fisher Scientific, RainDance Technologies, Bio-Rad Laboratories
Electrochemical Array	Enzo Biosciences
HDA (Helicase Dependent Amplification)	New England Biolabs, Meridian Biosciences, Great Basin Scientific (Roche), QuidelOrtho
In-situ Hybridization	QIAGEN/Digene, Roche/Ventana, Tripath/BD, Abbott/Vysis, Dako/Agilent
LIPA	Innogenetics/Fujirebio
LLA	Bio-Rad Laboratories
LAMP	Eiken and licensees
Microarray/Biochip	Affymetrix, Thermo Fisher Scientific
NASBA	bioMérieux
PCR/QPCR	Roche Diagnostics and licensees
SDA	BD Diagnostics
Sequencing	Roche Diagnostics, Illumina, Thermo Fisher Scientific, Complete Genomics (BGI) and more
TMA	Hologic/Gen-Probe

Source: Kalorama Information

One aspect of making molecular tests more accessible to healthcare professionals is the automation of these tests and the commercialization of new platforms that build on basic technologies. Of interest are platforms for sequencing and mass They are slowly transitioning to clinical applications used primarily in large medical centers and reference laboratories.

More importantly, test platforms that use digital formats such as digital PCR, gel drop PCR and integrated circuits, eliminate the fluorescent label step. This, according to the developers, allows for more precise quantification of target nucleic acid molecules, enabling accurate determination of copy number variation and the detection of rare mutation events, such as those seen in certain tumors and mutated pathogens. Applications of these capabilities could provide new strategies for diagnosing inherited disorders, cancer, and infectious diseases.

Devices using flow-through microfluidic cassettes, lateral flow, and biochip arrays set the stage for integrating molecular testing into routine practice by simplifying sample-to-result testing into a one-step procedure.

Tabletop systems are considered the prerequisite technological advancement to providing molecular testing in small laboratories and resource-limited test sites anywhere in the world. The market is moving beyond these systems and the next generation of sample-to-result molecular test instruments is focusing on bringing genetic medicine to a much broader audience. The commercialization of these platforms and tests is the next major development in the future of molecular diagnostics, as they have the potential to improve the quality of healthcare by enhancing the affordability and accessibility of advanced diagnostic solutions, even in remote areas where challenges of skilled manpower and infrastructure are acute. Government investments in academic research and initiatives to support startup companies in the field are also driving growth in the molecular diagnostics sector.

QIAcube workstations of QIAGEN enable automated sample processing, and they are now launching the next-generation QIAcube Connect with advanced digital capabilities and full connectivity. These solutions assure standardization of sample preparation and save Cepheid is a molecular diagnostics company that develops, manufactures, and markets integrated systems for testing in the clinical and non-clinical markets. Its systems enable molecular testing for organisms and genetically based diseases by automating manual laboratory procedures. The company's main platform is the GeneXpert system, a benchtop PCR system that integrates sample preparation, DNA amplification, and detection. The Smart Cycler system from Cepheid integrates DNA amplification and detection to enable sample analysis. Cepheid also offers a wide range of tests that can be run on the Xpert system.

Roche provides the cobas Prime Pre-analytical System to improve efficiency in molecular diagnostic laboratories. The system minimizes repetitive manual tasks associated with processing the wide variety and high volume of sample tubes, vials and containers seen in today's molecular lab.

Bruker markets its LiquidArray Gastrointestinal PCR Assay for broad syndromic testing. The LiquidArray Gastrointestinal is a syndromic panel that enables simultaneous detection of up to 26 pathogens.

PathogenDx developed its first UTI assay using its D3 Array technology. The D3 Array offers multiplexed, targeted sequence detection designed to mimic a three-dimensional structure microarray. It can simultaneously provide identification and drug-resistance results in a single test and detect a wide variety of bacteria, viruses and fungi. It can detect over 100 targets in a single reaction.

The chart below presents a selection of molecular test platforms that are planning to make their mark as novel approaches to molecular testing. Some are based on miniaturization and biochip technology. Of interest are platforms for sequencing and mass spectrometry – sophisticated technologies traditionally used in research settings. Since many molecular tests are still used in research mode, the mix of new technologies and tests provides some idea of the evolution of molecular tests.

Table 8-8: Selected Molecular Test Platform Innovations

Company	Location	Area	Details
Agena Bioscience	U.S.	mass spec	MassARRAY 24-Well System, low volume labs
Biocartis	Switzerland	PCR	Idylla, PCR from PPFA tissue
BioFire Diagnostics/ bioMérieux	U.S.	PCR	FILMARRAY Torch platform, advanced
BioFire Diagnostics/ bioMérieux	U.S.	PCR	BioFire FILMARRAY 2.0 system
Bio-Techne	U.S.	sequencing	Protein Simple
Coyote Bioscience	China	PCR	InstantGene, miniature gene sensor
DestiNA Genomics	Scotland	genetic	SMART Nucleobase technology: DNA/RNA
DestiNA Genomics	Scotland	genetic	e-BRID System with STMicroelectronics' In-Check Platform
Diasorin	Italy	PCR	ELITe InGenius automated sample to answer
Diasorin	U.S.	PCR	ARIES sample to answer molecular system
Diasorin	U.S.	sequencing	Aries M1, a low throughout version of Aries System
Direct Genomics	China	genetic	GenoCare, Helicos-based sample to result, clinic
Douglas Scientific (LGC)	U.S.	PCR	IntelliQube & Array Tape liquid handling, detection, IT
Eiken Chemical Co	Japan	LAMP	automated multi-plex chip, sample to answer
Enzo Biochem	U.S.	PCR	AmpiProbe -based Real Time Amplification Detection platform
Genomic Vision	France	genome	high-throughput scanner for molecular combing
Genomic Vision	France	genome	Genomic Morse Code: Molecular Combing System
Genomica	Spain	cancer	CLART (Clinical Array Technology) platform
HTG Molecular Diagnostics	U.S.	sequencing	molecular tests on Thermo Fisher's Ion Torrent PGM NGS
HTG Molecular Diagnostics	U.S.	cancer	Edge RNA analysis automation, extraction free

Company	Location	Area	Details
HTG Molecular Diagnostics	U.S.	sequencing	HTG EdgeSeq on Thermo Fisher Ion Torrent
Illumina	U.S.	sequencing	desktop MiniSeq system
Illumina	U.S.	sequencing	Bio-Rad's droplet technology with sequencing
Illumina	U.S.	sequencing	desktop MiniSeq system, targeted sequencer
Illumina	U.S.	sequencing	Project Firefly, semiconductor sequencing system
Illumina	U.S.	cell	Illumina's sequencing with Bio-Rad ddPCR for single cells
Illumina	U.S.	sequencing	MiSeq FGx Forensic Genomics System
IncellDx	U.S.	flow	InCellCept assay: molecular markers in cells
Intel Corporation	U.S.	chiparray	silicon microarray chip
Medical Innovation Ventures	Malaysia	PCR	GenoAmp Real-Time RT-PCR
Oxford Nanopore Technologies	UK	nanopore	MinION, PromethION and GridION, single molecule
Pacific Biosciences (PacBio)	U.S.	genome	Sequel, tech & IT for Single Molecule, Real-Time sequencing, Revio
QIAGEN	Netherlands	PCR	QIAsymphony RGQ MDx system for clinical labs
QIAGEN	Netherlands	sequencing	GeneReader benchtop NGS sequencer enhancements
QIAGEN	Netherlands	genetic	multi-DNA/RNA copy numbers, expression levels, mutations
Savyon Diagnostics	Israel	chiparray	NanoCHIP: automated DNA-to-Result
Standard BioTools	U.S.	mass spec	Helios, a CyTOF single cell analysis
Standard BioTools	U.S.	cancer	Precision Cancer Monitoring platform, urine
Takara Bio	U.S.	chiparray	Multi-Patient Array for Infiniti, chiparray instrument
Takara Bio	U.S.	sequencing	NGS clinical tests on Seq-Ready SmartChip TE
Thermo Fisher	U.S.	genomic	Axiom genotyping platform

Company	Location	Area	Details
Thermo Fisher	U.S.	gene/ immuno	Luminex with ProcartaPlex immunoassays & QuantiGene Plex
Vela Diagnostics	Singapore	sequencing	Sentosa, automated NGS platform
Zeesan Biotech	China	platform	Sanity 2.0 System fully integrated and automated molecular diagnostic platform

Source: Kalorama Information

Major Players

Since 2000, sales of all molecular tests have increased almost tenfold, and the number of companies and tests has literally exploded. At least 950 companies are actively involved in molecular diagnostics. This is not surprising, given there are molecular applications in just about every segment of the IVD industry. Company revenues include sales of molecular tests in all segments of the IVD market. It is beyond the scope of this report to segment company molecular revenues by test segment with certainty.

Table 8-9: Molecular Test Revenues of Selected IVD Vendors, 2022, 2023, 2024, and estimated 2025 ($ million)

Company	2022	2023	2024	2025 (E)
Danaher	4,901	3,576	3,393	4,901
Exact Sciences	1,724	2,179	2,432	2,820
Roche	3,159	2,295	2,604	2,618
bioMérieux	1,609	1,576	1,766	2,503
Thermo Fisher	1,448	1,071	916	1,448
QIAGEN	1,160	1,067	1,021	1,402
Hologic	2,123	1,256	1,294	1,312
Agilent	833	956	1,013	1,029
Myriad Genetics	678	746	838	838
Illumina	674	700	672	665

Source: Kalorama Information

It is beyond the scope of this research to tease out these companies' revenues for genomic molecular tests. These leaders market a wide portfolio of automated infectious disease tests and have been launching tests for cancer diagnosis and companion diagnostics for cancer therapeutics.

These major companies hold more than 70% of the total world market for molecular tests. Their dominance derives from a continuous involvement in the most dynamic molecular test segments – infectious diseases, cancer assays and HPV testing.

Below is a brief overview of selected molecular company participants.

Cepheid provides the Xpert Xpress CoV-2/Flu/RSVplus, which is a rapid molecular test for qualitative detection of the COVID-19 virus. Cepheid markets the Xpert Xpress CoV-2plus. The test is a rapid molecular test for the qualitative detection of COVID-19. The plus portion of the test enables consistent virus detection, incorporating a 3rd conserved genetic target for SARS-CoV-2 detection. Cepheid offers its Xpert nPM1 Mutation, a molecular test for quantifying mutant nPM1 mRNA transcripts in peripheral blood from patients with AML.

Roche Diagnostics offers a broad product portfolio, which includes molecular diagnostic tests for oncology, virology, microbiology, and blood screening. The company's molecular test revenues are bolstered by the continued dominance of Ventana Medical's histology business. The company continues to expand geographically with special emphasis on the top seven emerging countries: Brazil, Russia, India, China, South Korea, Mexico and Turkey.

Roche offers its high-throughput monkeypox test. The test, MPXV, is designed to be run on the cobas 6800/8800 Systems and is a real-time PCR test for the qualitative detection of DNA from MPXV. The test targets two different regions of the MPXV genome.

Hologic, Inc. is a leading developer, manufacturer and supplier of diagnostic products, medical imaging systems and surgical products dedicated to women's health. Hologic provides products for mammography and breast biopsy, radiation treatment for early-stage breast cancer, cervical cancer screening, treatment for menorrhagia, permanent contraception, osteoporosis assessment, preterm birth risk assessment, mini C-arm for extremity imaging, and molecular diagnostic products, including HPV and reagents for a variety of DNA and RNA analysis applications. Hologic's PANTHER Fusion EBV Quant Assay and PANTHER Fusion BKV Quant Assay are innovative additions to the market. The assays are in vitro NATT tests that are run on the PANTHER Fusion system. PANTHER Fusion EBV Quant is used with whole blood and plasma for the management of transplant patients, monitoring viral levels. The BKV Quant is used with plasma and urine samples to identify important biomarkers when using quantitative NAATs for the diagnosis and management of transplant patients.

The company markets its PANTHER Fusion SARS-CoV-2/Flu A/B/RSV assay. The test is a molecular test that detects and differentiates four of the most prevalent respiratory viruses in a single sample. The new test, called the RespDirect collection kit, runs on the PANTHER Fusion system.

Exact Sciences is a molecular diagnostics company that has mostly focused on colorectal cancer. The company has exclusive intellectual property protecting its non-invasive, molecular screening technology for the detection of colorectal cancer. Stool-based DNA (sDNA) technology is included in the colorectal cancer screening guidelines of the American Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer. Exact Sciences markets the OncoExTra therapy selection test. The test is an NGS-based comprehensive DNA and RNA genomic test for profiling tumors.

Molecular diagnostics is a growing focus for BD, as evidenced by the rollout of infectious disease products, including the BD MAX platform for HAI and syndromic panel testing, and BD Viper for sexual and women's health testing using PCR and SDA protocols. The company's molecular diagnostics portfolio includes STD testing systems, RNA probe-based tests for vaginitis, and GeneOhm tests for HAIs. The BD MAX competes primarily in the molecular HAI and enteric testing markets. BD has developed its own assays for the BD MAX platform and also partnered with other companies to strengthen its test menu. Clinical assays for the BD MAX include Chlamydia, gonorrhea, and Trichomonas vaginalis C. difficile, MRSA, MRSA extended detection, S. aureus/MRSA, carbapenem-resistant organisms, an enteric bacterial panel (Salmonella, Campylobacter, Shigella/enteroinvasive E. coli, Shiga toxin genes), and an enteric parasite panel (Giardia, Cryptosporidium, and E. histolytica).

Market Analysis

The clinical market for DNA assays includes:

- Infectious disease (discussed in Chapter 11)
- Blood bank screening (discussed in Chapter 12)
- Thrombophilia SNPs (discussed in Chapter 10)
- Oncology- CDx,
- Genetic/Inherited Diseases
- Tissue Typing (HLA)
- Prenatal test services - NIPT

Markets in this chapter focus on genomic testing and smaller molecular segments; the markets for molecular tests for infectious diseases, blood screening, and thrombophilia SNPs are covered in their respective chapters.

The 2025 market for oncology, transplant, and genetic assays worldwide is estimated at $4,417 million. Over the forecast period, the market will grow at roughly 11% annually and reach $7,400 million worldwide in 2030. The NIPT market will grow to $1,530 million by 2030, with a 7% CAGR.

Table 8-10: Global Genomic, HLA, NIPT, and Oncology Molecular Test Sales, by Type with NIPT, 2025-2030 ($ million)

Type	2025	%Mkt	2030	%Mkt	CAGR
Oncology Assays (incl. CDx)	2,570	58%	4,400	60%	11%
Genetic/Inherited Disease Assays	1,010	23%	1,650	22%	10%
Transplant Testing (HLA)	837	19%	1,350	18%	10%
Subtotal	**4,417**	**100%**	**7,400**	**100%**	**11%**
Prenatal Testing - NIPT	1,070	--	1,530	--	7%
Total	**5,487**	**--**	**8,980**	**--**	**10%**

Source: Kalorama Information

Oncology

One of the most explored applications of molecular diagnostics is oncology; it is used for screening, therapy selection, diagnosis, and relapse monitoring of cancer. Genetic analysis of samples using PCR and NGS technologies enables the detection of mutations, gene fusions, copy number variations, and epigenetic changes in tumor tissues, helping physicians determine the most effective treatment options for individual patients. In recent years, molecular testing has expanded beyond diagnosis to include minimal residual disease (MRD) detection, in which highly sensitive assays identify trace levels of circulating tumor DNA after treatment, enabling earlier detection of recurrence and more informed decisions regarding adjuvant therapy.

Since at least the mid-1900s, testing of formalin-fixed paraffin-embedded (FFPE) tissue biopsy material using histological staining, immunohistochemistry (IHC), and in situ hybridization (ISH) has been the mainstay of cancer diagnostics. Histopathology remains the gold standard for initial diagnosis and tumor classification. However, as targeted therapies have become more prevalent, molecular techniques have increasingly complemented histology. Methods applied to FFPE-derived material now include PCR, targeted sequencing panels, fluorescence in situ hybridization, and broader genomic profiling to identify actionable biomarkers.

Histological staining of tumor tissue remains an important starting point, but the shift toward gene-targeted therapies has driven adoption of more advanced molecular tools. These include PCR-based assays, microarrays, SNP analysis, comparative genomic hybridization for copy number analysis, and sequencing approaches that provide detailed insight into tumor biology. At the same time, tumors are increasingly classified based on molecular and genomic profiles rather than tissue of origin alone, supporting the continued growth of precision oncology and biomarker-driven treatment strategies.

Cancer testing now extends well beyond diagnosis. Improved treatment outcomes have increased survival rates, creating a growing need for ongoing monitoring. Patients are often followed at regular intervals after treatment to detect recurrence. In this setting, invasive tissue biopsies are increasingly complemented by noninvasive approaches that analyze circulating tumor DNA and other biomarkers in blood and body fluids. These liquid biopsy techniques are also used to monitor treatment response and identify emerging resistance mutations during therapy.

Advances in cancer research continue to drive the development of molecular tumor marker testing in blood and urine. Early liquid biopsy approaches focused on DNA methylation signals, with Epigenomics playing a pioneering role in demonstrating that tumor-associated methylated DNA fragments could be detected in plasma using PCR-based methods. While early assays such as mSEPT9-based colorectal cancer testing established proof of concept, newer approaches now incorporate multiple molecular signals to improve performance and broaden clinical utility.

The field has evolved significantly with the emergence of multi-cancer early detection testing, which analyzes blood samples for molecular signals associated with multiple tumor types simultaneously. These assays combine methylation patterns, sequencing data, and other genomic features to improve early detection, although clinical adoption remains in the early stages and continues to depend on long-term outcome data and reimbursement support.

The analysis of circulating DNA and RNA fragments enables noninvasive approaches for early cancer detection, disease monitoring, and assessment of treatment effectiveness. The underlying technology has been validated through earlier applications, such as noninvasive prenatal testing, which demonstrated the feasibility of detecting rare DNA fragments in blood and helped accelerate the development of liquid biopsy applications in oncology.

Despite the promise of liquid biopsy and NGS technologies, their integration into routine clinical practice remains uneven. While adoption has accelerated in advanced healthcare markets, many tests are still offered through centralized laboratories rather than as widely distributed standardized kits. Regulatory complexity, reimbursement challenges, and the need for extensive clinical validation continue to influence the pace of adoption.

NGS enables comprehensive characterization of germline and somatic mutations as well as tumor RNA expression profiles, providing a depth of information beyond earlier single-marker assays. However, translation into routine clinical practice takes time, and well-established biomarkers such as EGFR, KRAS, and BRAF continue to play a central role in guiding decisions on targeted therapy. As a result, single-gene and small-panel molecular assays, particularly those based on real-time PCR, remain widely used due to their speed, cost-effectiveness, and clinical utility.

The molecular oncology diagnostics market is therefore evolving toward a complementary model. Tissue-based histopathology and molecular testing remain foundational, while liquid biopsy, MRD testing, and NGS-based profiling are expanding as important adjuncts.

Together, these technologies are gradually reshaping cancer diagnosis and management, with their full clinical impact continuing to develop as evidence, standardization, and access improve.

The global market for all molecular tests for cancer diagnostic testing is held almost exclusively in North America and Europe (83%). Japan and the rest of the world account for the remaining 17% of product sales.

Table 8-11: Global Molecular Cancer Test Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	54%
Europe	29%
Asia Pacific	9%
RoW	8%
Total	**100%**

Source: Kalorama Information

Enthusiasm for biomarkers is increasing, with major initiatives in Europe (European Medicines Agency) and the U.S. working to support their validation, and their path into routine testing is increasing. Several genetic biomarkers are endorsed for routine PGx testing – EGFR and associated gene mutations, HER, ALK, and BCR/ABL.

One of the developments expected to increase the utility of blood-based oncology tests is the detection of circulating nucleic acids. This differs from CTCs in that the targets for analysis are not cell-based but free nucleic acids in plasma.

Tests for HPV using cervical fluid are covered in Chapter 13. Commercial tests for cancer available - B and T cell gene arrangement studies for lymphoma, Bcr/abl for leukemia, HER2 for breast cancer, HPV for head and neck and cervical cancer, septin for colon cancer, EGFR mutations and FLT3 Mutation Assay. Most labs run research-use and lab-developed tests that they design in-house to meet their physicians' needs.

The market leaders in the molecular cancer assays are Natera, Roche, Illumina, QIAGEN, bioMérieux, Myriad Genetics, and Veracyte. In addition, there are three leaders in the POC molecular assay space-Exact Sciences, Guardant and Beckman Coulter.

Table 8-12: Selected Molecular Tumor Marker Test Innovations

Company	Location	Area	Details
Abbott Diagnostics	U.S.	FFPE	FGFR3 gene mutations, urine, FFPE, bladder cancer
Agendia	Netherlands	cancer	MammaPrint FFPE breast cancer recurrence test
Biocartis	Switzerland	PGx	Idylla BRAF & KRAS
BioRad	U.S.	dPCR	glioma-associated mRNA mutations from CSF
BioRad	U.S.	dPCR	RainDance HemOnc Consortium, hematological
BioRad	U.S.	sequencing	Cancer Panels: solid tumor, hematological
Bio-Techne	U.S.	FFPE	Quantidex DNA Assay, copy number in FFPE
Bio-Techne	U.S.	leukemia	Quantidex BCR-ABL IS CMR, leukemia
Biotype Diagnostic	Germany	PCR	Mentype AMLplexQS, multiplex AML
Bruker	U.S.	FFPE	186-gene signature for liver cancer, miRNA
Bruker	U.S.	platform	benchtop nCounter SPRINT Profiler, miRNA
Bruker	U.S.	FFPE	nCounter Dx FLEX & Prosignia Breast Cancer, miRNA
Bruker	U.S.	platform	nCounter MAX system for clinical labs
Bruker	U.S.	FFPE	nCounter PanCancer Progression Panel, miRNA
Bruker	U.S.	FFPE	nCounter RNA:Protein tumor profiling
CeGaT GmbH	Germany	sequencing	NGS panel to analyze more than 550 cancer-relevant genes
DiamIR	U.S.	niRNA	Universal Screening Test, miRNA
DxTerity Diagnostics	U.S.	PGx	REDI-Dx radiation PGx multi-test
EKF Molecular Diagnostics	UK	smpl enrich	PointMan DNA Enrichment
EKF Molecular Diagnostics	UK	PGx	PointMan cancer companion diagnostics

Company	Location	Area	Details
Epigenomics	Germany	lung	Epi proLung tissue assay, septin
Epigenomics	Germany	colon	Epi proColon septin colon cancer screen
Exact Sciences	U.S.	GI	gastrointestinal cancers with the Mayo Clinic
Exact Sciences	U.S.	lung	lung cancer with MD Anderson, blood
Exact Sciences	U.S.	colon	Cologuard
Exosome Diagnostics	U.S.	exoRNA	prostate cancer predictive score, exoRNA
Genomic Vision	France	breast	breast ca and Lynch on Genomic Vision's Morse Code
Genomica	Spain	PGx	CLART CMA KRAS•BRAF•PI3K and NedxA
Genomica	Spain	platform	CLART (Clinical Array Technology) platform
HTG Molecular Diagnostics	U.S.	miRNA	HTG EdgeSeq miRNA Whole Transcriptome, multiplex
HTG Molecular Diagnostics	U.S.	RNA	Edge RNA analysis automation, extraction free
HTG Molecular Diagnostics	U.S.	RNA	breast cancer panel with Merck
HTG Molecular Diagnostics	U.S.	sequencing	Illumina's sequencing technology for HTG EdgeSeq platform
Illumina	U.S.	FFPE	MiSeqDx for FFPE samples, NGS
Mirxes	Singapore	Cancer	GASTROCLEAR
Myriad Genetics	U.S.	cancer	Tumor BRACAnalysis CDx, breast
Natera	U.S.	Cancer	Signatera
Ovagene Oncology	U.S.	platform	oncology tests on HTG Edge Platform, gene expression
QIAGEN	Netherlands	exosomes	Exosome Diagnostics' biomarkers, lung cancer
QIAGEN	Netherlands	PCR	therascreen EGFR RGQ Plasma PCR kit, lung
Quest Diagnostics	U.S.	breast	BRCA 1/2 on Genomic Vision's Morse Code
Sophia Genetics	Switzerland	IT	Copy Number Variations algorithm in BRCA1/2, breast
Standard BioTools	U.S.	transrenal	urine-based cell-free BRAF & KRAS, PGx
Standard BioTools	U.S.	transrenal	Precision Cancer Monitoring platform, urine

Company	Location	Area	Details
Takara Bio	U.S.	sequencing	BRCA1/2 on Seq-Ready SmartChip TE, breast
Thermo Fisher Scientific	U.S.	sequencing	Ion AmpliSeq Cancer Hotspot Panel v2
Thermo Fisher Scientific	U.S.	sequencing	Oncomine Solid Tumor DNA panel, FFPE, lung, colon
Thermo Fisher Scientific	U.S.	sequencing	universal next generation for solid tumors on Ion PGM Dx
Transgenomic	U.S.	platform	Multiplexed ICE COLD-PCR (MX-ICP) for cfDNA
Ventana Medical/Roche	U.S.	PCR	cobas 4800 BRAF V600 Mutation Test
Ventana Medical/Roche	U.S.	PGx	Roche's HER2-targeted Perjeta and Kadcyla
Ventana Medical/Roche	U.S.	PGx	Translational Genomics prostate cancer
Ventana Medical/Roche	U.S.	PGx	companion tests with Incyte Corp
VolitionRx	Belgium	nucleosomes	NuQ Nucleosomics tests, epigenetic cancer screening
VolitionRx	Belgium	nucleosomes	NuQ test: ovarian cancer
VolitionRx	Belgium	nucleosomes	NuQ test: prostate cancer

Source: Kalorama Information

Inherited/Genetic Diseases, Thrombophilia SNPs and Other Disorders

Single nucleotide polymorphism (SNP) analysis of tissue, blood, urine and saliva is the main technique used for gene mutations for inherited diseases. SNPs are DNA sequence variations that occur when a single nucleotide (A, T, C, or G) in the genome sequence is altered. Many SNPs have no effect on cell function, but scientists believe others could predispose people to disease or influence their response to a drug. Although more than 99% of human DNA sequences are the same, variations in DNA sequence can have a major impact on how humans respond to disease, environmental factors such as bacteria, viruses, toxins, and chemicals, and drugs and other therapies. This makes SNPs valuable for biomedical research and for developing pharmaceutical products or medical diagnostics. SNPs are also evolutionarily stable—not changing much from generation to generation—making them easier to follow in population studies.

Given the human genome's approximately 25,000 genes and an estimated diagnostic significance of about 5%, the eventual commercialization of 1,500 gene-based tests can be expected. This is a huge market opportunity set to revitalize the market for molecular tests for inherited diseases including autoimmune disorders, diabetes, psychiatric conditions, neurological diseases and cardiac disease.

The market for molecular tests for inherited diseases comprises two segments: tests for thrombophilia and molecular assays and genetic tests for the diseases shown below.

Hemex Health offers the Gazelle Hb Variant test, a POC blood test designed to provide rapid diagnosis of sickle cell disease and beta-thalassemia. The Gazelle uses disposable cartridges to analyze a fingerstick blood sample. The test is available in more than 40 countries across Africa, India, the Middle East, and Southeast Asia.

Table 8-13: Most Frequently Requested Genetic Tests

Tests
AML
Apolipoprotein E genotyping
ASPA—Canavan disease
CML
Cystic Fibrosis
Duchenne muscular dystrophy
Familial adenomatous polyposis coli (APC)
Fetal sex
Fragile X
Gaucher's disease
Hemochromatosis
Hemophilia A
Huntington's disease
Lymphomas
Multiple Sclerosis
Myotonic dystrophy
Neurofibromatosis (NF-1)
Prader Willi/Angelman
Sickle Cell anemia
Spinal muscular atrophy
Thalassemia (alpha and beta)

Source: Kalorama Information

Research into the cardiac disease continuum has pointed to an increasingly important role of genetics in the evolution of hypercoagulopathies. More and more evidence has been collected that illustrates the use of genetic procoagulation and thrombolytic markers in assessing risk for CVD. In addition to the traditional coagulation cascade factors several related molecular markers have grown in importance. These tests include thrombophilia molecular assays Factor V Leiden, and Factor II Prothrombin, along with pharmacodiagnostic tests for anticoagulant dosing.

Thrombophilia markers such as Factor V Leiden and prothrombin G20210A mutations do have well-established associations with inherited clotting risk and are used in selected clinical scenarios, although their routine use varies depending on patient history and guidelines. In contrast, the clinical role of MTHFR testing has been significantly scaled back. While MTHFR is involved in folate metabolism and can influence homocysteine levels, common MTHFR polymorphisms are no longer considered clinically meaningful markers of thrombophilia in most settings. Mild to moderate elevations in homocysteine are influenced by multiple factors, including diet, renal function, and vitamin status, and the direct link between MTHFR variants and increased risk of cardiovascular disease or thrombosis has not been consistently supported in more recent evidence. As a result, routine MTHFR genetic testing is generally not recommended as part of standard thrombophilia workups.

Elevated homocysteine has been linked to cardiovascular risk and certain adverse pregnancy outcomes, but the relationship is complex and influenced by multiple factors beyond genetics alone. While folate and B-vitamin supplementation can lower homocysteine levels, this does not consistently translate into reduced cardiovascular risk. Neural tube defects, such as spina bifida, are strongly associated with inadequate folate status, which is why folic acid supplementation before and during early pregnancy remains the standard preventive approach rather than routine genetic screening for common MTHFR variants.

Factor V is a cofactor in blood coagulation, regulated by the Protein C system. The Factor V Leiden mutation results in hypercoagulability and is the leading genetic cause of venous thrombosis. Factor II Prothrombin is a key protein in the blood coagulation system. Mutations in the gene that codes for Factor II are indicative of a significant increase in risk for clotting disorders. These conditions are commonly treated with blood thinners such as coumadin (warfarin), which has led to the commercialization of several tests for warfarin sensitivity.

These genes have been implicated in diseases that are more common than generally realized. One in one thousand individuals develops deep vein thrombosis (DVT) or pulmonary embolism (PE) annually. These conditions are caused by acquired and genetic risk factors, including age, hospitalization, cancer, surgery, pregnancy, hormone therapy, and air travel.

The thrombophilia SNPs namely, Factor V Leiden, and Factor II Prothrombin, have become part of the molecular test establishment. The market for this group of tests is estimated at $218 million in 2025, with 2.2% annual growth, and will likely reach $243 million in 2030.

Table 8-14: Global Molecular Thrombophilia Assay Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	37%
Europe	36%
Asia Pacific	14%
RoW	13%
Total	**100%**

Source: Kalorama Information

Factor II and V assays were development targets for companies offering molecular diagnostic platforms for POC and decentralized testing. Historically, genetic testing was used almost exclusively in large hospitals and reference laboratories that had the resources to develop their own assays. Simplification of molecular tests by companies such as Hologic, Fujirebio, Luminex, QIAGEN and others is making these tests available to small and mid-sized labs. Further, the multiplexing capability of these newer platforms makes them ideal to detect mutation variations in patient populations. Many LDTs are currently available for detecting mutations in Factor II and Factor V. Approximately 2.2 million Factor II and Factor V genotyping tests are estimated to be performed annually worldwide (excluding Japan).

Genomic research is opening the possibility of genetic and protein marker tests for number of autoimmune diseases not usually diagnosed with PGx tests, including arthritis, disorders

of the gastrointestinal tract, Crohn's disease and inflammation. This area of personalized medicine is in the early phase of development.

Kalorama anticipates that the next five to ten years will likely bring moderate but steady growth in commercial molecular tests targeting gene-based inherited diseases. Growth will be supported by expanding clinical utility data, declining sequencing costs, broader adoption of carrier screening, and greater integration of genomics into specialty care.

However, several structural challenges continue to moderate adoption. One of the most significant barriers is aligning key stakeholders such as payers, physicians, researchers, health systems, and regulators to bridge the gap between research discovery and routine clinical implementation. While research has rapidly identified disease-associated variants, translating these findings into reimbursed, guideline-supported clinical tests requires extensive validation, health economic evidence, and consensus-building.

Reimbursement remains a critical constraint, particularly for expanded panels and exome/genome sequencing in inherited disorders, where evidence of clinical utility may still be evolving. Regulatory clarity around laboratory-developed tests and evolving oversight frameworks also influences commercialization timelines.

Physician education represents another important lever for market expansion. Many clinicians, particularly outside genetics and oncology specialties, require additional support in interpreting genomic results, understanding variant classification, and integrating findings into patient management. Expanded access to genetic counseling, decision-support tools, and standardized reporting formats will be essential to accelerate appropriate test utilization.

Overall, while the scientific foundation for inherited disease molecular testing is strong, market growth will depend as much on ecosystem alignment and clinical integration as on technological advancement.

Alzheimer's Disease and Dementia

Alzheimer's disease (AD) is an aging-associated disease that manifests as dementia. The progression of the disease is associated with declines in memory and cognition, impaired judgment, and deterioration of personality. The disease afflicts over 5 million in the United States and is expected to reach 16 million by 2050.

In vitro diagnostic testing for AD is represented by only a few companies. Thermo Fisher's Athena Diagnostics markets a blood-based LDT service, ADmark ApoE Genotype Analysis & Interpretation (Symptomatic), that types the ApoE gene for late-onset AD and PSEN1, PSEN2, or APP for early-onset AD. The company consolidated its position in the AD molecular testing market by collecting exclusive patent rights to the genes from Duke University. However, commercialization of its AD test service has not been well accepted in clinical care since there are no efficient drugs available for treatment. Without more effective therapy or preventive treatments for AD, molecular diagnostics developed in research are unlikely to find successful commercialization in routine clinical care.

Certain alleles of the apolipoprotein E (ApoE) gene are known to be major risk factors for the development of AD. The advent of economical whole-genome and exome sequencing in research has spurred investigation into weaker or secondary genetic loci for the disease. Whole genome sequencing of AD patients has identified several gene markers, including CLU, CRI, PICALM, BIN1, and CNTN5.

Cardiovascular Disease

Cardiovascular disease, including heart attack and stroke, is the leading cause of death in the world and claims more lives than all forms of cancer combined. The number of deaths from cardiovascular disease (CVD) worldwide is projected to reach approximately 24 million by 2030. Approximately 80% of CVD-related deaths are in low- and middle- income countries. In developed countries such as the United States, CVD is one of the leading killers. Globally, CVD is on the rise as a result of a sedentary lifestyle, changes in diet related to development (higher consumption of animal products), and smoking.

Cardiovascular health and heart disease events, such as heart attacks, are monitored and diagnosed primarily with immunoassays and clinical chemistry. Cholesterol panels, cardiac markers and other inflammation markers are used in primary care as well as acute care. Genetic testing is increasingly used in cardiovascular care to detect potential cardiac conditions and implement preventive care. Genomics also plays a significant role in therapeutic efficacy, as exemplified by anticoagulants discussed earlier in this chapter.

Some genes linked to CVD are involved in lipid metabolism, particularly in the removal of low-density lipoprotein (LDL) cholesterol from the bloodstream. Certain genotypes can result in the accumulation of LDL in arteries and the development of coronary artery disease. The ApoE gene is one of several genes found to affect LDL blood levels.

Table 8-15: Selected Genomic Tests for Inherited Diseases

Company	Location	Area	Details
Almac Diagnostics	UK	Alzheimer's	Exonhit Aclarus Alzheimer test
Ambry Genetics	U.S.	cardiac	cardiovascular genetic testing panels
ArcticDx	Canada	mac degen	Macula-Risk macular degeneration
ARUP	U.S.	cardiac	whole genome sequencing: pulmonary hypertension
Athena Diagnostics/Quest	U.S.	epilepsy	Epilepsy Advanced Sequencing Evaluations
Autogenomics	U.S.	fever	INFINITI FMF Panel, familial Mediterranean Fever
Avant Diagnostics	U.S.	MS	Diogenix's MSPrecise, NGS relapsing multiple sclerosis
Axial Biotech	U.S.	scoliosis	ScoliScore AIS Prognostic Test
Blueprint Genetics	U.S.	Autism	Autism Spectrum Disorders Panel
Canon Biomedical	U.S.	platform	Novallele genotyping assays for inherited diseases
CapitalBio Corp	China	deafness	deafness gene mutation detection array
Chronix Biomedical	U.S.	neuro	neurological disease PGx service
Chronix Biomedical	U.S.	rare diseases	next gen sequencing, orphan diseases
Circadian Tech	Australia	lung	lymphangioleiomyomatosis, lung disease
Clinical Data	U.S.	cardiac	FAMILION DCM Test, cardiomyopathy
CombiMatrix (Invitae)	U.S.	autism	ATScan, pre-disposition screening, autism
Diagnósticos da América	Brazil	wellness	Pathway Genomics wellness assays
Emory Genetics Lab	U.S.	autism	Targeted sequencing-based test for autism
Exagen Diagnostics	U.S.	gastro	eXaUC/CD, ulcerative colitis/Crohn’s disease
Genetic Analysis	Norway	gastro	Applied BioCode’s Barcoded Magnetic Bead Technology
Genetic Analysis	Norway	gastro	GA-map IBS Dysbiosis, gut microbiota for IBD
Genoma SA	Switzerland	autism	IntegraGen's autism spectrum disorder genetic risk
Genomas	U.S.	cardiac	statin drug PGx on WaferGen INFINITI
Genomas Inc.	U.S.	cardiac	PhyzioType System, statin PGx
Genomics Ltd.	UK	rare diseases	EchiDNA rare disease gene variant database, IT

Company	Location	Area	Details
Global Genomics Group	U.S.	cardiac	integrated Omics plus Big Data, cardiac disease, IT
Google Genomics	U.S.	autism	Autism Speaks MSSNG Google Cloud Platform
Illumina	U.S.	cystic fibrosis	MiSeqDx cystic fibrosis tests
Illumina Clinical Lab	U.S.	rare diseases	TruGenome Undiagnosed Disease Test
Innogenetics (Fujirebio)	Belgium	Alzheimer's	CSF kit for Aβ42, tau
IntegraGen	France	autism	ARISk Risk Assessment Test
Interleukin Genetics	U.S.	periodontal	Interleukin Genetics' PST genetic test
Labcorp	U.S.	rare diseases	ExomeReveal, whole exome pediatric diseases
Labor Dr. Bayer/synlab	Germany	gastro	Genetic Analysis GA-map IBS Dysbiosis, gut microbiota
Luminex	U.S.	cystic fibrosis	xTAG Cystic Fibrosis 39 Kit v2
Myriad Genetics	U.S.	musc dystrophy	Multi-Analyte Profiling, Spinal Muscular Atrophy
PGXL Laboratories	U.S.	sleep	Obstructive Sleep Apnea
Progenika Biopharma	Spain	cardiac	Seqpro Lipo IS, lipid genes
Progenika Biopharma/ Grifols	Spain	cardiac	LipoChip
Progenika Biopharma/ Grifols	U.S.	pancreatitis	LPLchip, LPL gene mutations in blood or saliva
Prometheus Labs	U.S.	gastro	PROMETHEUS Crohn's Prognostic test
Quest Diagnostics	U.S.	ALS	Athena ALS
Quest Diagnostics	U.S.	cardiac	Celera's real-time PCR KIF6 gene
RainDance Technologies (Bio-Rad)	U.S.	autism	Syndromic Autism 62-Gene Panel
RainDance Technologies (Bio-Rad)	U.S.	arthritis	RainDance HLASeq Research Screening Panel
Randox Laboratories	Ireland	cardiac	Familial Hypercholesterolemia (FH) Arrays
Randox Laboratories	Ireland	cardiac	Cardiac Risk Prediction Array
Selventa	U.S.	arthritis	Clarify-RA, TNF responders database
Selventa	U.S.	gastro	ClarifyIBD, anti TNF responders

Company	Location	Area	Details
Sophia Genetics	Switzerland	cystic fibrosis	CFTR IVD Solution CF single NGS, IT
Tepnel Diagnostics	UK	cardiac	Elucigene FH20, familial hypercholesterolemia
Thermo Fisher	U.S.	Intellectual disability	CytoScan Dx Assay detects chromosomal aberrations
Transgenomic	U.S.	rare diseases	Nuclear Mitome Test, mitochondrial disorders
Transgenomic	U.S.	scoliosis	Axial Biotech's ScoliScore
Xceed Molecular	U.S.	gastro	Inflammation Xpress Chip

Source: Kalorama Information

Depression and Psychiatric Disorders

A number of molecular and pharmacogenetic test services have been introduced for psychiatric disorders over the past decade, particularly in the area of psychotropic medication response. However, broad adoption among psychiatrists remains variable. While pharmacogenomics (PGx) has gained some traction—especially for antidepressant and antipsychotic prescribing—many clinicians remain cautious due to ongoing debate regarding clinical utility, guideline integration, and payer reimbursement.

Genes commonly included in commercially available psychiatric pharmacogenomic panels typically fall into two categories:

1) Pharmacokinetic genes (drug metabolism and transport):

- CYP2D6, CYP2C19, CYP1A2, CYP3A4/5 – cytochrome P450 enzymes affecting metabolism of antidepressants, antipsychotics, and mood stabilizers
- UGT1A4 – glucuronidation pathway involved in drug metabolism
- ABCB1 (P-glycoprotein) – influences drug transport across the blood–brain barrier

2) Pharmacodynamic / neurotransmitter-related genes (variable evidence strength):

- SLC6A4 – serotonin transporter
- HTR2A / HTR2C – serotonin receptors

- DRD2, DRD4 – dopamine receptors
- SLC6A3 (DAT1) – dopamine transporter
- COMT – catechol-O-methyltransferase
- CACNA1C – calcium channel gene associated with mood disorders
- ANK3 – neuronal membrane protein linked to bipolar disorder risk
- OPRM1 / OPRK1 – opioid receptors
- MTHFR – folate metabolism (clinical relevance in psychiatry remains debated)
- GABA receptor genes – occasionally included in extended panels

Several companies offer commercially available psychiatric pharmacogenomic testing services. Genomind markets the Genecept Assay, a multi-gene panel that evaluates variants involved in drug metabolism and selected pharmacodynamic pathways relevant to psychiatric medication management. Myriad Genetics offers GeneSight Psychotropic, one of the most widely marketed psychiatric PGx panels, which focuses primarily on CYP450 metabolism genes along with selected receptor markers to help guide antidepressant and antipsychotic selection. Castle Biosciences provides IDgenetix, a pharmacogenetic test designed to support psychiatric medication management, based largely on polymorphisms in metabolic genes. Pathway Genomics previously marketed the Mental Health DNA Insight panel, an SNP-based psychiatric pharmacogenetic test, although its current market visibility is more limited than in prior years. SureGene's STA2R panel has also been referred to as a medication-response genetic test, though its current commercial status is less clear. In addition to these branded panels, numerous clinical laboratories offer standalone testing for genes such as MTHFR and various CYP450 enzymes; however, professional guidelines increasingly caution against overinterpretation of isolated MTHFR variants in psychiatric practice without a broader clinical context.

Clinical adoption of psychiatric pharmacogenomic testing continues to evolve as evidence accumulates and professional guidance becomes more refined. Major pharmacogenomic consortia, including the Clinical Pharmacogenetics Implementation Consortium (CPIC), now provide dosing guidelines for medications affected by variants in genes such as CYP2D6 and CYP2C19, which has supported selective payer coverage in certain clinical scenarios. Even so, broader reimbursement depends on continued demonstration of clear clinical utility and outcome improvement. Standardized reporting frameworks and expanded clinician education are essential to ensure appropriate interpretation and integration into practice. Many

psychiatrists still rely primarily on symptom-based treatment algorithms and clinical experience rather than genetic stratification alone. As a result, psychiatric molecular testing remains largely a laboratory service–driven market with limited penetration of FDA-cleared kit-based IVD products. While pharmacogenetics is expected to continue to grow incrementally, expansion into predictive genetic testing for psychiatric disease susceptibility remains constrained by evidentiary limitations and ongoing ethical considerations.

Prenatal and Newborn Testing

Noninvasive prenatal testing is more accurate than traditional serum biochemical and nuchal translucency screening tests for fetal anomalies and, consequently, is less likely to result in invasive follow-up tests. But the higher price tag affects decisions about using it upfront. This is a fast growing area but mostly driven by LDTs and the revenues will be generated largely from the sales of instruments, reagents and consumables for offering LDT services. The basis of prenatal screening is an analysis of the 23 pairs of chromosomes that every human being has. Using a variety of techniques, a cytogeneticist examines the number, shape and staining pattern of these chromosomes to detect extra chromosomes, missing chromosomes, or rearranged chromosomes. Most common disorders include Down syndrome (chromosome 21 trisomy), Turner's syndrome, Fragile X syndrome for mental retardation, neural tube defects, spina bifida, inherited diseases (cystic fibrosis, Thalassemia, Canavan disease, Tay-Sachs, sickle cell disease), chronic myelogenous leukemia (CML), and Burkitt's lymphoma. Prenatal genetic testing is performed while a fetus is still in utero and considered to be at risk. It is also used to analyze embryos before implantation in in vitro fertilization (IVF) to ensure that disease-free embryos are implanted. Finally, genetic testing can be performed on newborns to screen for a wide number of gene-based diseases.

Kalorama estimates the world market for prenatal test services by cell-free NIPT is $1,070 million in 2025 and, with 7.4% annual growth, will reach $1,530 million in 2030. Growth is increasingly related to consumers opting for prenatal carrier testing and the use of genomic screening of embryos for in vitro fertilization. The reader is reminded that products in this test segment are used by test service providers.

The U.S. market is fairly mature, and payer groups negotiate lower payments; however, demand is increasing. Europe is also beginning to mature and face the same restraints in payment structures. Therefore, future growth is expected to come from the more developed

emerging economies in Asia Pacific, Latin America, and the Middle East, including India, China, and Brazil.

Table 8-16: Global Prenatal Test Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	46%
Europe	27%
Asia Pacific	20%
RoW	7%
Total	**100%**

Source: Kalorama Information

The most advanced technology in this test segment is non-invasive prenatal testing (NIPT), which sequences DNA extracted from fetal cells in the mother's blood. This test segment has become very hot lately, partly because the test technologies are becoming more user-friendly, using Illumina's arrays and sequencing tools primarily. There has also been growing consumer demand, which is endorsed by medical guidelines and screening programs supported by payer groups.

The information presented below clearly illustrates the quite amazing market acceptance of NIPT and other advanced prenatal screening tests (beyond the major companies). Labs worldwide are beginning to offer these tests, and companies that have commercialized market-clearing tests have seen significant success. Further, the wide availability of NIPT democratizes prenatal screening for women everywhere, and especially in countries that recognize the CE Mark.

Myriad Genetics expanded into the consumer prenatal segment through its acquisition of Gateway Genomics, developer of the SneakPeek early gender DNA test, a direct-to-consumer assay that analyzes fetal cell-free DNA (cfDNA) from maternal blood early in pregnancy. In the clinical reproductive market, Natera strengthened its position by acquiring

select reproductive health assets from Invitae, reinforcing its Panorama® non-invasive prenatal testing (NIPT) and carrier screening portfolio. Natera also offers a cfDNA-based fetal RhD test that noninvasively determines fetal RhD status and supports more targeted administration of Rh immune globulin. Expanding NIPT offerings internationally, Yourgene Health offers IONA Care+ in the UK in 2025, an enhanced version of its IONA test that broadens screening beyond common trisomies to include selected sex chromosome abnormalities and microdeletion syndromes, reflecting the continued evolution of expanded NIPT panels.

Table 8-17: Selected Prenatal Services Provided

Company	NIPT	Average Pregnancy	Miscarriage	Preimplant Testing
Agilent	X			
ARUP	X			
Berry Genomics	X			
BGI	X			
Invitae	X		X	X
Illumina	X			X
Eurofins LifeCodexx	X			
Myriad Genetics	X	X		
Natera	X	X		X
Igenomix	X			
Roche Diagnostics	X			
Quest	X			
Labcorp	X	X		

Source: Kalorama Information

Table 8-18: Selected Molecular Tests for Prenatal Analysis

Company	Location	Details
Agilent	U.S.	Clarigo
Annoroad Genomics	China	NIPT with Illumina's HiSeq 2500
ARUP Labs	U.S.	Non-invasive Prenatal Aneuploidy Screen
BGI	China	NIFTY, NIPT
BGI	China	NIFTY platforms BGISEQ-1000, BGISEQ-100 & reagents
Biominis	France	NIPT with Illumina's HiSeq 2500 Ninalia
Bio-Reference Laboratories	U.S.	Natera's Panorama NIPT
Birmingham Women's NHS	UK	NIPT with Illumina's HiSeq 2500
DiagCor	Hong Kong	Natera's Panorama NIPT in Hong Kong
Diagnomics	U.S.	NGS NIPT with Maverix Dx Cloud IT
Echevarne	Spain	Natera's Panorama NIPT in Spain
Enzo Clinical Lab	U.S.	Sequenom's MaterniT21
Genea Limited	Australia	GeneSyte - Prenatal NIPT Screening
Genoma	Netherlands	Tranquility test using Premaitha's technology in Geneva
Genoma	Italy	NIPT with Illumina's HiSeq 2500
Genomed	Switzerland	BGI's NIFTY
Genomed	Switzerland	Aneufast QF-PCR Test
Igenomix	Spain	NACE NIPT
Illumina	U.S.	Illumina’s Verinata Health's Verifi test
Inex Innov	Singapore	amniocentesis, FISH
Inex Innovations	Singapore	iGene whole genome sequencing
Innovations Exchange	Singapore	BGI's GeneScreen
Innovations Exchange	Singapore	FlashFISH prenatal screen amniocentesis

Company	Location	Details
Innovations Exchange	Singapore	NIPT microchip and rare cell isolation with A*STAR
Labcorp	Japan	Sequenom's MateriT21
Labcorp	U.S.	EmbryVu, a preimplantation genetic screen
Labcorp	U.S.	informaSeq Prenatal Test
Laboratoire Cerb	France	Sequenom's MateriT21 in the Middle East
Lifelabs Medical	Canada	Natera's Panorama test
MAP Diagnostics	UK	MA-Test urine screen Down Syndrome
Mayo Medical Lab	U.S.	Sequenom's MateriT21
MedGenome	India	Natera's Panorama NIPT, exclusive license for India
Myriad Genetics	U.S.	SneakPeek Early Gender Test
Myriad Genetics	U.S.	self-collection kit under the SneakPeek brand
Myriad Genetics	U.S.	Foresight Carrier Screening, Prequel, SneakPeak
Natera	U.S.	Panorama NIPT
NewBridge Pharmaceuticals	UAE	Verinata verifi prenatal test in the Middle East
NIPD Genetics	Cyprus	methylation enrichment of fetal DNA & PCR
NIPD Genetics LTD	Cyprus	Veracity test
NX Prenatal	U.S.	NeXosome, microvesicles/exosomes spontaneous preterm birth risk
Prenetics	Hong Kong	Prenetics V Test, technology from Stanford University
Primary Health Screen	Australia	INEX's GeneScreen in Australia
ProPath Pathology	U.S.	Natera's Panorama NIPT
Quest	U.S.	Natera's Panorama NIPT
Quest Diagnostics	U.S.	Sequenom's MateriT21
Quest Diagnostics	U.S.	replace Natera with own QNatal Advanced
Randox Laboratories	UK	Pre-Pregnancy Genetic Screen
Rarecells Diagnostics	France	ISET-PND, fetal cells in blood

Company	Location	Details
Recombine (Cooper Genomics)	U.S.	FertilityMap, Illumina microarray, infertility markers
Revvity	U.S.	Vanadis, NIPT digital analysis of cfDNA for routine labs
Sonic Healthcare	Australia	Ariosa's Harmony in Australian and UK labs
St George's University Hospitals	UK	Premaitha IONA test in house
Standard BioTools	Singapore	Sequenome's VisibiliT in Asia
Teva Pharmaceuticals	Israel	Verinata verifi prenatal test in Israel
UniLabs	Switzerland	Natera's Panorama NIPT in Europe
Yourgene Health	UK	IONA

Source: Kalorama information

Transplant Diagnostics

The proteins encoded by the Human Leukocyte Antigen (HLA) system are located on the surface of body cells and are unique to each person. The immune system uses HLAs to distinguish self-cells from non-self-cells. Any cell displaying that person's HLA type belongs to that person and, therefore, is not an invader. Thus, the HLA system is involved in cases of pathogen invasion and the presence of unrecognizable (and therefore foreign) tumor cells and autoimmune antigens.

HLA typing is the process of testing patient or donor blood or other tissue samples for HLA antigens. The results can then be used to determine compatibility between the donor and patient (HLA matching). More precise HLA matching through the application of molecular-based typing methods has been shown to significantly improve transplant outcomes, particularly for bone marrow transplants.

HLA testing, also referred to as tissue typing, is therefore a key component in determining the compatibility between potential donors and recipients prior to transplantation to maximize the chances of graft survival and minimize serious immunologic transplant complications. The better the HLA type match, the higher the likelihood of a successful transplant.

In addition to transplantation-related applications, knowledge of an individual's HLA type is also relevant to infectious disease progression and autoimmune disorders. HLA assays are expected to play a key role in personalized medicine, as evidenced by recent developments and research. Such tests include, among others, the typing of the HLA-B*5701 allele - a test to assess the risk of AIDS patients for severe adverse reactions to the widely prescribed HIV drug component Abacavir.

The global market for molecular transplant (HLA) testing is a growing, competitive segment. Illumina's efforts in facilitating and expanding access to NGS testing technologies have resulted in a growing market segment. Longer-term, much of the HLA testing by sequencing will be offered as lab-developed tests.

At this time, the major application of HLA testing is for transplant management. The total worldwide market is estimated at 172,400 organ transplants and 8,000 bone marrow transplants per year. More than 46,000 organ transplants were performed in the U.S in 2023 and a similar number are performed in Western Europe. Approximately 80% of HLA testing is used for whole-organ transplants, and 20% for bone marrow transplants.

Table 8-19: Global Molecular HLA Testing Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

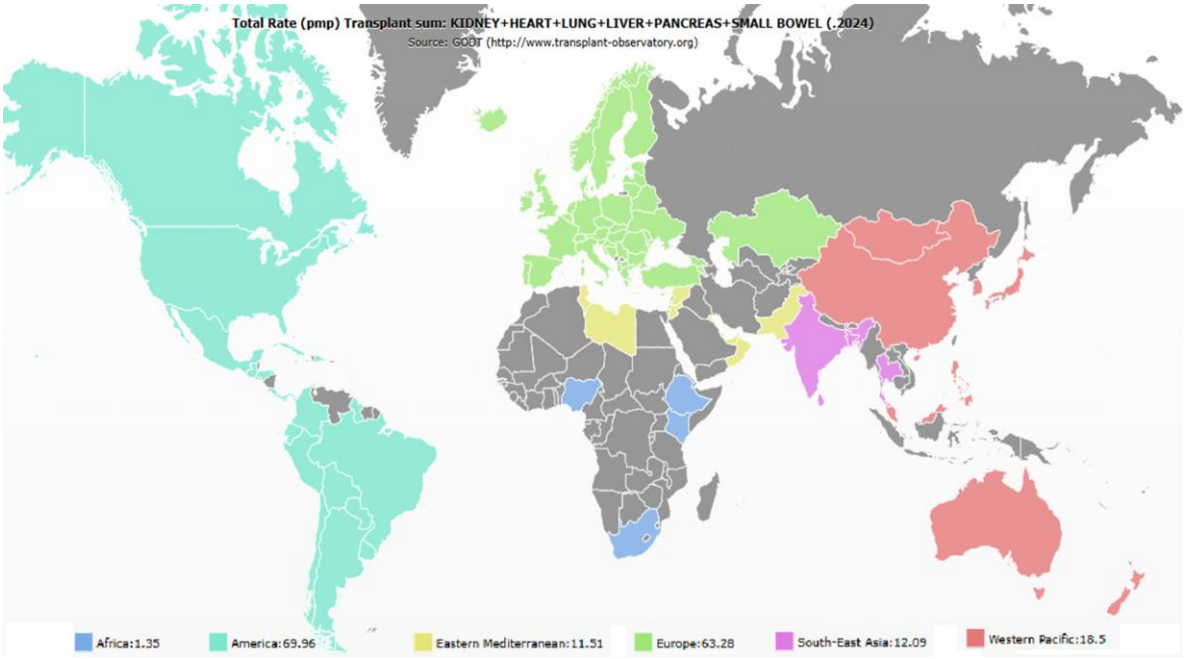
Region	% Mkt
North America	46%
Europe	26%
Asia Pacific	23%
RoW	5%
Total	**100%**

Source: Kalorama Information

Organ transplantation is practiced primarily in developed countries, which are the main markets for molecular transplant diagnostics. In 2023, there were more than 103,223 people in the US on the national transplant waiting list. Kidney took the lion's share of 86% of all the organs, for which most people are waiting in the US, followed by liver, heart, and lung

at 9.8%, 3.2%, 1% respectively in 2023. Approximately 46,632 organ transplants were performed in the US in 2023 as of March 2024.

Figure 8-1: Global Transplant Rate, by Region, 2024



Source: Data of the WHO – ONT Global Observatory on Donation and Transplant Patients

Key drivers of the molecular transplant diagnostic market in the US include an increase in public and private funding for the development of HLA typing technologies, a growing number of solid organ transplantation procedures, and a continuous reduction in the average cost of gene sequencing.

In Europe, more than 45,000 organ transplantations were reported in 2024. Demand in Europe is expected to grow at a 10.1% CAGR, reaching $348 million by 2030.

Asia is the most populated region in the world, but has one of the lowest rates of organ transplantation and the greatest growth rate for the number of people entering chronic and end-stage organ failure.

China, by far, has the shortest waiting time for organ transplantation in the world. Government statistics suggest that approximately 20,000 organ transplantations take place per year in China. However, the volumes could be much higher than the official statistics.

The transplant diagnostics market in North America is primarily driven by factors such as increased public and private funding for HLA typing technology development, a growing number of solid organ transplantation procedures, and a continuous reduction in the average cost of gene sequencing. However, financial constraints faced by market players are limiting the growth of the transplant diagnostics market in this region.

The Asia Pacific is poised to grow at about equal to North America and Europe, with a CAGR during the next five years at 10.2%, owing to factors such as increasing focus of global life science companies in emerging markets, growing public and private support to develop novel HLA typing technologies, and strengthening healthcare infrastructure across the region.

HLA typing has traditionally been performed using serological techniques for immunological markers. However, this technique does not detect subtle differences between individuals. An HLA test requires that some six genes be screened in parallel, with each displaying about 100 important (known) local variants. This requirement lends itself to technologies such as microarrays and sequencing, which can screen for multiple targets.

The molecular transplant diagnostics space is a competitive market with many companies offering PCR- and bead-array-based test kits for characterized HLA genes. Until recently, PCR and microarray platforms together accounted for the largest market share in the segment, with serology and immunoassays sharing the remaining market demand. NGS has been growing in the segment.

Table 8-20: Selected Innovations of Molecular Transplant Diagnostics

Company	Location	Product Details
Biofortuna, UK	UK	Freeze-Dried SSPGo HLA- typing kit (PCR-based)
CareDX	USA	AlloSeq Tx 17
Fujirebio	Belgium	INNO-LiPA HLA-DQA1(PCR-based)
GeneDx	Netherlands	SBTexcellerator HLA (Sanger Sequencing-based)
GeneDx	Netherlands	NGSgo-AmpX, HLA (NGS-based)
GMS Biotech	USA	High-Throughput HLA-Typing (micro array based)
Illumina	USA	TruSight HLA Sequencing Panel & Conexio Genomics analysis IT (NGS-based)
Immucor	USA	MIA FORA NGS FLEX HLA Typing Kit (NGS-based)
Linkage Biosciences	USA	LinkSeq, HLA PCR (PCR-based)
PharmiGene, Inc.	Taiwan	HLA-B*1502 Assessment Test (PCR-based)
QIAGEN	Netherlands	QuantiFERON Monitor (QFM), immune function, organ transplant, (PCR-based)
Roche Diagnostics	USA	Cobas CMV viral load on 6800 & 8800, transplant (PCR-based)
Thermo Fisher	USA	LinkSeq, HLA PCR (PCR-based)
Thermo Fisher	USA	SeCore kits (HLA Sequence-Based Typing)

Source: Kalorama Information

Women's Health

The global market for women's health test products is estimated to be worth $14.6 billion in 2024. For a more in-depth report see Kalorama Information's *Women's Health Diagnostics Markets: Global Outlook and Forecast to 2030.*

A notable development in the women's health market includes Heranova introduction of its LDT, HerResolve, for endometriosis detection. The test uses miRNA biomarkers to provide an actionable positive or negative result and employs quantitative PCR to measure the levels

of the biomarkers present. AI and ML are used to train a model to interpret the levels. The company is seeking FDA clearance for the test once all clinical data is received.

The Commercial Outlook for Molecular Tests

The development of the molecular diagnostics market has proceeded in tandem with the evolution of molecular technologies. It has become an indispensable tool in clinical medicine that touches all aspects of healthcare including treatment decisions in terms of identifying antimicrobial resistant (AMR) infections at the earliest, companion diagnostics assisting in the evaluation of suitability of various cancer treatment options, pharmacokinetics or patient metabolism of drugs for HIV, psychiatric conditions or blood thinners; cancer prognosis and therapy, organ matching, blood safety, and the diagnosis of latent and neonatal conditions. Rather than replacing other major IVD modalities such as immunodiagnostics, the molecular diagnostics market has expanded by addressing clinical needs that have not been met or never envisioned with other major testing disciplines. As they become more affordable, the displacement of other diagnostics, such as immunodiagnostics, has also occurred owing to the high sensitivity and unique insights that molecular diagnostic methods offer. Certain IVD segments have been, or are in the process of being, remade worldwide through the application of molecular methods, including blood screening, POC diagnostics, cytogenetics, and tissue typing.

Since its inception, molecular diagnostics has steadily progressed from research-emergent, highly complex tests performed in a few labs to increased adoption of analyzer-integrated and automated sample preparation and analysis. In its earliest stages, clinical molecular diagnostics consisted of polymerase chain reaction (PCR) amplification of target sequences, followed by detection of amplicons through interpretation of bands on gel electrophoresis gels or through in situ hybridization of molecular probes to complementary sequences within tissue and liquid samples. In-situ hybridization required microscopy for the detection of fluorescence, chromogenic change or antibody-antigen complexes (if molecular probes present an attached antigen for detection).

The development of real-time PCR (qPCR) profoundly expanded the role of molecular diagnostics in healthcare; the technology registers amplification-generated fluorescence or other optically detected changes in real time to determine positive results and the relative amount of analyte or target nucleic acid sequence in the sample. Real-time PCR enables quantitative molecular results and has been integral to expanding molecular testing capabilities beyond high-complexity labs. The technology minimizes “hands-on” time or user requirements, improves test sensitivity, and speeds up the time to results while also reducing staff burden. In addition to qPCR, molecular diagnostics is performed with

isothermal amplification technologies, endpoint detection using microarrays, and nucleic acid sequencing technologies.

Molecular assays and lab tests in general hold the key to outcomes research for the new generation of biotherapeutics. These face the risk of poor market penetration unless they can demonstrate to payer groups that they will improve patient outcomes and be cost-efficient relative to incumbent techniques. The only way to do this is to first show that a genetic defect is present, and then to demonstrate that a drug's effect is best shown by a reduction in the physiological element targeted by the drug. Only lab medicine can provide this information. This will become more important as DNA-based diagnostic and therapeutic interventions evolving from the Human Genome Project come to market. Payers often cover therapeutics that prove economically valuable based on rigorous outcomes research.

The market for SNP detection is limited more by the utility of these tests than by the technology required to perform them. Utility and reimbursement go hand in hand. Almost daily, medical researchers announce their findings linking genes and gene sets to diseases.

The application of molecular technologies to clinical analyses has attracted widespread attention worldwide. They have already made their mark in diagnostic systems and will continue to expand their market share. There are several key issues that impact market success, including:

- Significant changes in healthcare delivery herald a new era in diagnostic testing needs. This new era requires, on one hand, very sophisticated, sensitive assays for infectious disease management, disease detection, and drug treatment decisions. On the other hand, these tests should be user-friendly and very cost-effective. This bodes well for fully automated, sample-to-result test platforms.
- There is a demand for faster test turnaround time from sample collection to results availability.
- There is a demand for a large menu of tests available on a single platform since molecular tests must account for variability in test targets. These tests must have high sensitivity for analytes in very small concentrations, be quantitative, and use small whole blood, urine, saliva, and CSF samples.
- There is a demand for test systems that are easy to use by non-laboratory and laboratory personnel. This is especially crucial for the growing use of diagnostic

assays in the physicians' office setting, multi-disciplinary medical clinics and small to mid-sized hospitals.

- There is a demand for low-cost molecular systems as the industry is cost-conscious in an attempt to do more with less.
- The ensemble of these elements creates a market for multiplexed, rapid, user-friendly test platforms such as microarrays, liquid bead arrays and other user-friendly technologies.

Among the leading technology platforms in the molecular diagnostics market, PCR accounts for the largest share of the global market. Though NGS used for true molecular diagnostics purposes (as opposed to pharma research and development or biomarker discovery, RUO sales) represents less than 20% currently, it is the platform of the future and in this analysis, the fastest-growing molecular diagnostics segment sales of systems are indicative of a bright future for molecular sales once regulatory approvals are secured and more applications are discovered. Liquid biopsies, consumer DTC testing, new competitors, and the reduction in the cost of whole-genome sequencing are all drivers of growth.

Chapter 9: Hematology

Scope

Hematology is the study of blood and blood-forming tissues, primarily focused on the analysis of peripheral blood and bone marrow cells to diagnose a wide range of blood disorders, including leukemias, anemias, clotting abnormalities, and autoimmune diseases. The cornerstone of hematology testing is the complete blood count (CBC), which provides essential information about various blood components, such as hemoglobin, hematocrit, red blood cells (RBCs), white blood cells (WBCs), reticulocytes, and platelets. This is segmented into laboratory-based and decentralized or POC hematology testing.

Overview of Hematology and Trends

The routine hematology test menu remains centered on the complete blood count (CBC) with differential, along with related parameters such as hematocrit, hemoglobin (automated and manual), erythrocyte sedimentation rate, reticulocyte count, total white blood cell (WBC) count, platelet count and indices, and red blood cell (RBC) count. Modern analyzers now routinely include expanded parameters, such as RBC indices (MCV, MCH, MCHC, RDW), platelet indices, and flags for immature granulocytes and nucleated red blood cells, thereby reducing the need for manual review. There continues to be discussion about using a 5-part versus a 3-part differential, although current practice favors the 5-part differential in most hospital and high-volume laboratory settings. White blood cells play a central role in immune defense, and differentiating their subtypes supports the diagnosis and monitoring of infection, inflammation, and hematologic disorders. A 3-part differential groups leukocytes into granulocytes, lymphocytes, and monocytes, and remains sufficient for basic screening in smaller or cost-sensitive settings. In contrast, a 5-part differential provides a more detailed breakdown into neutrophils, lymphocytes, monocytes, eosinophils, and basophils, offering greater clinical insight. Neutrophils are key responders to bacterial infections; lymphocytes are central to viral and adaptive immune responses; eosinophils are associated with parasitic infections and allergic conditions; monocytes are involved in inflammation and tissue repair; and basophils are primarily linked to allergic and inflammatory responses. As a result, most medium- to high-volume laboratories rely on 5-part differentials as standard, supported by advances in automation, digital morphology, and flagging algorithms, while 3-part systems continue to be used and marketed in physician offices and lower-resource environments due to their lower cost and operational simplicity.

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Table 9-1: Hematology Analyzer Distribution of Sales, by Menu Capability, 2025 estimated (%)

Analyzer by Menu Capability	Distribution of Unit Sales
5-part diff analyzers	77%
3-part diff analyzers	19%
Other analyzers	4%
Total	**100%**

Note: Distribution based on sales of leading analyzer vendors and reported distribution

Source: Kalorama Information

Over the past several decades, the CBC has become one of the most widely used and clinically important laboratory tests, playing a central role in patient management across both inpatient and outpatient settings. It is routinely performed on hospitalized patients and commonly included in general health evaluations, providing clinicians with essential information for diagnosing and monitoring a wide range of conditions, including infection, anemia, inflammation, and hematologic disorders.

Since the late 1990s, hematology technology has advanced beyond impedance-based cell counting, originally established by the Coulter Principle, through the integration of optical and fluorescence-based techniques adapted from flow cytometry. These innovations have significantly improved cell identification and classification, allowing automated analyzers to detect and quantify cell populations that previously required manual microscopy, while increasing accuracy and throughput.

Product differentiation in hematology analyzers focuses on expanding the range of available parameters, extending testing beyond whole blood to body fluids such as cerebrospinal and serous fluids, and advancing automation. Modern systems routinely provide enhanced parameters, including reticulocyte counts, immature granulocytes, and advanced platelet metrics. At the same time, laboratories are adopting automation strategies that include integration with core lab tracks, automated slide preparation and staining, digital cell imaging, and advanced informatics, all of which streamline workflow and improve consistency.

High-end hematology analyzers deliver rapid, near real-time results and support on-demand testing with minimal manual intervention. Improved flagging algorithms and imaging capabilities have significantly reduced the need for manual differential slide review, limiting it primarily to abnormal or flagged samples. Major vendors such as Sysmex, Roche, Beckman Coulter, Mindray, and Siemens Healthineers compete by enhancing automation, expanding clinical parameters, and improving overall laboratory efficiency.

Table 9-2: Lab-based Hematology Sales, by Analyte Average Annual Distribution, 2025 (%)

Analyte	Distribution of Sales
CBC	58%
Hemoglobin	27%
Other specialized	15%
Total	**100%**

Source: Kalorama Information

Digital Image Analysis

Advances in imaging, automation, and connectivity have driven steady adoption of digital workflows in hematology, particularly in the review of peripheral blood smears. Laboratories are combining automated analyzers with integrated image analysis systems to streamline differential white blood cell counts and reduce reliance on manual microscopy. Standardized slide preparation, including automated smearing and staining, improves consistency and supports reliable image capture and analysis. Once prepared, slides can be digitized and reviewed on-screen, allowing for remote consultation, centralized review, and more flexible workload distribution across laboratory networks.

CellaVision remains the leading supplier of digital cell morphology systems for hematology. Its platforms use automated microscopy and image analysis to locate, classify, and present white blood cells for review, while also supporting assessment of red blood cell morphology and platelet estimation. These systems improve efficiency by reducing the time required for manual differentials and standardizing the review process, while still allowing technologists to verify and adjust classifications. Adoption has been strongest in mid- to high-volume laboratories, but smaller, more compact systems have expanded use into lower-volume

settings. Growth continues to be driven by staffing constraints, the need for standardization, and increasing acceptance of remote review.

Digital morphology in hematology is distinct from broader digital pathology, which focuses on whole slide imaging of tissue samples. Companies such as Roche, Philips, and Leica Biosystems lead in that segment with platforms designed for histopathology. While these systems are part of the same overall shift toward digital imaging, hematology applications remain more specialized, centered on blood and body fluid analysis, with increasing overlap in areas such as image management, software integration, and AI-assisted interpretation.

Table 9-3: Selected Hematology Image Analysis Innovations

Company	Location	Details
Abbott Diagnostics	U.S.	CellaVision's digital microscopy, Europe
Beckman Coulter	U.S.	DxH Slidemaker Stainer II
CellaVision AB	Sweden	CellaVision Image Capture System, hospital networks
CellaVision AB	Sweden	CellaVision Advanced RBC analysis
CellaVision AB	Sweden	DC-1
MilliporeSigma/Amnis	U.S.	Amnis ImageStreamX Mark II
Equalis	Sweden	CellaVision Proficiency Software, hematology quality control
HORIBA Medical	Japan	Medica’s EasyCell cell image system
HORIBA Medical	France	Medica's EasyCell assistant with Horiba analyzers
Medica Corporation	U.S.	EasyCell assistant cell image analyzer, differential
Morphogo	China	Morphogo hematology
Roche	U.S.	Cobas m 511 Bloodhound
Scopio Labs	US	Scopio X100
Sysmex Corp	Japan	MilliporeSigma Amnis imaging cytometry for hematology
Sysmex America	U.S.	Medica's EasyCell assistant with Sysmex analyzers
Sysmex Corp	Japan	Sysmex DI-60 cell image analysis workcell, CellaVision
West Medica	Austria	Vision Hema Capture digital microscopy
West Medica	Austria	Vision Hema hematology analyzer differential automated

Source: company reports, Kalorama Information

Digital Evolution

Hematology laboratories, like their histology counterparts, continue to adopt technologies that reduce cost and turnaround time while maintaining or improving quality. Digital imaging has become an important tool in this effort, using cameras, optics, and controlled illumination

to convert images of blood cells into digital data that can be analyzed, stored, shared, and reviewed beyond the limits of traditional microscopy. This supports standardized workflows, remote access, and more efficient use of skilled personnel. CellaVision offers widely used systems for digital differential analysis, enabling images from smaller or satellite laboratories to be reviewed at centralized sites, thereby extending expertise across networks and addressing staffing constraints. Its platforms, including compact systems designed for small- to mid-sized laboratories, enable facilities to transition from manual microscopy to digital workflows by automating parts of the white blood cell differential and supporting red blood cell morphology assessment and platelet estimation. More recent developments include expanded software capabilities that improve workflow, case review, and cross-site collaboration, as well as the ability to compare current and historical patient results.

Digital morphology is also advancing into more specialized applications, such as bone marrow analysis, reflecting a broader trend toward standardization in complex hematology workflows. At the same time, integration with automated slide preparation, staining systems, and hematology analyzers is becoming more seamless, supporting end-to-end automation and faster turnaround times. Partnerships and connectivity with major analyzer vendors such as Sysmex Corporation are further accelerating adoption, positioning digital hematology as an increasingly routine part of modern laboratory operations rather than a niche capability.

Quality Control Measurement Programs

A number of companies offer quality control for hematology. A selected list is compiled below.

Table 9-4: Selected Quality Control Hematology FDA Registrations, 2024

Company	Product
Abbott Laboratories	CELL-DYN Retic Plus Control
Advanced Instruments, LLC	GloCyte Automated Cell Counter System; GloCyte Low- and High-Level Controls
AirScan, Inc.	HemaTechnologies ESR Control
Beckman Coulter - Danaher	4C Plus TRI Pack 4C-ES Cell Control 5C Cell Control 6C Cell Control; 6C Plus Cell Control (PN C07297) AcT 5diff Control Plus Body Fluid Control FLOW-SET IMMUNO-TROL LOW CELLS IMMUNO-TROL WHOLE BLOOD CONTROL LIN-C Linearity Control LIN-X Linearity Control Retic-C Cell Control; Retic-X Cell Control TruColor Giemsa Stain Kit; TruColor May Grunwald Stain Kit; TruColor Wright Buffer Kit; TruColor Wright Giemsa Stain; TruColor Wright's Giemsa Buffer Kit; TruColor Wright's Giemsa Stain Kit; TruColor Wright's Stain Kit
BECTON, DICKINSON & CO.	BD FACSPresto CD4/Hb Cartridge; BD FACSPresto CD4/Hb Cartridge Kit; BD FACSPresto System; BD Multi-Check CD4 Low Control; BD Multi-Check Control; Eurotrol FACSPresto Hb Controls (Levels 1-3) BD Leucocount Combo Control; BD Leucocount PLT Control; BD Leucocount RBC Control; BD Retic-Count Control; BD Multi-Check CD4 Low Control; BD Multi-Check Control; BD Stem Cell Control
Bioarray Solutions Ltd	PreciseType HEA BeadCheck Kit
Bionostics, Inc.	RNA Medical QCHGB Control

Company	Product
Bio-Rad Laboratories	Liquichek Hematology Control (X) Liquichek Hematology Control (A) Liquichek Hematology Control (C) Liquichek Hematology Control (S) Liquichek Hematology-16T Control Liquichek Reticulocyte Control (A) Liquichek Reticulocyte Control (A-1) Liquichek Reticulocyte Control (C) Liquichek Reticulocyte Control (S) Liquichek Reticulocyte Control (X) Meter Trax Control
EKF Diagnostics GmbH	Hemocontrol
High Technology Inc	Hemoglobin Control Set
Horiba/ABX	ABX DIFFTROL ABX ERYTROL ABX Minotrol 16 ABX MINOTROL CRP ABX MINOTROL RETIC
JAS Diagnostics/Drew Scientific	DS360 HbA1c 2-Level Control Kit; DS5 HbA1c 2-Level Control Kit EX-Trol Controls (Low, Normal, High) EX-Trol Plus Controls (Low, Normal, High)
MedTest Dx (Horiba)	Hemoglobin A1c Controls (H7546-CTL); MedTest DX Hemoglobin A1c Controls (HBAQ400, HBAQ480) Hemoglobin Controls
Microgenics Corporation	Thermo Scientific HEMA-TROL¿ Whole Blood HGB
Mindray DS USA Inc	BC-3D Control B55 Hematology Control BC-6D Hematology Control BC-RET Hematology Control BC-BF Hematology Control SC-CAL Plus Hematology Calibrator
Nova Biomedical Corporation	Nova 16 Nova Stat Profile Critical Care Xpress Nova Stat Profile PHOx Nova Stat Profile PHOx Basic Nova Stat Profile PHOx Plus C Stat Profile PHOx Plus L Stat Profile Prime Plus

Company	Product
Progenika Biopharma S.A.	ID CORE CONTROL
Quantimetrix Corporation	Spinalscopics Spinal Fluid Cell Count Control
R&D Systems Inc	3K Retic Hematology Control 4K Retic Hematology Control BC-5D Hematology Controls Body Fluid Control Body Fluid-I Control CBC-3D; CBC-3D For Mindray CBC-3D+CRP Hematology Control CBC-3K; CBC-4K; CELL-DYN Drift Control CBC-4K Plus Retics CBC-5D Hematology Control CBC-5D Plus Retics Hematology Control CBC-7; CBC-7 For Hemocue; CBC-8; HGB Extended CBC-LINE For HemoCue Linearity Kit; CBC-LINE Linearity Kit; CBC-LINE Low Range Linearity Kit; CBC-LINE Ultra Low Linearity Kit; CBC-LINE Ultra Low Plus RBC Hematology Linearity Kit; PLT-LINE Linearity Kit CBC-SYS Hematology Control CBC-Tech CBC-X CBC-XE Hematology Control CSF Automated Control Diesse ESR Control; SEDRite III; SEDRite Plus HC WBC Hematology Control HCT Extended Control LH-NRBC Hematology Control Platelet-Trol II QBC Hematology Control R&D ADVIA Retic Plus R&D Platelet-Trol Extended R&D Retic-I Plus Retic Hematology Control; Retic-I RET-LINE B Linearity Kit; RET-LINE C Linearity Kit; RET-LINE Linearity Kit XERet Hematology Control

Company	Product
Randox Laboratories Ltd	RANDOX HEMATOLOGY CONTROL - LEVEL 1 (HAEM CNTL - LEVEL 1); RANDOX HEMATOLOGY CONTROL - LEVEL 2 (HAEM CNTL - LEVEL 2); RANDOX HEMATOLOGY CONTROL - LEVEL 3 (HAEM CNTL - LEVEL 3)
Shenzhen Mindray Bio-Medical Electronics Co., Ltd	BC-3D CONTROL (Low, Normal and High) BC-5D Hematology Control
Siemens	ADVIA 120; ADVIA 120/2120; ADVIA 2120 ADVIA 120; ADVIA 120/2120; ADVIA 2120 ADVIA Hematology
Stanbio Laboratory	Hematology Quality Control
Streck, Inc	Alinity H-Series Control 29P Beckman Coulter IQ Body Fluids Cell-Chex Auto CELL-DYN Retic Plus Control; Retic-Chex for CELL-DYN CSF Reagent (1 X 8 ML) CVA; CVA for CELL-DYN; Sysmex Plt-CHECK; Sysmex RANGE CHECK X II; Sysmex RANGE CHECK X III; WRP CHECK; WRP CHECK EX EIGHTCHECK-3WP; EIGHTCHECK-3WP X-TRA; Para Check Para 4 Retic-Chex II Retic-Chex Linearity For BC Sysmex E-CHECK XE Sysmex E-CHECK; Sysmex E-CHECK XS TESTpoint CSF Controls (2 X 3 ML) TESTpoint Retic High Control (4 X 4 ML); TESTpoint Retic Low Control (4 X 4 ML) UA-Cellular For IQ XN CHECK XN CHECK BF XN-L CHECK XW QC CHECK
STS Corporation	STSC, General, Mixture, Hematology Quality Control
Sysmex America Inc	Plt-CHECK; WRP CHECK; WRP CHECK EX XW QC CHECK

Company	Product
Sysmex Corporation	E-CHECK(XE) E-CHECK; E-CHECK(XS) EIGHTCHECK-3WP; EIGHTCHECK-3WP IQAS Plt-CHECK; WRP CHECK; WRP CHECK EX XN CHECK XN CHECK BF XN-L CHECK XW QC CHECK

Source: FDA database

Laboratory-based Hematology Testing

Laboratory-based hematology IVD testing is a cornerstone of clinical diagnostics, combining automated cell counting with coagulation testing, flow cytometry, and, increasingly, molecular and genomics-based methods. The field is more integrated and digitized than in the past, with automation, connectivity, and advanced parameters supporting faster decision-making and more consistent results. Hematology plays a huge role in infection management, anemia evaluation, oncology support, and overall patient monitoring, while more specialized genomic insights are typically generated on separate molecular platforms and then integrated into clinical workflows.

Sysmex Corporation continues to lead the market with its XN series, including high-throughput systems such as the XN-9000, which provide advanced parameters such as nucleated red blood cells, immature granulocytes, reticulocyte hemoglobin, and immature platelet fraction, along with strong automation and connectivity. Beckman Coulter is a major competitor with its DxH series and integrated slide maker and stainer systems, supporting automated workflows, advanced flagging, and reduced manual intervention. Abbott Laboratories offers its Alinity h-series with integrated slide preparation and scalable automation, while Siemens Healthineers provides high-volume solutions through the Atellica HEMA systems, emphasizing workflow efficiency and system-wide integration.

Mindray has become an increasingly important competitor, particularly in high-throughput and cost-sensitive segments. Its BC-6800 series uses multi-dimensional cell analysis to improve detection of abnormal cell populations, while the CAL-8000 system integrates analyzers with slide-making and staining into a fully automated workcell capable of continuous loading, intelligent sample routing, and minimal manual handling. The company has also expanded into compact systems that combine CBC and ESR testing, extending advanced hematology capabilities into smaller laboratories and decentralized settings.

The cobas m 511 is Roche's offering in the hematology analyzer market, and it's positioned differently from most competitors. It combines a standard CBC with integrated digital morphology in a single system, enabling it to perform cell counts and automatically prepare, stain, image, and classify blood cells within a single workflow. This is a key differentiator, as most other vendors rely on separate systems (like CellaVision) for digital morphology.

Horiba continues to compete with its Yumizen and Pentra platforms, offering compact systems with 5-part differentials, reticulocyte analysis, and integrated ESR capabilities, particularly for mid- and lower-volume laboratories. Across the market, the main areas of advancement include tighter integration of analyzers with slide preparation, staining, and digital imaging; expanded clinical parameters that support earlier detection of conditions such as sepsis and iron-restricted erythropoiesis; and improved middleware and decision-support tools that standardize workflows. High-end systems now function as part of fully automated workcells with bidirectional sample transport, automated rerun and reflex testing, and the ability to prioritize urgent samples without interrupting routine operations. At the same time, vendors continue to introduce smaller, lower-cost systems with advanced capabilities, reinforcing the shift toward fully integrated, automated, and connected hematology solutions rather than standalone instruments.

Table 9-5: Selected Hematology Innovations

Company	Location	Details
Abbott	U.S.	Alinity h-series integrated hematology testing system
Diatron MI Plc	Hungary	Abacus 3CP, automated, bench-top hematology analyzer
HORIBA Medical	Japan	Microsemi CRP hematology analyzer, CBC & CRP
HORIBA ABX	France	ABX Micros ES 60, desktop
HORIBA ABX	France	Pentra XLR, fluorescent retics
HORIBA ABX	France	Yumizen H500 hematology systems
HORIBA ABX	France	Yumizen H550 hematology solution
HORIBA Medical	Japan	Pentra DX Nexus analyzer, 8-part diff
HUMAN Diagnostics	Germany	HumaCount 80TS, automated 3-part differential
Mindray Medical	China	Mindray BC-5390 Auto Hematology Analyzer & BC-7500
Mindray Medical	China	BC-5150, 5-part mid-sized volume, BC-700 Series
Mindray Medical	China	BC-30s Auto Hematology Analyzer, compact 3 part
Mindray Medical	China	CAL-8000, BC-6800 analyzer with slide maker/stainer SC-120
Mindray/MedTest Dx	China	Mindray BC-3600 Auto Hematology Analyzer
Nihon Kohden	Japan	MEK-1303 automated hematology analyzer
Radiometer America	U.S.	ABL90 blood gas analyzer
Roche Diagnostics	U.S.	Cobas m511 integrated hematology analyzer
Shenzhen Dymind	China	DH-56 hematology with flow cytometry
Siemens Healthineers	Germany	Atellica HEMA
Sysmex Corp	Japan	XN series of automated hematology analyzers
Trinity Biotech	U.S.	Premier Resolution System

Source: Kalorama Information, company reports

Table 9-6: Global Laboratory-based Hematology Test and Instrument Market, 2025 and 2030 ($ million)

Market	2025	2030	CAGR
Lab-based hematology analyzers/reagents	5,495	7,455	6.3%

Source: Kalorama Information

Regional Laboratory-based Hematology Test and Instrument Market

The United States and Canada account for the largest share of sales for hematology in the laboratory segment with 44%, followed by Europe with 30%, Asia Pacific with 20% (of which Japan accounts for over half of Asia Pacific sales) and ROW with the remaining 6%.

Table 9-7: Global Laboratory-based Hematology Test and Instrument Market, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	44%
Europe	30%
Asia Pacific	20%
RoW	6%
Total	**100%**

Source: Kalorama Information

Decentralized Hematology Testing

The complete blood count is one of the most widely used diagnostic tests, and its role has expanded beyond the central laboratory into decentralized and near-patient settings. Growth in physician offices, outpatient clinics, urgent care centers, and oncology treatment sites is driving demand for compact hematology systems that deliver rapid results with minimal operator intervention. While centralized laboratories still account for the majority of testing volume, decentralized hematology is gaining traction, with an estimated 10%–20% of testing performed outside the core lab, depending on region and healthcare structure. This shift is supported by the need for faster turnaround times, reduced dependence on highly trained staff, and the continued movement of patient care into outpatient settings.

Technology in this segment focuses on ease of use, a small footprint, and workflow simplification. Decentralized systems are typically benchtop analyzers rather than fully handheld devices, but they are designed to support both venous and capillary samples, including fingerstick collection. Many systems incorporate cartridge-based or closed-tube systems to minimize sample handling and reduce contamination risk. At the same time, improved connectivity allows these instruments to link with laboratory information systems and provide remote oversight, enabling centralized review of results across distributed sites.

Sysmex Corporation, Beckman Coulter, Abbott Laboratories, Siemens Healthineers, and Mindray all offer compact hematology analyzers designed for lower-volume environments, extending core lab capabilities into decentralized settings. Other companies, such as PixCell Medical, are helping to define the emerging near-patient segment with cartridge-based systems like HemoScreen, which provide 5-part differentials using small sample volumes and simplified workflows.

Despite these advances, true point-of-care CBC testing remains an emerging segment, with most decentralized testing still performed on small analyzers that operate similarly to laboratory instruments. Adoption is expected to grow steadily as technology continues to simplify operations, integrate quality control, and expand clinical parameters. Increasing use of advanced CBC-derived metrics—such as immature granulocytes, reticulocyte hemoglobin, and platelet indices—at the point of care is also enhancing clinical decision-making without requiring additional tests

Hemoglobin/Hematocrit at the POC

Dedicated POC devices for hemoglobin/hematocrit have been available for many years. Hemoglobin test systems are used by office labs, hospitals, blood banks, dialysis centers, and public health agencies. The pioneer and leader in this field is HemoCue (now part of Danaher), whose portable red device is readily recognizable in most hospitals in the U.S. Europe and in Asia. HemoCue's B-Hemoglobin Photometer was granted CLIA waived status in 1993.

Table 9-8: POC Hematology Distribution, by Specialty, 2025 (%)

[Hematocrit/Hemoglobin vs. Other Routine Hematology (WBC, Erythrocyte, Platelet)]

Specialty	Distribution of Revenue (%)
Hematocrit/Hemoglobin POC	60%
Other routine hematology POC (WBC, erythrocyte, platelet, etc.)	40%
Total	**100%**

Source: Kalorama Information

Decentralized hematocrit and hemoglobin testing has expanded as care has shifted to physician offices, outpatient clinics, urgent care centers, and blood donation settings. These tests are among the most commonly performed near the patient because they are simple, rapid, and clinically useful for screening anemia and monitoring chronic disease. The market is driven by the need for fast turnaround, minimal sample preparation, and ease of use for non-specialized staff, with many systems designed to operate with both capillary and venous samples.

Established providers such as EKF Diagnostics and HemoCue offer widely used devices for quantitative measurement of hemoglobin and hematocrit in decentralized settings, particularly in clinics and blood banks. Abbott Laboratories and Nova Biomedical provide handheld and near-patient systems that include hemoglobin and hematocrit as part of broader critical care and blood gas testing menus. In addition, Radiometer, Siemens Healthineers, and Werfen play important roles through blood gas and acute care platforms that incorporate hemoglobin and hematocrit measurements in hospital and near-patient environments.

Masimo Corporation and OrSense Ltd. have developed noninvasive technologies that allow continuous or spot-check hemoglobin monitoring without a blood draw, primarily for screening and trending rather than definitive diagnosis. Technology trends in this segment emphasize portability, rapid turnaround, often within seconds to a minute, and built-in quality control and connectivity. Many systems now include data management features, wireless communication, and integration with laboratory or hospital information systems, allowing centralized oversight of decentralized testing. Additionally, capillary sampling is becoming more common, reducing the need for phlebotomy and improving patient access. While noninvasive methods are advancing, blood-based measurement remains the standard for diagnostic accuracy.

Table 9-9: Selected POC Hemoglobin and Hematocrit Systems

Company	Chemistry System
Abbott Diagnostics	i-STAT (waived)
ApexBio	HemoSmart (non-U.S.)
Boditech	Hemochroma PLUS (non-U.S.)
Clarity Diagnostics	Clarity Hb Check (waived)
DiaSys	QDx Hemostat
Diatron	Aquila (non-U.S.)
EKF Diagnostics	Hemo Control (waived), HemoPoint H2 Hemoglobin System (waived), DiaSpect
Germaine Laboratories	AimStrip Hgb (waived)
GlysBy	Hematocrit Quantitative Rapid Test
HemoCue (Radiometer)	Hb 201+, Hb 201 DM, Hb 301 systems (waived); Plasma/Low Hb system
Masimo	Pronto-7, Rad-67
Separation Technology (EKF Diagnostics)	UltraCrit (waived)
Stanbio Laboratory (EKF Diagnostics)	STAT-Site M Hgb (waived)

Source: Kalorama Information

Hematology analyzers for small laboratories and near-patient settings represent one of the most competitive segments of the market, with numerous manufacturers and OEM suppliers offering compact, lower-cost systems. These instruments are typically semi-automated and often provide 3-part differentials, although newer models increasingly include expanded parameters and improved automation. While many are described as point-of-care, most function as low-volume laboratory analyzers rather than true bedside devices. Companies such as Nihon Kohden, Mindray, Boule Diagnostics, Diatron, QBC Diagnostics, and Orphée remain active in this segment, particularly in regional and cost-sensitive markets.

For hemoglobin and hematocrit testing specifically, decentralized solutions are well established and widely used. Nova Biomedical offers near-patient systems such as StatStrip that provide rapid, direct measurement of hemoglobin and hematocrit from capillary or venous samples and are used in blood banks, dialysis centers, and outpatient settings. EKF Diagnostics and HemoCue continue to lead in dedicated hemoglobin testing devices for screening and monitoring. Abbott Laboratories and Radiometer, along with Siemens Healthineers and Werfen, provide hemoglobin and hematocrit measurements through blood gas and critical care platforms used in near-patient and hospital environments.

Additional innovation is occurring in noninvasive and home-based testing. Masimo Corporation and OrSense Ltd. offer noninvasive hemoglobin monitoring technologies for screening, while Sanguina provides a home-use hemoglobin test for consumer screening. Emerging systems, such as those from Ad Astra Diagnostics, are working to bring more advanced hematology parameters closer to the point of care, although adoption remains in its early stages.

Table 9-10: Selected POC Hematology Analyzer Systems

Company	System*
Abbott Diagnostics	Cell-Dyn Emerald, Cell-Dyn Pearl
Beckman Coulter	Ac·T 5diff, Ac·T diff, Ac·T diff2, DxH 50 AL
Boule Diagnostics	Medonic M-16/M-20 (various sample configurations), Swelab Alfa, Quintus
DiaSys	Innova Star, SensoStar
Diatron	Abacus 5, Abacus 380, Abacus 3 CT, Abacus Junior 30, Abacus Junior 30 ND
HORIBA Medical	Pentra 60, Pentra 60C+, Pentra ES 60, Micros 60, Micros ES 60, Micros CRP 200, Microsemi CRP, Yumizen H500
Instrumentation Labs	GEM Premier 4000
Mindray	BC-5300, BC-5150, BC-5000, BC-3600, BC-3200, BC-3000Plus, BC-2800, BC-2300
Nihon Kohden	Celltac F MEK-8222, Celltac Es MEK-7300, Celltac E MEK-7222, Celltac a MEK-6500, Celltac a MEK-6400
Orphée	Mythic 18, Mythic 22 AL, Mythic 22 OT, Mythic 22 CT
PixCell Medical Technologies	HemoScreen Hematology Analyzer
QBC Diagnostics	QBC STAR
Radiometer	ABL FLEX90 PLUS
Siemens Healthineers	RAPIDPOINT 405
Sysmex	pocH-100i, XP-300, KX-21N, XW-100

Note: *Not all systems available in the United States

Source: Kalorama Information

As the industry develops, there is a concerted demand for lab-style and handheld hematology test devices for physician offices and clinics, as well as rural centers, worldwide. The handheld-style device is especially in demand in developing countries, where almost no diagnostic services are available outside urban centers. Therefore, Kalorama estimates that the world market for decentralized hematology tests and instruments is $951 million in 2025

($723 for lab-style instruments and $228 for handheld devices). With 5.3% annual growth, this market segment will reach $1,230 million by 2030.

Table 9-11: Decentralized Hematology Test and Instrument Market, by Type, 2025 and 2030 ($ million)

[Instruments, Lab-Style; Handheld Devices]

Type	2025	2030	CAGR
Lab-type instruments	723	947	5.5%
Handheld devices	228	283	4.4%
Total POC Hematology	**951**	**1,230**	**5.3%**

Source: Kalorama Information

Market Analysis: Leading Suppliers

Growth in the hematology market is being fueled by several key factors, including the increasing adoption of automated hematology instruments, expanding market penetration of POC hematology testing, and the introduction of technologically advanced analyzers.

In the United States, sales remain moderate. Growth is supported by an aging population and a heightened emphasis on laboratory testing as a critical tool for diagnosis and treatment. Nevertheless, the overall market has been tempered by a highly cost-conscious healthcare environment. Additionally, replacement demand for hematology analyzers in this mature market has been affected by continued laboratory consolidation and the growing influence of group purchasing organizations, which have contributed to pricing pressures and slowed instrument turnover.

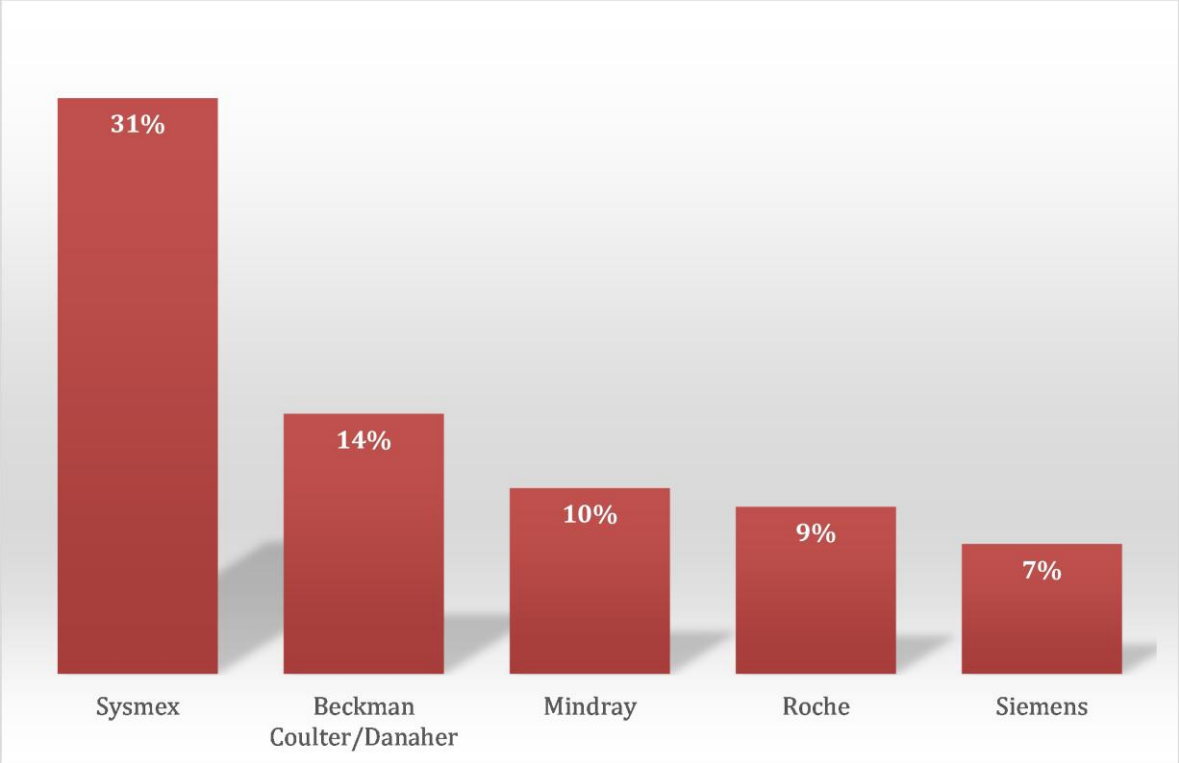
The indicators mentioned above, in addition to other macro-economic factors provide, Kalorama's estimate indicates that hematology vendors can expect the global market to show 2% annual growth from $6,446 million in 2025 to $7,175 million in 2030, including lab based and POC. The major players in this discipline are Sysmex, Beckman Coulter/Danaher, Roche, Mindray and Siemens Healthineers. In 2025, the top five companies hold approximately $4.6 billion or nearly 71% of the hematology market.

Table 9-12: Top Hematology Company Revenues (Laboratory and POC), 2025 ($ million)

Company	Revenues	Market Share %
Sysmex	$2,019	31%
Beckman Coulter/Danaher	$884	14%
Roche	$630	10%
Mindray	$607	9%
Siemens	$453	7%
Others	$1,853	29%
Total	**$6,446**	**100%**

Source: Company reports and Kalorama Information

Figure 9-1: Market Share for Top Hematology Companies (Laboratory and POC), 2025 (%)



Source: Kalorama Information

Sysmex Corporation continues to hold a strong global position, supported by its leadership in Asia and ongoing expansion into emerging markets. China remains an important region, although growth has moderated compared with earlier periods, particularly in more mature segments such as hemostasis instruments. The company maintains a well-balanced geographic revenue mix across EMEA, the Americas, Japan, China, and the broader Asia Pacific region, reflecting its diversified global footprint.

Sysmex's competitive strength is driven by the breadth of its product portfolio and its ability to integrate systems into automated core laboratory environments. Its hematology platforms, led by the XN series, are widely used and can be connected to track-based automation systems for high-throughput laboratories. Sysmex has strengthened its position by expanding the range of advanced clinical parameters available on its systems, including immature granulocytes, reticulocyte hemoglobin, and immature platelet fraction, which are increasingly used for infection detection, anemia management, and clinical decision support.

The company also benefits from a strong installed base supported by recurring reagent and service revenue, which reinforces long-term customer retention. Sysmex has expanded its reach into mid- and low-volume laboratories with compact analyzers and simplified workflows, enabling it to compete more effectively in decentralized and emerging-market settings.

Table 9-13: Global Hematology (Laboratory-based and POC) Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	43%
Europe	32%
Asia Pacific	19%
RoW	6%
Total	**100%**

Source: Kalorama Information

The Commercial Outlook for Hematology Tests

The hematology market in 2025–2026 continues to evolve, driven by steady clinical demand, advances in automation, and ongoing pressure to improve laboratory efficiency. Growth remains largely incremental rather than disruptive, with innovation focused on enhancing the clinical value of routine testing and improving workflow. The expansion of advanced parameters on hematology analyzers and the broader use of body fluid analysis have helped sustain interest in the sector, while laboratories continue to upgrade to more automated and connected systems.

In developed markets, growth is modest due to high penetration of automated hematology systems, while growth is stronger in emerging regions as access to diagnostics improves. Vendors such as Sysmex Corporation, Beckman Colter, and Mindray are driving the adoption of fully automated workcells that integrate analyzers with slide preparation, staining, and digital imaging. These systems support higher throughput, reduce manual intervention, and address ongoing staffing constraints in laboratories.

A trend is the increasing use of advanced CBC-derived parameters for clinical decision support. Measurements such as immature granulocytes, reticulocyte hemoglobin, neutrophil-to-lymphocyte ratio, and platelet indices are increasingly used to support early detection of infection, assess sepsis risk, and guide anemia management without requiring additional tests. At the same time, digital morphology solutions, including those from CellaVision, are becoming more widely adopted, enabling automated pre-classification of cells, remote review, and improved standardization across laboratory networks.

Decentralized and near-patient hematology testing is also gaining traction, particularly in outpatient and lower-volume settings, supported by smaller instruments, simplified workflows, and improved connectivity. However, most testing continues to be performed in centralized laboratories, with decentralized systems functioning as an extension of the core lab.

Chapter 10: Coagulation

Scope

The coagulation market consists of all products, technologies and services used to assess blood clotting function for diagnosis, monitoring and associated reagents. It is divided into laboratory-based systems and decentralized/POC devices and consumables.

Overview and Trends of Coagulation and Immunohematology Tests

Hemostasis is a complex physiological process that maintains blood flow while preventing excessive bleeding. It involves a balance among coagulation, platelet function, and fibrinolysis, ensuring that clots form when needed and are removed once healing occurs. In clinical practice, disruption of this balance can lead to bleeding or thrombotic disorders, making hemostasis testing a critical component of patient management.

Anticoagulant and antithrombotic therapies are widely used to reduce the risk of thrombotic events such as stroke, myocardial infarction, deep vein thrombosis, and pulmonary embolism. Warfarin remains in use, particularly in patients with mechanical heart valves and certain high-risk conditions and requires regular monitoring using prothrombin time expressed as the international normalized ratio (PT/INR) to maintain appropriate dosing. However, direct oral anticoagulants such as rivaroxaban, apixaban, and dabigatran are now widely used and generally do not require routine laboratory monitoring. When testing is performed for these agents, it is typically in specific clinical situations such as bleeding, urgent surgery, or suspected overdose, and standardized testing approaches are still evolving across laboratories.

Heparin continues to be used primarily in hospital settings, with monitoring performed using activated partial thromboplastin time (aPTT) or, increasingly, anti-factor Xa assays, which offer improved specificity and are now widely adopted. Heparin-induced thrombocytopenia remains a serious immune-mediated complication requiring confirmation through antibody and functional testing.

The routine coagulation test menu includes PT/INR and aPTT for screening, as well as fibrinogen, D-dimer, and molecular coagulation testing. More specialized testing includes coagulation factor assays for conditions such as hemophilia and von Willebrand disease, as well as evaluation for antiphospholipid syndrome using markers such as anticardiolipin and anti-beta2 glycoprotein I antibodies. Genetic testing for thrombophilia, including Factor V Leiden and Prothrombin G20210A, is used selectively in patients with unexplained or recurrent thrombotic events, with more targeted use in current clinical practice and is discussed in Chapter 8.

Advances in automation and integration have expanded the role of coagulation testing within the core laboratory. D-dimer and certain chromogenic assays are now commonly performed on high-throughput chemistry and immunoassay platforms, improving turnaround time and

workflow efficiency. At the same time, dedicated coagulation analyzers continue to support both routine and specialized testing, increasingly integrated into automated laboratory lines with middleware and decision-support rules.

Demand for decentralized coagulation testing is also increasing, particularly in anticoagulation clinics and physician offices, where point-of-care PT/INR systems allow rapid dose adjustment for warfarin therapy. Growth is driven by the number of patients on anticoagulant therapy and the need for timely clinical decisions. Special Topics

There are several developments that warrant special discussion as they have significant impact on the development of coagulation testing.

COVID-19

COVID-19 is recognized as a hypercoagulable state, particularly in moderate to severe disease. Early in the pandemic, clinicians observed increased rates of venous thromboembolism, microvascular thrombosis, and, in critical cases, disseminated intravascular coagulation, although the coagulopathy seen with COVID-19 differs from classic consumptive DIC and is often characterized by elevated fibrinogen and D-dimer rather than severe factor depletion. Coagulation biomarkers, especially D-dimer, were strongly associated with disease severity and outcomes, and monitoring of D-dimer, prothrombin time, platelet count, and fibrinogen became standard in hospitalized patients to support risk assessment and management.

Management has since evolved. Routine prophylactic anticoagulation remains standard for hospitalized patients, but more aggressive anticoagulation strategies are now applied selectively based on risk. While thrombotic complications remain a concern, rates have declined compared with the early pandemic period due to improved treatment protocols and vaccination.

In post-acute and long-COVID settings, evidence of persistent coagulation abnormalities is variable, but there is continued clinical interest in potential endothelial dysfunction and low-grade hypercoagulability in some patients. This remains an area of ongoing research rather than a clearly defined clinical standard.

Professional organizations such as the American Society of Hematology, the International Society on Thrombosis and Hemostasis, the American College of Cardiology, and the British Society for Hematology continue to provide guidance on thrombosis risk assessment and anticoagulation management in COVID-19, though current recommendations are more refined and less aggressive than those issued early in the pandemic.

Direct Oral Anticoagulants (DOACs)

Direct oral anticoagulants (DOACs)—including apixaban, rivaroxaban, edoxaban, and dabigatran—remain the standard of care in 2026 for many thromboembolic conditions, including nonvalvular atrial fibrillation and venous thromboembolism. No new DOACs have been introduced in recent years, and this group continues to dominate due to predictable pharmacokinetics, fixed dosing, and the lack of routine monitoring requirements. Clinical practice emphasizes targeted laboratory testing only in specific situations such as bleeding, urgent procedures, renal impairment, or suspected overdose, rather than routine monitoring.

The most important area of innovation in this space is the development of next-generation anticoagulants targeting Factor XI and Factor XIa in the coagulation cascade. These agents are being evaluated as potential successors to current therapies, with the goal of reducing thrombotic risk while minimizing bleeding complications, which remains the primary limitation of existing anticoagulants. Early clinical data suggest that they may offer comparable efficacy with improved safety, particularly regarding bleeding risk. In addition to oral agents, some are being developed as long-acting injectable therapies, offering the potential for less frequent dosing and greater flexibility in patient management.

Although monitoring is not required for patients on DOAC therapy, it has been recognized that there are exceptions when measurement may be appropriate. Examples include patients who present to the ED with an adverse event, require immediate reversal of anticoagulation, experience renal or liver failure, have suspected or known interaction with other drugs, or require verification of pre-operative drug clearance.

It is beyond the scope of this research to quantify the market for DOAC tests with certainty. However, coagulation leaders Diagnostica Stago and Werfen remain committed to this genre of tests.

D-dimer

D-dimer testing has been in clinical use since the 1990s and has become a routine tool for evaluating suspected thrombotic disease. It measures a fibrin degradation product formed when cross-linked fibrin is degraded during fibrinolysis, and its presence indicates recent or ongoing clot formation and breakdown. D-dimer testing is widely used to help exclude conditions such as deep vein thrombosis and pulmonary embolism in selected patients, and it is also used in the evaluation of disseminated intravascular coagulation. Its clinical value lies primarily in its high sensitivity and strong negative predictive value rather than specificity, and it is now increasingly used within structured diagnostic algorithms, including age-adjusted and risk-adapted approaches that improve clinical efficiency and reduce unnecessary imaging.

Testing is performed using both laboratory-based and point-of-care methods. Laboratory testing remains dominant and is carried out on automated coagulation analyzers as well as on core laboratory chemistry and immunoassay platforms. Over time, D-dimer has become one of the most prominent coagulation assays to migrate into the core laboratory environment, driven by high-throughput immunoassay methods, continuous availability, and faster turnaround times. Point-of-care and near-patient D-dimer testing has expanded in emergency and acute care settings, providing rapid triage and clinical decision-making.

A wide range of manufacturers offer D-dimer assays across different platforms, including Roche, Abbott Laboratories, Beckman Coulter, Siemens Healthineers, Sysmex Corporation, and Thermo Fisher Scientific, along with coagulation-focused specialists such as Werfen and Diagnostica Stago, and specialty reagent providers including Diazyme Laboratories and Nordic Biomarker.

Annually, over 67 million D-dimer tests are performed worldwide. Considering the test cycle and an increase in population growth over the forecast, and an average cost of $18-$19 per test (which includes cost of reagents, calibration and devices) the market for D-dimer tests performed in laboratories is $1,475 million in 2025. With 3.0% CAGR the market for D-dimer tests is likely to reach $1,710 million in 2030.

European coagulation professionals were the first to recognize the D-dimer test as an important tool for evaluating a patient's risk of a cardiac event related to thrombotic activity. In the U.S., this linkage was slower to take effect. As such the demand for D-dimer tests is robust in Europe in terms of volume accounting for about half of all test volume; however,

in the U.S. most tests are performed on special coagulation instrumentation, which, in turn, carries a slightly higher unit cost. Together, this places the market value about equal for North America and Europe with roughly 37% and 36% respectively.

Table 10-1: Global D-dimer Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	37%
Europe	36%
Asia Pacific	14%
RoW	13%
Total	**100%**

Source: Kalorama Information

Horiba offers D-dimer testing within its Yumizen G hemostasis platform, including systems such as the G200, a two-channel analyzer designed for lower-throughput laboratories. These systems enable small and mid-size labs to perform routine coagulation screening, clotting factor assays, and D-dimer testing as part of an integrated workflow. Horiba has also expanded functionality on its hematology platforms, including malaria screening on the ABX Pentra XL 80 and Pentra XLR, although this is separate from its coagulation portfolio.

LumiraDx (Roche) developed a rapid, quantitative D-dimer test capable of delivering results from a fingerstick sample within minutes, with a CE-marked exclusion claim for use in ruling out venous thromboembolism when combined with clinical probability assessment. The system demonstrated very high negative predictive value at standard cutoff levels, supporting its use in low-risk patients to avoid unnecessary imaging.

Market Analysis

The increasing complexity of both routine and specialized coagulation assays has driven the use of information technology tools to support clinical decision-making. As test menus expand and interpretation becomes more complex, particularly with newer anticoagulants and specialized assays, clinicians rely more on digital resources to guide test selection and understand results. While early adoption included standalone mobile applications, the trend has shifted toward integration of decision support within laboratory information systems, middleware, and electronic medical records, allowing more seamless and standardized interpretation at the point of care.

Diagnostica Stago provides educational tools such as the iHemostasis application, which offers reference material on the coagulation cascade, fibrinolysis, testing pathways, and interpretation guidelines. Although standalone apps remain available, most vendors now emphasize integrated digital platforms, automated flagging, and rule-based interpretation embedded within laboratory workflows. Other educational tools illustrate the broader availability of decision-support resources, though these are generally supplementary rather than central to clinical practice.

Anticoagulants are widely prescribed for conditions such as atrial fibrillation, deep vein thrombosis, pulmonary embolism, stroke prevention, and other thrombotic disorders. Coagulation testing plays a critical role in assessing patients prior to procedures and in monitoring therapies that affect clotting. It has long supported individualized treatment decisions, particularly in warfarin management, and continues to contribute to more personalized approaches to anticoagulation therapy.

Technologies used in coagulation testing include clot-based assays, chromogenic assays, and immunoassays, with molecular diagnostics applied selectively for thrombophilia evaluation. The market is typically segmented into central laboratory testing and decentralized testing. Central laboratory testing includes routine screening assays such as PT/INR and aPTT, along with D-dimer and specialized coagulation factor assays. Professional point-of-care testing includes PT/INR systems, ACT testing for heparin monitoring, and selected near-patient coagulation assays used in acute care settings. Patient self-testing is largely limited to PT/INR monitoring for individuals on long-term warfarin therapy.

Overall product development in coagulation testing has focused on expanding anti-factor Xa assays for heparin and selected anticoagulant monitoring, increasing adoption of viscoelastic testing systems for real-time clot assessment, and advancing fully automated coagulation workcells integrated with core laboratory platforms. Vendors such as Werfen and Diagnostica Stago continue to expand automated systems and assay menus, while Sysmex and others are extending automation and connectivity across laboratory networks. Compact systems such as those from Horiba are bringing coagulation testing, including D-dimer and routine assays, to smaller and decentralized laboratories. Digital integration and middleware-based decision support have become an important part of new product development, helping laboratories standardize interpretation and improve workflow efficiency.

Table 10-2: Global Coagulation Sales, by Segment, 2025-2030 ($ million)

[D-dimer; Molecular; Professional POC; Professional Self; PT/INR Labs]

Segment	2025	% Mkt	2030	% Mkt	CAGR
PT/INR Labs	1,576	38%	1,855	39%	3%
D-dimer	1,475	36%	1,710	36%	3%
Professional POC	805	19%	892	18%	2%
Molecular	218	5%	243	5%	2%
Professional Self	90	2%	95	2%	1%
Total	**4,164**	**100%**	**4,795**	**100%**	**3%**

Source: Kalorama Information

The 2025 global coagulation tests market (lab-based and all POC) is valued at $4,164 million and is expected to see 3.0% annual growth to reach sales of $4,795 million in 2030. The market is fueled by POC tests and steady performance expected for D-dimer performed in the laboratory. D-dimer generates $1,475 million for 2025, is added to the coagulation testing market highlighting its growing role in the market. D-dimer, growing at 3.0% annually, is expected to reach $1,710 million by 2030.

Overall, North America and Europe each account for about 37% of the market, Asia Pacific approximately 13%, and ROW 13%. While more INR/PT and PTT tests are performed in

North America than in Europe, European labs perform more specialized coagulation factor tests than labs in North America.

Table 10-3: Global Coagulation Test and Instrument Market, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	37%
Europe	37%
Asia Pacific	13%
RoW	13%
Total	**100%**

Source: Kalorama Information

Lab-based Testing

Coagulation testing and instrumentation have advanced from early manual clot detection methods, with recent innovation focused on automation, workflow efficiency, and expanded test menus rather than entirely new test types. Increasing test volumes and ongoing laboratory staffing constraints have driven demand for higher levels of automation, integrated systems, and improved throughput in coagulation analyzers.

The menu of laboratory-based coagulation tests is extensive and includes routine screening assays such as prothrombin time (PT/INR) and activated partial thromboplastin time (aPTT), along with specialized tests such as D-dimer, fibrinogen, coagulation factor assays (Factors II, V, VII, VIII, IX, X, XI, XII, XIII), antithrombin, protein C and protein S, plasminogen, and tests for fibrinolysis and platelet function. Molecular assays, including Factor V Leiden and prothrombin gene mutation testing, are used selectively for thrombophilia evaluation. Some older tests, such as bleeding time, are now largely obsolete in routine practice and have been replaced by more standardized platelet function assays.

The PT/INR test remains one of the most widely used coagulation assays and is commonly ordered to evaluate bleeding risk and to monitor warfarin therapy. PT assesses the extrinsic and common pathways of the coagulation cascade, while aPTT evaluates the intrinsic and common pathways. Together, these tests provide a broad assessment of coagulation function. INR standardization allows comparison of PT results across laboratories and is essential for consistent warfarin dosing. While test volumes are high globally, growth has stabilized in many regions due to increasing use of direct oral anticoagulants, which do not require routine monitoring.

Modern coagulation analyzers are fully automated and perform clot-based, chromogenic, and immunologic assays on a single platform. Current systems support high-throughput testing, automated sample handling, and integrated quality control. Newer generations of analyzers are designed to integrate into automated laboratory tracks, including advanced data management and connectivity, and offer expanded assay menus, including D-dimer and anti-factor Xa testing. Anti-factor Xa assays are now widely used in many laboratories for heparin monitoring and, in selected cases, for assessment of direct oral anticoagulants.

Diagnostica Stago offers its STA R Max and STA Compact Max systems, which are widely used for coagulation testing and anticoagulant monitoring. Sysmex Corporation offers the CN series, including systems such as the CN-6000, designed for automated, high-throughput

coagulation testing with integrated workflow capabilities. Other major participants in lab-based coagulation testing include Werfen, with its widely used ACL TOP analyzer family, and Siemens Healthineers, which offers the CS and Atellica COAG systems, both of which are widely deployed in automated core laboratory environments. Roche offers the cobas t 511 and cobas t 711 coagulation analyzers for mid- to high-volume laboratories, supporting routine and specialized coagulation testing.

Table 10-4: Selected Lab-based Coagulation Innovations

Company	Location	Area	Details
ARUP Laboratories	U.S.	PGx	PGXL's PerMIT/warfarin
Diagnostica Stago	France	DOAC	DOAC anticoagulant menu expansion
Diagnostica Stago	France	instrument	STA MAX systems - high and low volume labs
Diagnostica Stago	France	instrument	STA-ECA II Assay for Dabigatran
Diagon Ltd	Hungary	instrument	COAG family of hemostasis diagnostics systems
HUMAN Diagnostics	Germany	instrument	HumaClot Pro, fully automated bench top coagulation analyzer
Instrumentation Laboratory (Werfen)	U.S.	PT/INR	ACL TOP 300/500/700 CTS Hemostasis Testing Systems
Mayo Medical Lab	U.S.	PGx	The Tailored Antiplatelet Therapy, personalized platelet therapy
PGXL Laboratories (Prescient Medicine)	U.S.	PT/INR	PerMIT/warfarin
Roche	E.U.	instrument	Cobas t 511/ t 711
Sekisui Diagnostics	U.S.	PT/INR	CP3000 coagulation
Sekisui Diagnostics	U.S.	PT/INR	Coapresta 2000 (CP2000) Coagulation System
Siemens	U.S.	factors	Sysmex CS-2500
Sysmex	Japan	factors	Revohem FVIII chromogenic assay reagent
Sysmex	Japan	PT/INR	Revohem PT reagent

Source: Kalorama Information

Genetic Markers of Hypercoagulopathies

Coagulation testing has been a component of individualized patient care, particularly in anticoagulant selection, dosing, and monitoring. While the broader concept of personalized medicine has gained attention in oncology and other fields, coagulation testing has historically played a similar role, especially in warfarin management and in assessing thrombotic risk. Thrombophilia genetic testing has been part of the clinical toolbox for more than two decades, although its use today is more selective than in the past.

Advances in the understanding of thrombosis and cardiovascular disease have contributed to both acquired and genetic risk factors. Molecular testing for inherited thrombophilia most commonly includes Factor V Leiden and the prothrombin G20210A mutation, which are associated with increased risk of venous thromboembolism. These tests are used in selected patients, such as those with unexplained or recurrent thrombosis, thrombosis at a young age, or a strong family history, rather than as routine screening tools. Although these markers are well established, they are not considered part of standard testing for all patients with thrombotic disease and are not typically used to guide routine anticoagulant selection.

The clinical role of some previously common tests has changed. MTHFR polymorphism testing is now widely regarded as having little clinical utility in the evaluation of thrombophilia or cardiovascular risk and is generally not recommended in current clinical practice. Earlier assumptions linking MTHFR variants and mild hyperhomocysteinemia to thrombotic risk have not been consistently supported, and use of this test has declined accordingly.

Pharmacogenetic testing for warfarin sensitivity, involving genes such as CYP2C9 and VKORC1, was once expected to play a larger role in guiding therapy. In practice, its use has remained limited, partly due to variability in clinical benefit and the increasing use of direct oral anticoagulants, which do not require routine monitoring or genetic guidance.

Venous thromboembolism remains a common condition, with an estimated incidence of roughly 1 to 2 cases per 1,000 individuals annually. These events are influenced by a combination of genetic and acquired risk factors, including age, immobility, surgery, cancer, pregnancy, and hormone therapy. While genetic testing can provide useful information in selected cases, most clinical management decisions continue to rely on patient history, clinical presentation, and standard laboratory testing.

Molecular thrombophilia testing represents a relatively small and mature segment of coagulation diagnostics, with modest growth and stable demand. Utilization has historically been strong in Europe and is well established in the United States, although current practice emphasizes targeted testing based on clinical need rather than broad population screening.

Table 10-5: Related CMS Codes for Reimbursement National Limits, Molecular, 2025

Code	Description	Reimbursement National Limit
81241	F5 (Coagulation factor V) (e.g., hereditary hypercoagulability) gene analysis, 20210G>A variant	$73.37
81400	Molecular pathology procedure, Level 1 (e.g., identification of single germline variant [e.g., SNP] by techniques such as restriction enzyme digestion or melt curve analysis)	$63.96

Source: CMS

Table 10-6: Global Molecular - Thrombophilia SNP Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	37%
Europe	36%
Asia Pacific	14%
RoW	13%
Total	**100%**

Source: Kalorama Information

There is a chance the availability could become more commonplace with the migration of these molecular analyzers offered by companies including Cepheid, Roche and Illumina.

Even with moderate acceptance of these molecular tests, the segment has attracted new entrants, partly with test services, targeting cardiac patients and anticoagulant dosing. Of particular interest is Agena Bioscience's test, IMPACT Dx (developed by Sequenom), using

a mass spectroscopy platform. The table below presents a selection of molecular coagulation test innovations.

Table 10-7: Selected Molecular Coagulation Test Innovations

Company	Location	Details
Affinity Biologicals	Canada	VisuDep-F Frozen Factor VIII/XI Deficient Plasma
Agena Bioscience	U.S.	Sequenom's Impact Dx Factor V Leiden/Factor II
ARUP Laboratories	U.S.	warfarin
Cepheid	U.S.	Xpert FII & FV; genetic risk thrombosis assay
GenMark Diagnostics	U.S.	Thrombophilia Risk Test with eSensor technology
SeraCare Life Sciences	U.S.	ACCURUN 611 coagulation gene markers, quality control

Source: Kalorama Information

Additionally, the development of the LDT segment for specialty coagulation testing, such as Factor II (prothrombin), and DNA analysis offered by Lab Corp. is also emerging at a faster rate.

Leading Suppliers: Laboratory Systems

The market is highly diversified and, for the most part, a different set of companies is active in each subsegment. The table below presents coagulation revenues for the major companies involved in the laboratory coagulation test market.

Table 10-8: Top Coagulation Company Market Share Laboratory-based, 2025 (%)

Company	Market Share %
Werfen	21%
Diagnostica Stago	21%
Sysmex	16%
Siemens Healthineers	13%
Beckman Coulter	5%
Others	24%
Total	**100%**

Note: Includes some revenues for D-dimer

Source: Kalorama Information

This market is highly competitive with no real dominance by any one company. These five companies account for roughly 76% of the global market for laboratory coagulation instruments and reagents. Sysmex and Werfen are the strongest instrument vendors; the strongest reagent vendors are Siemens Healthineers, Stago and Beckman Coulter/Danaher. Other companies involved in the coagulation reagent business include Grifols, Roche, Menarini, and Mindray.

Decentralized Coagulation Testing – Professional Use

Most decentralized coagulation testing for professional use occurs in hospitals, physician office laboratories and specialized anticoagulation clinics. The activated clotting time (ACT) test is commonly performed in patients receiving heparin during cardiovascular surgery and interventional procedures such as those performed in catheterization laboratories. The PT/INR test is used to monitor and adjust warfarin therapy in patients with conditions such as atrial fibrillation, mechanical heart valves, and other thrombotic disorders.

Point-of-care coagulation systems are used in several key clinical settings. One major application is in acute cardiovascular care, where coagulation testing complements cardiac markers in patient triage and management. A second important use is real-time monitoring of heparin therapy during surgical and interventional procedures using ACT testing. A third area is professional near-patient monitoring of PT/INR in anticoagulation clinics and outpatient settings, although this segment has narrowed with the increasing use of direct oral anticoagulants that do not require routine monitoring.

The primary professional POC coagulation tests include PT/INR and ACT, with more limited use of aPTT and D-dimer in decentralized settings. Growth in this segment is driven more by procedural testing, critical care needs, and demand for rapid turnaround times, rather than by the expansion of warfarin monitoring alone.

Kalorama estimates that the global market for professional POC coagulation testing is $805 million in 2025 and, with 2.0% CAGR, will reach $892 million in 2030. The U.S. accounts for approximately 38% of the market, Europe 40%, Japan 7% and the ROW 15%. Growth is partly attributed to a growing base of people on warfarin therapy.

ACT testing remains stable at $118 million and is an essential segment of decentralized coagulation testing, supported by its role in cardiac surgery and interventional cardiology. Multiple manufacturers provide ACT systems, including Roche, Werfen, Helena Laboratories, and Medtronic. No single company dominates this segment, and demand remains steady due to ongoing procedural requirements.

CLIA-waived PT/INR systems have enabled broader use of coagulation testing outside central laboratories. These systems support connectivity, electronic data management, and integration with anticoagulation management programs. Examples include systems from Roche, such as the CoaguChek platform, and devices from Werfen, including the Hemochron

Signature Elite. Abbott Laboratories also offers PT/INR and ACT testing through its i-STAT handheld system as part of a broader critical care testing menu. Siemens Healthineers provides the Xprecia Stride analyzer for professional near-patient PT/INR testing, supporting decentralized anticoagulation management.

Recent developments in professional decentralized coagulation testing include emerging technologies for rapid assessment of anticoagulant activity in acute care settings. Emerging companies such as Perosphere are developing portable whole-blood coagulometers designed to assess anticoagulation status, including heparin and direct oral anticoagulants, at the bedside. Other companies, such as DOASENSE, are developing rapid detection methods for direct oral anticoagulants to support urgent clinical decision-making. Established vendors continue to enhance their existing platforms by improving speed, connectivity, and workflow integration.

Decentralized Coagulation Testing – OTC

Self-monitoring can involve either self-testing, where the user performs the INR test themselves and then contacts a health professional for advice on any change to the dosage of anticoagulant that may be required, or self-managing, where the user performs the INR test themselves and then adjusts the dosage of their anticoagulant medication by following an agreed care protocol.

Proponents of self-testing highlight that greater use of self-monitoring offers clinical and patient benefit, and over time is likely to result in reductions in heart attacks and strokes caused by blood clots.

The world market for OTC coagulation testing is estimated to grow at an average annual rate of 1.1% by 2030. Roche Diagnostics has pioneered the coagulation self-test market since the mid-1990s. A significant increase was anticipated in the U.S.; however, only about 5% of patients on warfarin perform self-testing, compared with at least 20% in Europe, particularly in Germany. Most patients are elderly and the devices for PT will have to evolve with more user-friendly features similar to those developed for glucose self-testing

New biosensor-based devices have emerged from companies such as Microvisk and T2 Biosystems. This advanced technology helps simplify and standardize POC coagulation tests. Also, POC D-Dimer immunoassays are a part of the market. POC D-dimer in 2025 totaled $81 million.

HemoSonics offers a POC QStat Cartridge assay, which provides hemostasis data during trauma and liver transplantation procedures. The cartridge is designed for use with the Quantra Hemostasis System.

The table below presents a selection of innovations in decentralized coagulation testing.

Table 10-9: Selected POC Coagulation Test Innovations

Company	Location	Area	Details
Akers Biosciences	U.S.	prof	PIFA PLUSS PF4 Rapid Assay, HIT whole blood
bioMérieux	France	prof	Vidas D-dimer/Vidas D-dimer Exclusion II, immunoassay
Diagnostica Stago	France	app	iHemOStasis app coagulation cascade information
Diagon Ltd	Hungary	prof	COAG S handheld point-of-care INR
Haemonetics	U.S.	prof	TEG 6s system
Helena	U.S.	PT/INR	Cascade Abrazo
Microvisk Technologies	UK	prof	CoagMax PT/INR system, strip sensor
Microvisk Technologies	UK	OTC	CoagLite device, home PT/INR
Mitsubishi Chemical	Japan	Prof, D-dimer	Pathfast chemiluminescent immunoassay
Point of Care Decision Support	U.S.	IT	POC software anticoagulant treatment support
Point of Care Decision Support	U.S.	IT	POC anticoagulation Software update
Roche Diagnostics	U.S.	PT/INR	CoaguChek XS Plus meter
Roche Diagnostics	U.S.	D-dimer	Cobas h 232 POC system
Roche Diagnostics	U.S.	PT/INR	CoaguChek Vantus
Siemens	U.S.	prof	Xprecia Stride, PT/INR

Source: Kalorama Information, company reports.

Platelet Testing

Platelet function testing has been studied extensively in relation to antiplatelet therapies such as aspirin and clopidogrel (Plavix), which are used to reduce thrombotic risk in cardiovascular disease but can increase bleeding risk in certain patients. Variability in patient response to these agents has been observed, although the concepts of "aspirin resistance" and "clopidogrel resistance" are not consistently defined and remain areas of ongoing investigation.

Aspirin remains widely used for secondary prevention of cardiovascular events, though its use in primary prevention is now more selective. Interest in decentralized platelet function testing has been driven by the need to assess the effectiveness of antiplatelet therapy, particularly in cardiology and perioperative settings. However, adoption has been limited by the lack of standardized testing methods and the absence of clear evidence linking test results to improved clinical outcomes. As a result, routine platelet function testing is not broadly recommended and is generally reserved for selected high-risk or specialized patient populations.

Several systems have been commercialized for near-patient platelet function assessment. Werfen markets the VerifyNow system, which is widely used in cardiology settings to assess platelet response to antiplatelet agents. Helena Laboratories offers the Plateletworks test, a bedside platelet aggregation assay used in specific clinical environments. Other assays, including aspirin response tests such as AspirinWorks, have been introduced, but their clinical role remains limited and adoption has been uneven. Some earlier or smaller developers have had reduced visibility in recent years as the market has consolidated and clinical demand has narrowed.

Hematology analyzer manufacturers have expanded platelet-related parameters in routine complete blood count testing, including the immature platelet fraction and other platelet indices that provide indirect information about platelet production and activity. Companies such as Sysmex Corporation have enhanced these capabilities, although these measurements do not replace dedicated platelet function testing.

More recent developments have focused on laboratory-based automation rather than true decentralized expansion. Randox Laboratories has introduced automated platelet function assays designed for core laboratory use, reflecting a shift toward centralized testing for more complex platelet assessments. At the same time, early-stage innovation is exploring new

point-of-care approaches that more closely replicate physiologic clot formation using whole-blood and shear-based systems, although these technologies are not yet widely commercialized.

Table 10-10: Selected Platelet Activity Test Innovations

Company	Details
Corgenix (Werfen)	AspirinWorks Test
Helena Labs	Plateworks Bedside Platelet Aggregation test
Roche	Multiplate analyzer
Werfen	VerifyNow II System, POC, platelet PGx
Werfen	VerifyNow P2Y12 Test, anticoagulants added

Source: Kalorama Information compilation

Leading Suppliers: POC Systems

The market is highly diversified and, for the most part, a different set of companies is active in each subsegment.

The leader in the POC market is Roche Diagnostics, with estimated 2025 sales of approximately $330 million, generated by professional and self-test devices. Next, in order of market share, are Radiometer, Werfen, Siemens Healthineers and Abbott.

For some companies, the growth strategy involves separating from distribution agreements. However, for others distribution is the key to success.

The table below presents Kalorama Information's estimated coagulation revenues for the top companies involved in the POC coagulation test market.

Table 10-11: Top Coagulation Company Revenues, POC, 2025 ($ million, estimated)

Company	Revenues
Roche Diagnostics	330
Radiometer	162
Werfen	126
Siemens Healthineers	81
Abbott	29

Source: Kalorama Information

The Commercial Market for Coagulation Tests

Several factors contribute to growth in the coagulation testing market, including an aging population, rising incidence of cardiovascular disease and thrombotic disorders, and ongoing improvements in laboratory and near-patient testing technologies. While earlier research in coagulation focused heavily on bleeding disorders such as hemophilia, there has been increasing recognition over the past decade that disorders of excessive clotting play a major role in conditions such as venous thromboembolism and other cardiovascular diseases.

Advances in understanding the coagulation cascade and its interactions with inflammation and the immune system have led to the development of more specialized assays that provide insight into both clot formation and breakdown. This includes tests that assess fibrinolysis, coagulation factors, and thrombotic risk markers. Recent trends in coagulation testing include increased use of anti-factor Xa assays for heparin monitoring and selected anticoagulant assessment, as well as broader adoption of D-dimer testing in emergency and core laboratory workflows.

Specialized coagulation tests, such as D-dimer, selected thrombophilia genetic assays, and antibody-based tests, have become well established in developed healthcare markets, where they are used in clinical practice. However, their adoption is more limited in lower-resource regions, where testing is often focused on routine assays due to cost constraints, limited infrastructure, and clinical priorities. At the same time, thrombophilia testing is now applied more selectively, reflecting a more targeted approach to genetic risk assessment.

The introduction and widespread use of direct oral anticoagulants has reshaped the testing landscape. These drugs generally do not require routine monitoring, thereby reducing demand for some traditional coagulation tests, such as PT/INR. However, they have also created a need for targeted laboratory assessment in specific situations such as bleeding, urgent procedures, or suspected drug interactions.

Coagulation testing is increasingly being integrated into fully automated core laboratory environments, with track-based systems, middleware, and rule-based workflows improving efficiency and turnaround time.

Table 10-12: Major Anticoagulants Uses and Tests

Drug	Test Options	Users	Uses
Apixaban	anti-factor Xa	oral self-medication	Prevents stroke and blood clots in people with (AFib) not caused by a heart valve problem
Argatroban	PTT	intravenously in hospitalized patients	Prevent & treat thrombosis in patients with heparin-induced thrombocytopenia (HIT)
Bivalirudin	ACT	in hospitalized surgical patients	As an alternative to heparin
Dabigatran	Thrombin Time for residual anti-factor Xa	oral self-medication	Prevents stroke and blood clots in people with (AFib) not caused by a heart valve problem
Edoxaban	anti-factor Xa	oral self-medication	Treatment of deep vein thrombosis and pulmonary embolism.
Fondaparinux	anti-factor Xa	subcutaneous injection by patient or in hospital	Prevention of deep vein thrombosis in patients who have had orthopedic surgery as well as for the treatment of deep vein thrombosis and pulmonary embolism.
Heparin	PTT, anti-factor Xa	in hospitalized surgical patients	Prevents the formation of blood clots
Heparin, LMW	anti-factor Xa	in hospitalized surgical patients	Prevents the formation of blood clots
Lepirudin	PTT	intravenously in hospitalized patients	Treatment of heparin-induced thrombocytopenia (HIT)
Rivaroxaban	anti-factor Xa	oral self-medication	Prevent blood clots for people who had deep vein thrombosis or pulmonary embolism
Warfarin	PT/INR	oral self-medication	Prevents the formation of blood clots in the blood vessels and their migration elsewhere in the body

Source: Kalorama Information, company reports.

Point-of-care coagulation systems are used in several key clinical areas. One major application is in acute and emergency care, where rapid coagulation results may complement other tests in patient triage, although cardiac markers remain the primary tools for diagnosing a heart attack. A second, more established use is monitoring heparin therapy during cardiovascular surgery, catheterization procedures, and other interventions, in which activated clotting time testing is routinely used. A third area is near-patient and self-testing of PT/INR for patients on warfarin therapy, particularly in anticoagulation clinics and selected home settings. However, this segment has become less prominent due to the increasing use of direct oral anticoagulants, which do not require routine monitoring.

Recent developments in point-of-care coagulation testing have focused on technological and workflow improvements rather than on the introduction of entirely new test types. Newer systems increasingly use microfluidic and electrochemical detection methods to improve speed, accuracy, and ease of use. There has also been expanded use of POC coagulation testing in emergency, trauma, and critical care settings, where rapid results are essential for clinical decision-making. In addition, ongoing product development emphasizes miniaturization, connectivity, and integration with laboratory and hospital information systems. Early efforts toward multiplex and multi-parameter testing are emerging, although these remain in the early stages of adoption.

Chapter 11: Microbiology and Virology

Scope

For decades, the gold standard in clinical microbiology has been culture-based testing—growing microorganisms on selective or differential media, followed by organism identification and antimicrobial susceptibility testing (AST) using additional reagents, media, and antimicrobials. These processes were traditionally manual and labor-intensive, requiring skilled microbiologists and significant time—often 24 to 72 hours or more—to deliver actionable results to clinicians.

While automation has long transformed other diagnostic disciplines such as clinical chemistry and hematology, microbiology remained largely insulated from these advances, due in part to the inherent complexity and variability of microbial growth and behavior. That resistance to automation is now rapidly eroding. Rising demand for microbiology testing, fueled by the global burden of infectious disease, combined with critical shortages of trained technologists, has accelerated the adoption of next-generation microbiology automation platforms.

Modern microbiology labs are increasingly adopting automated culture systems, digital imaging for plate reading, and automated ID/AST platforms, allowing faster, more standardized, and scalable workflows. These tools are helping laboratories manage higher test volumes while maintaining accuracy and reducing turnaround times.

The Real Impact of Infections

Infectious diseases are particularly concerning not only because of their acute effects but also because of their long-term consequences that may persist or emerge well after the primary infection has been treated. These secondary effects, including cancer, cardiovascular disease, and autoimmune conditions, raise the stakes for early and accurate diagnosis and highlight the growing importance of comprehensive microbiology testing.

Traditionally, microbiology has focused on identifying active infections. However, mounting evidence shows that certain pathogens may act as triggers or contributors to chronic disease, suggesting a broader role for infectious disease diagnostics in risk stratification, preventive care, and long-term monitoring.

Herpes and Alzheimer's Disease

Researchers are investigating whether HSV-1 infection and/or reactivation is associated with an increased risk of Alzheimer's disease, with accumulating epidemiologic and mechanistic evidence but no definitive proof of causation. Alzheimer's risk may also be influenced by other viral infections. In addition, experimental work suggests VZV-related inflammatory events can reactivate latent HSV-1, providing a plausible indirect pathway linking VZV to AD-relevant changes.

Ebola and Cancer

EBV infection increases a person's risk of getting nasopharyngeal cancer and certain types of fast-growing lymphomas, such as Burkitt lymphoma. It may also be linked to Hodgkin's lymphoma and some cases of stomach cancer. Many scientists believe that the immune system is also important in attacking and destroying newly formed cancer cells. A weak immune system might let new cancer cells survive long enough to grow into a serious, life-threatening tumor.

HIV and Cancer

HIV infection has been linked to a higher risk of developing Kaposi sarcoma and cervical cancer. It is also associated with several forms of non-Hodgkin lymphoma, particularly primary central nervous system lymphoma. Infection with HHV-8 is causally associated with

Kaposi sarcoma and has also been linked to rare lymphoid malignancies such as primary effusion lymphoma.

H pylori and Cancer

Long-term infection of the stomach with Helicobacter pylori (H. pylori) can cause peptic ulcers and chronic inflammation that damages the stomach lining. Over time, these changes may increase the risk of gastric cancer, particularly cancers arising in the lower portion of the stomach. H. pylori infection is also associated with certain lymphomas of the stomach, especially mucosa-associated lymphoid tissue (MALT) lymphoma.

Bacteria and Parkinson's

Some researchers have proposed that bacteriophages may contribute to the gut microbiome changes observed in Parkinson’s disease. Studies have reported differences in bacteriophage abundance between patients with Parkinson’s disease and healthy individuals, suggesting that phages may influence bacterial populations associated with neurological pathways. Certain gut bacteria, including Streptococcus and Lactobacillus species, can produce microbiota-derived neurochemicals such as dopamine-related compounds, which may interact with the gut–brain axis and potentially influence Parkinson’s disease pathology. However, these relationships remain under active investigation and have not yet been established.

HPV and Cancer

Human papillomaviruses (HPV) are a group of more than 150 related viruses. A subset of high-risk HPV types is the primary cause of cervical cancer and is also associated with cancers of the penis, anus, vagina, vulva, and oropharynx (mouth and throat).

Microbial Antibiotic Resistance – The Role of Clinical Tests

For nearly as long as antibiotics have existed, the medical community has voiced concern about antimicrobial resistance (AMR), which is a growing global health threat that undermines the effectiveness of life-saving treatments. To combat this, antimicrobial stewardship programs (ASPs) have become central to promoting appropriate antibiotic use.

Professional guidelines consistently encourage clinical microbiology laboratories to participate in these programs. However, the recommended stewardship interventions have historically involved limited use of laboratory diagnostics—often focusing instead on prescribing practices, formulary restrictions, or clinician education.

That dynamic may be poised to change. With advances in diagnostic technology, especially in rapid molecular testing, pathogen identification, and resistance gene detection, laboratories are now better equipped to play a more active, frontline role in stewardship efforts. Faster, more precise diagnostic tools can support earlier de-escalation or escalation of therapy, guide targeted treatment, and reduce unnecessary broad-spectrum antibiotic use—key goals of ASPs.

As these technologies mature and integrate more fully into clinical workflows, microbiology laboratories are likely to evolve from passive participants to core drivers of stewardship success.

Fast Identification

The long-standing goal of the clinical microbiology laboratory is to develop a test that can rapidly identify a pathogen and determine antimicrobial susceptibility, guiding treatment decisions during the same clinical encounter—ideally within 30 minutes or less. While this benchmark has not yet been fully achieved for most organisms, significant advances in rapid diagnostics have dramatically shortened the time required to identify pathogens and detect resistance.

Traditional microbiology methods rely on culturing microorganisms, identifying them through staining and microscopy, and performing antimicrobial susceptibility testing (AST). These conventional workflows often require 48–72 hours or longer to produce definitive results. In recent years, however, the introduction of molecular diagnostics, mass

spectrometry, multiplex PCR panels, and rapid phenotypic susceptibility platforms has significantly accelerated microbial identification and resistance detection.

Multiplex molecular diagnostics systems such as the BIOFIRE FILMARRAY and the Luminex VERIGENE System enable rapid identification of bacteria, viruses, and antimicrobial resistance markers directly from clinical specimens or positive blood cultures without requiring traditional culture-based identification steps. These syndromic testing platforms have transformed the detection of bloodstream, respiratory, and gastrointestinal pathogens.

At the point of care, rapid diagnostic tests are now widely available for infectious diseases such as HIV, malaria, influenza, respiratory syncytial virus, and group A Streptococcus. Many of these assays operate on compact molecular platforms designed for decentralized testing environments. Examples include the cobas Liat System and the ID NOW, which provide results in approximately 5–20 minutes for several respiratory and infectious disease targets. Rapid molecular point-of-care assays are also available for sexually transmitted infections, including Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis.

Rapid phenotypic antimicrobial susceptibility testing remains a critical objective in microbiology. One of the most notable commercial systems designed to shorten AST turnaround time is the Accelerate Pheno System developed by Accelerate Diagnostics. The system's blood culture test panel can identify a range of bacterial and yeast pathogens directly from positive blood cultures and determine antimicrobial susceptibility. The platform uses automated fluorescence in situ hybridization (FISH) for organism identification and time-lapse imaging to measure bacterial growth in the presence of antibiotics, providing a true phenotypic measurement of susceptibility. Organism identification can be achieved in approximately 90 minutes, with susceptibility results typically available in about 7 hours, significantly faster than conventional culture-based AST.

Another approach to rapid microbial identification is matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry, which is widely used for routine organism identification in microbiology laboratories. Systems such as the MALDI Biotyper from Bruker Corporation allow laboratories to identify bacteria and fungi within minutes once cultures are available. Bruker expanded its capabilities in antimicrobial susceptibility testing through the acquisition of MERLIN Diagnostika, whose MICRONAUT

system provides phenotypic susceptibility testing and customizable antibiograms, using panels that cover a broad range of antibiotics.

Other companies have explored alternative rapid AST technologies. Roche previously pursued rapid detection approaches by acquiring GeneWEAVE BioSciences, whose Smarticles technology used engineered bioparticles to detect viable bacteria and antibiotic resistance via luminescent signaling. Although Roche later discontinued the commercial development of this platform, the concept illustrated ongoing efforts to achieve rapid detection of viable pathogens and antimicrobial resistance directly from clinical samples.

Overall, advances in molecular syndromic panels, MALDI-TOF identification, rapid phenotypic AST systems, and decentralized molecular testing platforms have significantly reduced the time required to identify infectious organisms. While the goal of obtaining both pathogen identification and full antimicrobial susceptibility information within 30 minutes remains largely aspirational, continued innovation in microfluidics, digital imaging, AI-assisted phenotypic analysis, and direct-from-specimen testing is expected to further shorten diagnostic timelines in the coming years.

bioMérieux markets the VITEK REVEAL AST System, which qualitatively determines antimicrobial susceptibility using an array of sensors that detect organic compounds produced by growing bacteria.

These and other companies developing and commercializing faster methods for microbial antimicrobial identification and susceptibility/resistance testing are summarized in the following table.

Table 11-1: Selected Companies Developing Faster Identification, Some Also with Antimicrobial Susceptibility/Resistance Tests

Company	Activities Developing Faster ID/AST or ID/Resistance Tests
3iDx	Developing based on BioSpectrix technology; Pathogens are identified using infrared molecular profiling technology.
Abacus Diagnostica Oy (Uniogen)	GenomEra CDx products: •MRSA/SA Multi Swab •MRSA/SA Nasal Swab •MRSA/SA Diagnose •MRSA/SA AC (with mecC) •MRSA/SA Blood Culture
AB ANALITICA s.r.l.	•Reverse line blot tests for genotyping
Abbott (Acquired Alere)	Alere I, and Alere i Influenza A & B test, Alere i: Alere i RSV and Alere i Strep A test
Accelerate Diagnostics	•Accelerate Pheno system - Uses genotypic technology to identify (ID) pathogens and phenotypic technology to conduct antibiotic susceptibility testing (AST). •First test: Accelerate Pheno BC Kit, provides identification and antibiotic susceptibility test rests for patients with bacteremia or fungemia.
Akonni Biosystems, Inc.	TruDiagnosis - Point-of-Care testing platform: TruDx2000 and TruDx3000 (a fully integrated system)
Atlas Genetics Ltd. (now Binx Health)	io platform - includes the io instrument and io cartridge - •Sexually transmitted disease cartridges: Chlamydia trachomatis; Dual Chlamydia trachomatis & Neisseria gonorrhoeae (CT/NG); Trichomonas vaginalis (TV); Multiplex STI (mSTI) - CT, NG, TV and Mycoplasma genitalium (MG) Hospital acquired infections (HAIs) cartridges: Methicillin-Resistant Staphylococcus aureus (MRSA); Dual MRSA/MSSA (Methicillin-Sensitive Staphylococcus aureus); Clostridium difficile; Norovirus
AutoGenomics, Inc. (Diasorin)	INFINITI System, INFINITI PLUS Analyzer (PLUS), and INFINITI High Throughput System (HTS)On the market •Infiniti H. pylori •Infiniti HPV Genotyping •Infiniti HPV-HR QUAD •Infiniti RVP Plus •Infiniti Flu A-sH1N1 •Infiniti UroGen QUAD •Infiniti Bacterial Vaginosis QUAD •Infiniti Candida Vaginitis QUAD RUO tests in US for Bacterial Vaginosis QUAD, Bacterial Vaginosis QUAD, CT-NG QUAD, Flu A-sH1N1, HPV Genotyping, HPV-HR QUAD, Leuko QUAD (three STDs), MDR-TB, NTM Panel, Resolve QUAD, RVP Plus, STD-6, UroGen Plus QUAD, HCV QUAD, H. pylori QUAD, GUD QUAD RUO infectious disease tests in Europe.
Becton Dickinson (BD)	BD Max System: BD MAX CT/GC/TV

Company	Activities Developing Faster ID/AST or ID/Resistance Tests
Bruker	Advances for the MALDI Biotyper
Cepheid (A Danaher company)	•Hospital acquired infections: Xpert C. difficile, Xpert C. difficile/Epi, Xpert Carba-R, Xpert MRSA NxG, Xpert MRSA/SA BC, Xpert MRSA/SA SSTI, Xpert Norovirus, Xpert SA Nasal Complete, Xpert® vanA •Critical infectious diseases: Xpert MTB/RIF, Xpert Flu, Xpert Flu/RSV XC, Xpert EV, Xpert Xpress Flu, Xpert Xpress Flu/RSV, Xpert Xpress Strep A •Sexual Health: Xpert CT/NG, Xpert GBS, Xpert GBS LB, Xpert TV Rapid results (30 minutes or less): Xpress Flu, Xpert Xpress Flu/RSV, Xpert Xpress Strep A
Coyote Bioscience Co., Ltd. (China)	Mini8 Plus - Portable qPCR system
Curetis (OpGen)	Unyvero System: •Unyvero HPN Pneumonia Cartridge •Unyvero ITI Cartridge •Unyvero BCU Cartridge •Unyvero IAI Cartridge •Unyvero LRT Lower Respiratory Tract Cartridge
Diasorin S.p.A.	Simplexa molecular assays for use on the 3M Integrated Cycler
GenMark Diagnostics (Roche)	ePlex Instrument System panels: •ePlex Respiratory Pathogen (RP) Panel •ePlex BCID Fungal Pathogen (BCID-FP) Panel •ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel •ePlex Blood Culture Identification Gram-Negative (BCID-GN) Central Nervous System Panel (CNS) Gastrointestinal Pathogen Panel (GI) HCV Genotyping Panel (HCVg)
iCubate, Inc.	iCubate System (iC-system) - One step multiplex PCR platform •iCubate iC-GPC Assay [Gram Positive Cassette (FDA cleared) •Gram-Negative Cassette (In regulatory process) •Flu Typing; HAI; MYCO; STD products (in pipeline) •Respiratory-V; Respiratory-B; Diarrheal products (Research use only
LeukoDx	Accellix-HLADR system: Accellix platform and Accellix-HLADR Cartridge
Mesa Biotech (Thermo Fisher(	Mesa Biotech Dock and Flu A/Flu B Test Cassette
Micronics Inc. (A Sony Group Company)	PanNAT Molecular Diagnostic System. Assays in development: •Shiga-toxin producing E. coli (STEC) and other enteric pathogens •STDs, respiratory pathogens, HAIs •Other bacterial & viral pathogens
MP Biomedicals, LLC	FASTSURE TB DNA Rapid Test

Company	Activities Developing Faster ID/AST or ID/Resistance Tests
OptiGene	•Genie II and Genie III instruments - isothermal amplification •Assays: easyplex C. difficile; easyplex VRE; easyplex CSF easyplex SuperBug CRE; easyplex SuperBug complete A; easyplex SuperBug complete B; easyplex MRSA
Orion Diagnostica (Finland) (Aidian)	Orion GenRead Campylobacter Orion GenRead C. difficile
Q-linea AB (Sweden)	ASTrID - Automated platform that provides pathogen identification and phenotypic antibiotic susceptibility testing, directly from whole blood, delivering ID after four hours and AST in an additional six hours.
QuantuMDx Group	Q-POC- portable, battery-operated molecular diagnostic device: •Tuberculosis - Combined detection of and drug susceptibility determination •STI Panel Test •Malaria Assay •HPV - For diagnosis of high-risk strains
Roche	cobas Liat PCR System - Influenza A/B, Influenza A/B & RSV, and Strep A
Scanogen	Molecular diagnostic systems based on single molecule biosensors; TB assay
Stat-Dx (acquired by QIAGEN)	•DiagCORE - Small-footprint, portable system that utilizes disposable cartridges to power a broad menu of tests utilizing a variety of specimens and immunoassay or qPCR principles. •System branded QIAstat-Dx after acquisition by QIAGEN
T2 Biosystems, Inc.	•T2 Magnetic Resonance (T2MR) technology •T2Sepsis Solution - T2 Biosystems' products include T2Dx Instrument, T2Candida Panel, and T2Bacteria Panel

Source: Kalorama Information

Traditional Microbiology and Its Limits

The traditional microbiology market is distinct from other areas of infectious disease diagnostics. It is defined by the use of culture to amplify microbial presence, enabling downstream testing of isolates rather than direct clinical samples such as blood, urine, or stool. This culture-based approach enables phenotypic susceptibility testing, which remains essential for guiding effective treatment in an era of rising antimicrobial resistance.

As automation advances and integrates with digital technologies and molecular methods, microbiology is moving toward a new era of efficiency and clinical impact by balancing tradition with innovation.

Following culture of the sample, pathogen identification can be accomplished using fluorogenic and chromogenic substrates that react in the presence of a particular genus or species in the culture or cultured sample. Positive results are indicated by the fluorescence or color change of the substrate. If the results are inconclusive, it may be necessary to identify pathogens via microscopy, or to perform further testing using other diagnostic technologies such as immunoassay, molecular probes or diagnostic assays, or mass spectrometry.

Antibiotic susceptibility or resistance of bacteria is typically determined by exposing cultured organisms to graduated or variable drug concentrations. Visual examination, optical scanning, fluorogenic/chromogenic substrates or other reagents may be used to determine the growth or lack of growth of the bacteria exposed to antibiotics in individual wells, plates, or plate areas.

Antibiotic susceptibility testing systems are utilized to determine which antibiotics will be most effective in treating an organism. The organism is tested against various concentrations of drugs to determine the organism's resistance or susceptibility to the antibiotic.

Treatment decisions depend on which microbial agent is present. Also, antimicrobial drug resistance is a significant problem, and these decisions can result in patients being given an antibiotic that will not be effective for treatment of their infection. There is a clear need for tests that can identify the microorganism infecting the patient, and to determine which therapy will be effective in treating that infection.

Molecular microbiology is another changing segment of the microbiology lab. Polymerase chain reaction (PCR) and other nucleic acid amplification test (NAAT) technologies have

been used in microbiology laboratories since the 1990s, and these assays are now widely used for a range of different pathogens. Some multiplex assays are now available. A major change in the application of polymerase chain reaction in microbiology has been the development of syndromic assays – assays that test for a range of pathogens commonly associated with a particular syndrome such as a lower respiratory infection, a gastrointestinal infection, or another specific infection.

The development and use of immunoassays remain an important part of microbiology for certain pathogens. In addition, when new tests are needed for emerging pathogens, immunoassay technology is sometimes utilized (in addition to PCR or other molecular diagnostic technology).

The New Microbiology - Innovations

Meanwhile, the physician must immediately make a decision regarding which antibiotic to use to treat the patient. As a result, the treatment decision must be made empirically, without the results of a definitive diagnostic test. This can result in treatment with an antibiotic that will not work for that patient and microbial infection. A different antibiotic may be prescribed a few days later, but effective treatment has been delayed for that patient. Many patients may then respond to the second antibiotic and recover, suffering only from a delay before recovering from the infection. However, initial treatment with an ineffective antibiotic can sometimes result in complications and even death for certain patients.

Liquid Based Microbiology and Automation Innovations

Microbial identification and antimicrobial susceptibility testing are the endpoint of the majority of work performed in a microbiology lab on a daily basis and is very time consuming. Since the mid-1990s, ID/AST vendors have responded to the need for quicker test systems for many sample types. These systems can provide a definitive test result in 6 hours versus 1 to 2 days with non-automated systems. Other differentiating factors between systems are the reagent mix contained in the panels and bioinformatics that provide bacterial identification to the genus/species level.

Automation has greatly improved ID/AST by speeding up the process with more sensitive detection methods and hands-off sample or culture preparation. In contrast to core lab diagnostics, microbiology stations must handle a variety of samples beyond blood tubes including swabs, feces, sputum, pus, body fluid and urine that arrive in different containers and differ significantly as sample matrices. Automating ID/AST, particularly at the front end, has required unique innovation.

The leader in ID/AST automation is COPAN Diagnostics, which developed and assembled the pieces for Liquid Based Microbiology. Swabs stand apart among microbiology samples due to their incompatibility with otherwise liquid-based specimen handling lab infrastructure and workflows. Uniform liquid-based protocols in microbiology are more amenable to automation and streamlined processing, providing improved workflows and shaving time off of testing by removing the need for specimen transfer from swabs to other media.

Liquid-based microbiology systems are increasingly integrated with automated specimen processing and laboratory automation platforms to streamline microbiology workflows. One of the most widely adopted systems is the COPAN Walk-Away Specimen Processor (WASP), which automates specimen handling tasks including decapping, plating, streaking, and recapping of culture samples. The WASP functions as an open modular platform designed to interface with laboratory information systems (LIS) and major microbiology identification and antimicrobial susceptibility testing (ID/AST) systems. These capabilities allow microbiology laboratories to standardize specimen processing and reduce manual handling while improving reproducibility and turnaround time.

A central component of the liquid-based microbiology workflow is COPAN's ESwab collection system, which uses a flocked swab placed into a tube containing approximately 1 mL of liquid Amies transport medium. After collection, microorganisms are eluted into the liquid medium, maintaining organism viability for downstream culture or molecular testing. The liquid sample can be aliquoted multiple times for repeat or parallel testing, enabling compatibility with culture, molecular diagnostics, or other microbiology assays. The ESwab system integrates directly with the WASP automation platform, allowing seamless specimen processing and improved workflow efficiency in the microbiology laboratory.

Additional modules have expanded the capabilities of the WASP platform to support broader laboratory automation. After specimen processing, plates can be transferred via conveyor to the WASPLab automated incubation and digital imaging system. Within WASPLab, plates are barcoded, automatically loaded into incubators, and imaged at scheduled intervals to allow digital review of culture growth. Plates are automatically inverted during incubation to minimize condensation on the lid and prevent droplets from interfering with plated media. The system supports remote image review and digital culture interpretation, enabling microbiologists to analyze results from any location with secure network access.

COPAN has also developed specialized modules to automate additional microbiology tasks. The Gram SlidePrep module automatically prepares Gram stain slides immediately after specimen plating, producing standardized smears with controlled sample volumes and printing patient identification directly onto the slide using an integrated inkjet printer. Another WASP module enables automated inoculation of enrichment broths, while the ID Disc Application module places reagent discs onto culture plates for downstream identification workflows. These modules expand the scope of automated microbiology processing from specimen receipt through culture workup.

To support downstream microbiology analysis, COPAN also markets Colibrí, an automated colony picking and preparation instrument designed to select isolated colonies for MALDI-TOF identification or antimicrobial susceptibility testing. In conjunction with Colibrí, COPAN has introduced PhenoMATRIX software, including colony detection and tagging algorithms that assist laboratories in identifying and selecting colonies for workup, supporting the broader trend toward AI-assisted microbiology automation.

Major diagnostic companies have recognized the potential of full microbiology automation and liquid-based microbiology workflows. Several companies collaborate with COPAN to integrate automated specimen processing with downstream diagnostic systems. COPAN has announced partnerships and distribution agreements with major microbiology companies including Beckman Coulter (Danaher), bioMérieux, and Thermo Fisher Scientific, enabling laboratories to combine automated specimen processing with automated identification and susceptibility testing systems.

Thermo Fisher Scientific provides additional automation solutions for antimicrobial susceptibility testing through its Sensititre platform. The Sensititre AIM automates inoculation of microtiter plates used for minimum inhibitory concentration susceptibility testing and supports both dry and frozen antibiotic panels. The modular benchtop design allows the system to be placed in biosafety cabinets or on standard laboratory benches. Thermo Fisher also offers automated incubation and reading instruments such as the Sensititre Vizion or ARIS platforms, which enable laboratories to perform high-throughput ID/AST testing with automated data capture and interpretation.

Thermo Fisher also developed the VersaTREK automated culture system, designed to support blood culture testing, sterile body fluid culture, and mycobacterial detection and susceptibility testing on a single platform. VersaTREK systems are available in configurations capable of handling up to 240 or 528 culture bottles, with automated monitoring of cultures approximately every 24 minutes. The system detects microbial growth by measuring changes in gas consumption or production within culture bottles. Integrated software supports barcode tracking, automated bottle loading and removal, and workflow standardization across specimen types including blood, urine, and body fluids.

Another major automated blood culture system is the BacT/ALERT VIRTUO system from bioMérieux, which supports high-efficiency automated blood culture workflows and integrates with laboratory information systems for centralized data management. The system incorporates automated bottle handling, continuous incubation monitoring, and advanced

software to streamline laboratory operations. bioMérieux has also received FDA clearance for testing leukocyte-reduced apheresis platelets using the BacT/ALERT VIRTUO platform.

As microbiology laboratories become increasingly automated, middleware and software connectivity have become critical components of laboratory workflow integration. Systems such as bioMérieux's MYLA middleware centralize microbiology laboratory management by connecting multiple instruments, collecting workflow and performance data, and interfacing with LIS systems. These platforms support laboratory quality management, antimicrobial resistance monitoring, and infection control reporting. Thermo Fisher's Sensititre SWIN software provides similar integration capabilities by coordinating the operation of multiple Sensititre instruments and enabling LIS connectivity, as well as image capture and reporting through systems such as Sensititre Vizion.

Overall, automation platforms such as WASP, WASPLab, and automated AST systems are transforming microbiology laboratories by enabling standardized liquid-based specimen processing, digital culture imaging, and integrated data management. These technologies are supporting faster identification, improved workflow efficiency, and greater consistency in microbiology testing, while positioning laboratories for further advances in artificial intelligence-assisted interpretation and fully automated microbiology workflows.

Revvity's EUROIMMUN offers its UNIQ 160, an automated indirect immunofluorescence test (IIFT) system for autoimmune disease diagnostics. The product is available in CE mark countries. And is an all-in-one solution for sample preparation, incubation, washing and mounting of slides as well as image acquisition and analysis.

Personalis offers the NeXT Personal Dx which is a tumor-informed molecular residual disease liquid biopsy with ultra-high sensitivity and specificity for breast and lung cancer. The test uses whole genome sequencing k, advanced bioinformatics, and personalized signatures based on about 1800 variants.

Post-Blood Culture Microbial ID

Positive blood cultures have been a target for sensitive and rapid identification testing. Recent innovation has resulted in numerous identification assays for use with positive blood cultures. Multiple technologies including fluorescent in situ hybridization), multiplexed PCR and mass spectrometry are finding use as highly specific and rapid testing options. The vibrancy of the blood culture identification test space is a positive indicator for at least the

short-term health of the blood culture market within ID/AST. Alternative rapid tests for bloodstream infections directly from whole blood samples are available on the market but have yet to appreciably counter the strength of blood culturing in terms of cost (on significantly greater scales) and its comparable utility in most healthcare episodes.

Molecular amplification technologies have become increasingly important for the rapid identification of pathogens in positive blood cultures, significantly reducing the time required to identify bloodstream infections compared with conventional culture-based identification methods. These assays typically use multiplex PCR or other nucleic-acid amplification technologies to detect multiple bacterial and fungal targets, along with key antimicrobial resistance genes, directly from positive blood culture bottles.

Several diagnostic companies have developed multiplex molecular panels for rapid bloodstream infection identification. One of the most widely used systems is the BIOFIRE FILMARRAY Blood Culture Identification Panel, now available in updated formats such as BCID2, which detects a broad range of Gram-positive bacteria, Gram-negative bacteria, yeasts, and multiple antimicrobial resistance markers. The system performs fully automated sample preparation, amplification, detection, and analysis, delivering results in approximately one hour.

Another platform previously used in clinical laboratories was the Nanosphere Verigene system, which offered Gram-Positive, Gram-Negative, and Yeast Blood Culture Tests capable of detecting pathogens and resistance genes from positive blood cultures. The Verigene platform was later acquired by Luminex, and the product line has since been discontinued and replaced by newer multiplex molecular systems, including the Luminex VERIGENE II and the ePlex blood culture identification panels, which provide expanded organism coverage and resistance marker detection.

Becton Dickinson offers molecular testing for bloodstream infections through its BD MAX platform, including assays such as BD MAX StaphSR, designed for the rapid detection of Staphylococcus aureus and methicillin-resistant S. aureus. BD also markets the BD MAX Blood Culture Identification assays, which enable rapid molecular identification of pathogens from positive blood culture samples.

Additional molecular assays have been developed to identify bloodstream infections directly from blood samples without requiring prior culture, although adoption has been more limited due to sensitivity and workflow considerations. Examples include the Cepheid Xpert

MRSA/SA BC assay, which detects S. aureus and MRSA directly from positive blood culture bottles on the GeneXpert system. Another example was the Roche LightCycler SeptiFast test, which used multiplex PCR to detect multiple bloodstream pathogens directly from whole blood; however, the SeptiFast assay has since been withdrawn from the market in many regions.

Many of these molecular blood culture identification panels incorporate detection of clinically relevant antimicrobial resistance genes, such as mecA/mecC, vanA/vanB, KPC, NDM, VIM, IMP, and OXA-48–like carbapenemases. The ability to identify both pathogens and resistance markers rapidly allows clinicians to optimize antimicrobial therapy earlier in the course of infection, supporting antimicrobial stewardship programs and improving management of sepsis and other bloodstream infections.

Mass spectrometry has emerged as another alternative to blood culture identification. Mass spectrometry and activities of Bruker and bioMérieux in this market are discussed separately.

These and other companies are developing and introducing tests to improve identification and antibiotic susceptibility testing of blood culture samples. While these assays shorten turnaround time compared to traditional blood culture techniques, the overall blood culture process remains lengthy because a culturing step is still required.

PCR and Other NAAT-Based Tests for Infectious Diseases

Polymerase chain reaction and other nucleic acid amplification test (NAAT) technologies have been used in microbiology laboratories since the 1990s, and these assays are now widely used for a range of different pathogens.

For many years, polymerase chain reaction assays were limited to the detection of a single or a limited number of pathogens. This would mean that multiple tests might be required to identify which pathogen has infected a particular patient. A major change in the application of polymerase chain reaction in microbiology has been the development of syndromic assays. These are assays that test for a range of pathogens commonly associated with a particular syndrome, such as a lower respiratory infection, a gastrointestinal infection, or another specific infection.

PCR-based panels have been developed to detect pathogens and drug resistance genes from potentially long lists of microbes and resistance genes. These are often syndromic assays.

However, these assays are expensive, and PCR/NAAT-based tests for a single or a limited number of microbes are still often used to test low-risk, otherwise healthy patients. Examples include tests for influenza (or influenza and RSV) and also screening tests for chlamydia and gonorrhea.

Microarrays can perform more assays than PCR or other NAATs, but they cannot detect unknown microbial species.

Sequencing-based assays provide the most comprehensive information and can detect novel or unexpected microorganisms. Advances in workflow design, automation, and bioinformatics have reduced both costs and turnaround times, and sequencing is now increasingly used in clinical microbiology for targeted applications such as outbreak investigation, resistance profiling, and identification of difficult-to-identify organisms. However, compared with routine molecular methods, sequencing still requires more complex infrastructure, more data interpretation, and higher overall costs, which can limit its use in high-volume or time-sensitive settings.

MALDI-TOF mass spectrometry is now an established technology in microbiology laboratories. Laboratories considering adoption continue to face a significant upfront capital investment, but once installed, the cost per test is low, and the turnaround time for organism identification is very rapid. The technology performs best with cultured isolates and is less sensitive for detecting organisms present at low abundance or directly from primary specimens, although workflow improvements have expanded its use in certain direct-from-sample applications.

Table 11-2: Selected Nucleic Acid Amplification Test and Other Molecular Companies in Microbiology

Company	Technology/Product(s)
AB ANALITICA s.r.l.	Real-time PCR tests for CMV, EBV, HSV 1, HSV 2, HSV 6, HSV 7, HSV 8, VZV, Enterovirus, BK virus, JC virus, Parvovirus B19, Adenovirus, Mycobacterium tuberculosis complex,
Abbott	•Abbott m2000 RealTime System; Range of infectious disease assays available: Abbott m2000 RealTime System; Range of infectious disease assays available updated to Alinity m System • ID NOW
altona Diagnostics	•RealStar Zika Virus RT-PCR kit •RealStar MERS-CoV RT-PCR Kit US •Broad line of real-time PCR tests marketed under the RealStar PCR Kit name. Includes tests for: Human adenovirus, herpes- and polyomaviruses; Respiratory viruses, bacteria and fungi; Enteric viruses and bacteria; Blood borne viruses; Tropical and other viruses, bacteria and parasites
Atlas Genetics Ltd. (binx health)	io platform - includes the io instrument and io cartridge - •Sexually transmitted disease cartridges: Chlamydia trachomatis; Dual Chlamydia trachomatis & Neisseria gonorrhoeae (CT/NG); Trichomonas vaginalis (TV); Multiplex STI (mSTI) - CT, NG, TV and Mycoplasma genitalium (MG) Hospital acquired infections (HAIs) cartridges: Methicillin-Resistant Staphylococcus aureus (MRSA); Dual MRSA/MSSA (Methicillin-Sensitive Staphylococcus aureus); Clostridium difficile; Norovirus
Becton Dickinson (BD)	•BD Max System: BD MAX C.diff assay; Enteric Bacterial Panel; Enteric Parasite Panel; BD MAX GBS assay; BD Max MRSA XT assay; BD MAX Staph SR assay; BD MAX Vaginal Panel; BD Max CT/GC/GV, BD MAX SARS-CoV-2, BD MAX MTB, BD MAX Enteric Viral Panel •BD Viper LT System and BD Viper with XTR Technology; BD ProbeTec ET System – Chlamydia and gonorrhea

Company	Technology/Product(s)
BioFire Diagnostics, LLC (A bioMérieux Company)	FILMARRAY platforms: FILMARRAY Torch, FILMARRAY 2.0 system, and FILMARRAY EZ Configuration •FILMARRAY Respiratory Panel (RP) •FILMARRAY Meningitis/Encephalitis (ME) Panel •FILMARRAY Gastrointestinal (GI) Panel •FILMARRAY Blood Culture Identification (BCID) Panel •FILMARRAY Respiratory Panel EZ Respiratory Panel 2.1 (RP2.1) Blood Culture Identification 2 (BCID2) Pneumonia Panel Pneumonia Panel Plus Meningitis/Encephalitis Panel GI Panel Joint Infection Pane
Bioneer Corporation	ExiStation Universal Molecular Diagnostic System with multiple PCR-based infectious disease tests, ExiStation 48
Cepheid, Inc. (A Danaher Company)	• GeneXpert System •Hospital acquired infections: Xpert C. difficile, Xpert C. difficile/Epi, Xpert Carba-R, Xpert MRSA NxG, Xpert MRSA/SA BC, Xpert MRSA/SA SSTI, Xpert Norovirus, Xpert SA Nasal Complete, Xpert vanA •Critical infectious diseases: Xpert MTB/RIF, Xpert Flu, Xpert Flu/RSV XC, Xpert EV, Xpert Xpress Flu, Xpert Xpress Flu/RSV, Xpert Xpress Strep A •Sexual Health: Xpert CT/NG, Xpert GBS, Xpert GBS LB, Xpert TV
Check-Points B.V.	•Multiplex real-time PCR assays for screening and confirmation: Check-Direct CPE; Check-Direct ESBL (in development); Check-Direct CPE for BD MAX; Check-Direct CPE Screen for BD MAX; Check-Direct ESBL Screen for BD MAX™; Check-Direct ESBL Screen for BD MAX •Microarray assays (include amplification step): Check-MDR CT101 - For epidemiology of suspected ESBL- and AmpC-producers with a single test; Check-MDR CT102 - For carbapenem-resistant Enterobacteriaceae (CRE); Check-MDR CT103 XL - Comprehensive CE-IVD assay for molecular beta-lactamase identification •Ligation-mediated real-time PCR: Check-MDR Carba; Check-MDR ESBL
Coyote Bioscience Co., Ltd. (China)	Mini8 Plus - Portable qPCR system

Company	Technology/Product(s)
Curetis (OpGen)	Unyvero System: •Unyvero HPN Pneumonia Cartridge •Unyvero ITI Cartridge •Unyvero BCU Cartridge •Unyvero IAI Cartridge •Unyvero LRT Lower Respiratory Tract Cartridge
Diasorin S.p.A.	Simplexa molecular assays for use on the LIAISON MDX platform
GenePOC Inc. (Meridian Bioscience)	•GenePOC C.diff •GenePOC GBS LB - For Group B Streptococcus from Lim Broth samples •GenePOC GBS DS - For direct screening of Group B Streptococcus at intrapartum
Genetic Signatures	EasyScreen Gastrointestinal Parasite Detection Kit
Genmark Diagnostics (Roche)	•XT-8 system panels: Respiratory Viral Panel (RVP); HCVg Direct Test •ePlex Instrument System panels: ePlex Respiratory Pathogen (RP) Panel; ePlex BCID Fungal Pathogen (BCID-FP) Panel; ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel; ePlex Blood Culture Identification Gram-Negative (BCID-GN) •Central Nervous System Panel (CNS) •Gastrointestinal Pathogen Panel (GI) •HCV Genotyping Panel (HCVg)
Hologic, Inc.	•Platforms: PANTHER Fusion system, PANTHER system, Tigris DTS system, DTS system •PANTHER Fusion assays on the market: PANTHER Fusion Flu A/B/RSV Assay, PANTHER Fusion Paraflu Assay, PANTHER Fusion AdV/hMPV/RV Assay •PANTHER Fusion assays in development: MRSA, Clostridium difficile, Group B streptococcus (GBS), Infectious Disease, SARS-CoV-2 •Aptima assays on the market: Aptima Combo 2 Assay for CT/NG, Aptima Chlamydia trachomatis Assay, Aptima Neisseria gonorrhoeae Assay, Aptima Trichomonas vaginalis Assay, Aptima HPV Assay, Aptima HPV 16 18/45 Genotype Assay, Aptima Mycoplasma genitalium Assay, Aptima HIV-1 Quant Dx Assay, Aptima HCV Quant Dx Assay, Aptima HBV Quant Assay, Aptima HSV 1 & 2 Assay •Aptima assays in development: Bacterial vaginosis and Candida vaginalis, Atima SARS-CoV-2 •Cervista HPV tests •ThinPrep Pap tests (with instrumentation) •Prodesse ProGastroSSCS Assay, Prodesse ProFAST+ Assay (for FluA Sub-Typing), Prodesse ProFlu+ Assay, Prodesse Adeno+ Assay, Prodesse ProParaflu+ Assay, Prodesse Pro hMPV+ Assay, and Prodesse

Company	Technology/Product(s)
Luminex Corporation (Diasorin)	•Platforms: ARIES Systems; Verigene System; LUMINEX 100/200; MAGPIX System •Respiratory disease o Targeted testing: ARIES Flu A/B & RSV Assay, ARIES® Bordetella Assay, ARIES® Group A Strep Assay o Syndromic testing: NxTAG Respiratory Pathogen Panel o Flexible testing: VERIGENE Respiratory Pathogens Flex Test •Gastrointestinal disease o Targeted testing: ARIES C. difficile Assay and ARIES® Norovirus Assay (CE marked in June 2017, not FDA cleared) o Syndromic testing: VERIGENE Enteric Pathogens Test and xTAG® Gastrointestinal Pathogen Panel •Bloodstream infection o VERIGENE Gram-Positive Blood Culture test o VERIGENE Gram-Negative Blood Culture Test •Women's health o ARIES GBS Assay o ARIES HSV 1&2 Assay o MultiCode-RTx HSV 1&2 Kit o xMAP MultiFLEX Zika RNA Assay
Meridian Bioscience, Inc.	illumigene Molecular Diagnostic System with tests for: C. difficile, Group A Streptococcus, Group B Streptococcus, HSV 1&2, Mycoplasma, Mycoplasma Direct, Pertussis
Mesa Biotech (Thermo Fisher)	Mesa Biotech Dock and Flu A/Flu B Test Cassette
Mobidiag Ltd (Hologic)	•Amplidiag - Family of diagnostic tests for high-volume screening of gastrointestinal pathogens and antibiotic resistances •Novodiag - Fully automated molecular testing platform for diagnostics of infectious diseases; Cartridges in development for Gastrointestinal infections, Antibiotic resistances, Parasites, Meningitis
Molbio Diagnostics Pvt. Ltd. (India)	Truelab Real Time micro–PCR System - Includes Truelab Uno Real Time Micro PCR Analyzer and Truenat Chip Based Real Time micro–PCR Tests. •Available tests include: Mycobacterium tuberculosis (MTB), TB resistance, HBV viral load, Malaria Pf, Dengue, H1N1, Chikungunya, Salmonella •Products in development: Salmonella, HCV viral load, HIV viral load, HPV - Cervical Cancer, Chlamydia, Gonorrhea, Trichomonas

Company	Technology/Product(s)
OpGen (Acquired AdvanDx)	AdvanDx FISH product line: •QuickFISH Products: Staphylococcus QuickFISH; Enterococcus QuickFISH; Gram-Negative QuickFISH®; Candida QuickFISH® •PNA FISH Products: S. aureus/CNS PNA FISH; E. faecalis/OE PNA FISH; Gram-Negative PNA FISH; Candida PNA FISH"
OptiGene	•Genie II and Genie III instruments - isothermal amplification •Assays: easyplex C. difficile; easyplex VRE; easyplex CSF easyplex SuperBug CRE; easyplex SuperBug complete A; easyplex SuperBug complete B; easyplex MRSA
Omega BioTek	Mag-Bind Blood HIV DNA automated extraction
PreTect AS (Formerly called NorChip AS) (Wholly owned subsidiary of Holta Life Sciences AS)	•PreTect SEE - Qualitative NASBA assay for specific genotyping of E6/E7 mRNA from HPV 16, HPV 18 and HPV 45. •PreTect HPV-Proofer - Qualitative NASBA assay for specific genotyping of E6/E7 mRNA from HPV 16, HPV 18, HPV 31, HPV 33 and HPV 45. •PreTect HPV-Proofer HV - Qualitative NASBA assay for specific genotyping of E6/E7 mRNA from HPV 16, HPV 18, HPV 31, HPV 33 and HPV 45; 35, 52 or 58 is optional.
QIAGEN	•QIAsymphony system; includes Roto-Gene Q (Roto-Gene Q MDx in US) •Molecular assays (automated and/or manual) available for BK virus, CT/NG, CMV, EBV, HBV, HCV, HIV-1, HSV-1/2, M. tuberculosis, and VZV
QuanDx Inc.	• High Risk HPV Genotyping Assay • TB Drug-Resistant Mutation Test Kit • Q-MRSA Detection Kit
QuantuMDx Group	Q-POC - portable, battery-operated molecular diagnostic device: •Tuberculosis - Combined detection of and drug susceptibility determination •STI Panel Test •Malaria Assay •HPV - For diagnosis of high-risk strains

Company	Technology/Product(s)
QuidelOrtho	AmpliVue tests for Bordetella pertussis, C. difficile, Group B Streptococcus (GBS), and HSV 1 & 2 •Solana C. difficile Assay •Solana GAS Assay •Solana GBS Assay •Solana HSV 1+2/VZV Assay •Solana Influenza A+B Assay •Solana Respiratory Viral Panel •Solana RSV + hMPV Assay •Solana Strep Complete Assay •Solana Trichomonas Assay •Lyra Adenovirus Assay •Lyra Influenza A+B Assay •Lyra Parainfluenza Virus Assay •Lyra RSV + hMPV Assay •Lyra Direct C. Difficile Assay •Lyra Direct HSV 1+2/VZV Assay •Lyra Direct Strep Assay
R-Biopharm AG	RIDA GENE-kits - For detection of gastrointestinal, hospital acquired, and respiratory infections --Can be performed on common PCR instruments
Randox Laboratories	•Respiratory Multiplex Array (detects 22 viral and bacterial pathogens) •STI Multiplex Array (detects 10 viral, bacterial and protozoan STIs)
Roche	cobas 4800 assays… •Healthcare-associated infections – Clostridium difficile testing (cobas C.diff Test) and the cobas MRSA/SA Test •Sexually transmitted infections – cobas 4800 CT/NG Test and cobas® HPV Test •cobas® HSV 1 and 2 Test cobas 8800 system and the cobas 6800 system assays: •Infectious diseases and viral load include respiratory disease): HIV-1, HBV, HCV, CMV, HIV-1/2, Qual MTB (in development), MAI (in development), RIF/INH (in development) •Sexual health: HPV, CT/NG, TV/MG (in development)
Roche	cobas Liat PCR System - Influenza A/B, Influenza A/B & RSV, and Strep A, SARS-C0V-2, MTB-RIF/INH

Company	Technology/Product(s)
Seegene, Inc (Korea)	•Respiratory pathogen tests/panels: Allplex Respiratory Panel Assays; Allplex Respiratory Panel 1; Anyplex II RV16 Detection; Anyplex II RB5 Detection; Anyplex MERS-CoV(upE & orf1a) Real-time Detection; Anyplex FluA/B Typing Real-time Detection; Seeplex RV15 ACE Detection; Seeplex PneumoBacter ACE Detection; Seeplex RV7 Detection; Seeplex RV15 OneStep ACE Detection •Gastrointestinal pathogen tests/panels: Allplex Gastrointestinal Panel Assays; Seeplex® Diarrhea ACE Detection •Sexually transmitted infections: Allplex STI/BV Panel Assays; Allplex STI Essential Assay; Allplex Genital ulcer Assay; Allplex Candidiasis Assay; Allplex Bacterial Vaginosis Assay; Anyplex II STI-7 Detection; Anyplex II STI-5 Detection; Anyplex CT/NG Real-time Detection; Seeplex STI Master ACE Detection; Seeplex STD6 ACE Detection; Seeplex HSV2 ACE Detection •Human papillomavirus: Anyplex II HPV28 Detection; Anyplex II HPV HR Detection; Seeplex HPV4A ACE Detection •Tuberculosis: Anyplex II MTB/MDR Detection; Anyplex II MTB/XDR Detection; Anyplex MTB/NTM Real-time Detection; Seeplex MTB/NTM ACE Detection; Seeplex MTB Nested ACE Detection •Sepsis: Magicplex Sepsis Real-time Test •Meningitis: Seeplex Meningitis ACE Detection •Other: Anyplex VanR Real-time Detection; Seeplex VRE ACE Detection; Seeplex H. pylori-ClaR ACE Detection
Vela Diagnostics (VelaDx) (Singapore)	qPCR tests for •Human Herpes and Polyomaviruses: BKV Quant, CMV Quant, EBV Quant, HSV-1/2 Quant, HSV-1/2 Qual, VZV Quant •Respiratory viruses: Influenza A/B & RSV •Tropical infections: Zika Virus, Zika Triplex
Veredus Laboratories Pte Ltd (Singapore)	VereChip - Lab-on-Chip (multiplexed PCR followed by hybridization microarray)" •VereFlu: Detects, differentiates and identifies Influenza A: H1, H3, H5, H7, H9 with subtype ID's of H1N1, A/H1N1-2009, H3N2, H5N1 and H9N2 and Influenza B. •VereMTB: Detects, differentiate and identify: 10 different mycobacterium strains with special emphasis on Mycobacterium tuberculosis Complex (MTBC) and its Resistance to Rifampicin and/or Isoniazid from Pulmonary Clinical Specimens or Cultivated Samples (MDR-TB)

Source: Kalorama Information

A more recent development has been the introduction of syndromic tests that can detect and differentiate between a much larger number of pathogens associated with a specific disease syndrome such as respiratory or gastrointestinal infection. These syndromic tests can often also provide some information about antibiotic resistance genes, although identification of unknown pathogens complete information on antibiotic susceptibility are not yet available

from current syndromic tests. The growing development and use of syndromic tests will continue to fuel growth of the molecular microbiology market.

Microbiome-Related Microbiology Tests

While study of the microbiome has attracted enthusiastic media attention and venture capital, its findings are largely preliminary. However, some IVD companies are already developing a greater appreciation for the microbiome's contributions to human biochemistry and have launched tests that measure microbiome changes to monitor disease progression.

Illumina

Illumina launched the iSeq 100 Sequencing System, born out of the Firefly project that the firm initially announced in 2016. The iSeq system uses sequencing-by-synthesis chemistry coupled with CMOS detection technology. The iSeq 100 has a "cartridge-based upgrade roadmap" and is expected to open up new markets to next-generation sequencing (NGS), including monitoring hospital-acquired infections, testing for foodborne pathogens, and rapid microbiome sequencing.

The company has added additional platforms, including NextSeq 1000/NextSeq 2000, NovaSeq X/NovaSeq Plus

Bio-Rad

Bio-Rad acquired the distribution rights for the CE-marked GA-Map test developed by Genetic Analysis. The assay tests the gut microbiota and detects bacterial imbalances to diagnose and manage conditions such as inflammatory bowel disease and irritable bowel syndrome. GA-map uses 16S rRNA amplification and several proprietary analytical technologies.

Bio-Rad Laboratories entered into a collaboration with Genetic Analysis AS and Bioaster, a French microbiology research institute, to study alterations in the gut microbiome in metabolic disorders. The project will look for microbiota signatures of dysbiosis in metabolic disorders like diabetes and obesity in order to pursue diagnostics development. It will use Bioaster's deep and 16S-targeted sequencing technologies and advanced data analysis pipelines to highlight new gut microbiome biomarkers, according to a statement.

QIAGEN

QIAGEN and Biomillenia entered into a collaboration for the use of QIAGEN's Microbial Genomics Pro Suite to generate next-generation sequence data on microbes identified using Biomillenia's proprietary microbiome-on-a-chip technology. Biomillenia's approach can identify unculturable pathogen strains.

Biomillenia has developed a proprietary droplet-based microfluidics chip platform that cultures bacterial species directly from natural samples at the single-cell level. QIAGEN's bioinformatics platform provides an easy-to-run infrastructure for analyzing microbial genomes, from sequence assembly to microbe identification.

QIAGEN introduced its QIAseq 16S/ITS Panels and UCP Multiplex PCR Kit with a new generation of reagents to enable microbial community profiling from complex microbiome samples. QIAGEN offers solutions for sequencing through the launch of QIAseq Targeted DNA Pro Panels and the QIAseq UPXome RNA Library Kit. QIAGEN also offers its QIAseq Normalizer Kit, which speeds up the equalization of DNA concentrations.

Luminex (Diasorin)

The GA-map IBS Dysbiosis Test was CE marked and positioned as one of the first diagnostic tests for detecting dysbiosis in patients with IBS, and Genetic Analysis entered into an agreement with Luminex to develop, market, and sell the test on the Luminex instrument platform. This allowed the company to leverage its installed base of instruments while also expanding its placement in new laboratories, creating potential commercial synergies in gastrointestinal testing. Multiplexing technology remains well-suited for microbiome analysis, as it enables simultaneous detection of multiple targets and supports more efficient characterization of complex microbial communities, although the direct impact on clinical outcomes in IBS continues to be established. Luminex, now part of Diasorin, offers gastrointestinal pathogen panels based on xMAP technology, including assays that detect a broad range of bacterial, viral, and parasitic targets from stool samples using platforms such as MAGPIX, with the portfolio now integrated into DiaSorin's broader molecular diagnostics business.

inBiome BV

inBiome developed a microbiota-based diagnostic platform aimed at inflammatory bowel disease, building on earlier CE-marked components of its microbiome analysis technology and molecular tools for bacterial detection. While early positioning suggested it could become one of the first PCR-based microbiome diagnostics for IBD, the market has since evolved and multiple approaches to microbiome testing are now in development or use. Unlike most microbiome analysis methods, which rely on sequencing, inBiome's approach uses PCR to characterize microbial patterns in a sample. The method uses rRNA intergenic spacer, enhanced with fluorescent labeling to differentiate microbial groups, allowing fragment length and signal detection to estimate composition and relative abundance. This approach provides a rapid, culture-free workflow that can be completed in several hours and is compatible with standard PCR systems and capillary electrophoresis instruments. While effective for profiling microbial communities, the technique is generally better suited for pattern recognition than for precise species-level identification.

DNA Genotek

DNA Genotek offers the CE-marked OMNIgene•GUT microbiome collection kit, an all-in-one system that enables individuals to easily self-collect high-quality microbial DNA from feces/stool for gut microbiome profiling in clinical laboratory and research settings. The product ensures that the fecal sample is fully stabilized immediately upon collection and maintains an accurate and reliable profile for weeks at room temperature. The product is for research use only in the United States.

Thermo Fisher Scientific

Thermo Fisher markets the Applied Biosystems Axiom Microbiome Array for simultaneous detection of archaea, bacteria, fungi, protozoa and viruses in human and non-human samples. Developed in collaboration with the Lawrence Livermore National Laboratory, the array is designed to increase the understanding of microorganisms while accelerating the translation of these insights into human health and agricultural applications.

Others

Colorectal cancer remains one of the leading causes of cancer mortality worldwide, and interest in microbiome-based diagnostics continues to expand across oncology and other disease areas. A number of companies are developing tools that use microbial signatures to aid in detection, risk stratification, and disease monitoring, although the field is still emerging and not yet widely adopted in routine clinical practice. Efforts are underway to apply microbiome analysis to a range of conditions, including gastrointestinal cancers, head and neck cancer using saliva-based sampling, and the female reproductive tract microbiome. Other groups are exploring microbiome-driven liquid biopsy approaches to detect and differentiate cancers, as well as investigating links between the gut microbiome and neurological diseases such as Parkinson's disease.

At the same time, the broader system supporting microbiome diagnostics has matured. Long-read sequencing platforms are being used for more detailed characterization of pathogens and the microbiome, while plasma microbial cell-free DNA testing has established a role in the detection of infectious diseases. Advances in metagenomic analytics, sample preparation technologies, and sequencing kits have made microbiome research more accessible and scalable. Some companies are focused on microbiome-based diagnostics, while others are increasingly integrating these insights into therapeutic development and precision medicine strategies. Microbiome-based diagnostics are progressing, but their clinical utility is still being defined as evidence continues to build.

Next-Generation Sequencing-Based Microbiology Approaches

Nucleic acid sequencing has become an increasingly important tool in clinical microbiology as advances in sequencing technology have reduced cost, improved speed, and expanded analytical capabilities. While early methods such as Sanger sequencing were used primarily for research and had limited applications in infectious diseases, newer platforms now enable large-scale analysis of microbial genomes for pathogen identification, outbreak tracking, antimicrobial resistance detection, and microbiome characterization. Next-generation sequencing technologies enable simultaneous analysis of millions of DNA fragments, allowing comprehensive evaluation of both individual pathogens and complex microbial communities. These systems deliver far greater throughput and lower cost per base than

earlier approaches and have expanded sequencing use across clinical laboratories, public health settings, and infectious disease research.

Several companies are involved in the development of sequencing platforms widely used in microbiology. Illumina offers systems widely adopted in clinical and research environments, including MiSeqDx for clinical applications and higher-throughput platforms such as NextSeq and NovaSeq. Thermo Fisher Scientific provides Ion Torrent–based systems, such as the Ion GeneStudio S5, for targeted sequencing, pathogen identification, and antimicrobial resistance studies in clinical and public health laboratories.

Despite these advances, sequencing in routine microbiology diagnostics is still concentrated in reference laboratories, academic centers, and public health institutions. Many applications continue to be implemented as laboratory-developed tests, including pathogen identification, resistance profiling, viral genotyping, and metagenomic detection from complex samples. Whole-genome sequencing of bacterial pathogens is a particularly active area, enabling detailed characterization of organisms and improved understanding of resistance mechanisms.

Bioinformatics has become a critical component of sequencing-based diagnostics. Companies have developed platforms that link genomic data with curated databases to support interpretation and clinical decision-making. Efforts such as those developed by OpGen through its ARES Genetics unit combine genome sequencing with resistance databases to correlate genetic markers with antimicrobial susceptibility patterns and guide more targeted therapy.

Sequencing is expected to play an increasingly important role in clinical microbiology as workflows become more automated and interpretation tools improve. It is increasingly used in outbreak investigations, antimicrobial resistance surveillance, and the diagnosis of difficult-to-diagnose infections, and it is gradually moving closer to routine clinical use. QIAGEN supports sequencing workflows with products such as targeted DNA panels, RNA library preparation kits, and normalization tools that help streamline sample preparation and improve consistency in sequencing applications.

Table 11-3: Selected Companies Applying DNA/RNA Sequencing to Microbiology

Company	Sequencing Activity
Advanced Biological Labs (ABL Diagnostics)	NGS DeepCheck HIV genotyping
Curetis (OpGen)	Agreement with MGI (a fully owned subsidiary of BGI Group (China) to develop targeted next-generation sequencing (NGS) IVD assays for microbial infections. NGS -based molecular antibiotic susceptibility test
Pathogenetix	Developing the RESOLUTION Microbial Genotyping System based on Genome Sequence Scanning (GSS) technology.

Source: Kalorama Information

Syndromic/Multiplex Testing

Over the past decade, syndromic molecular testing has significantly advanced diagnostic testing for respiratory and other infectious diseases. Syndromic panels are multiplex molecular assays designed to simultaneously detect multiple pathogens associated with a particular clinical syndrome, such as respiratory infections, gastrointestinal illness, meningitis, or sepsis. These panels typically use PCR or other nucleic acid amplification technologies to detect a broad range of viral, bacterial, and sometimes fungal pathogens from a single patient specimen.

Traditional diagnostic approaches often relied on ordering tests for individual pathogens based on clinical suspicion. These methods included culture, antigen or antibody immunoassays, and single-target molecular tests. While culture can ultimately identify the causative organism and determine antimicrobial susceptibility when the pathogen is bacterial, results may require several days. Earlier molecular tests targeted only one organism at a time, so if the causative pathogen was not included in the ordered test, the infection could remain undiagnosed.

Syndromic molecular panels address this limitation by simultaneously testing for many of the most common pathogens associated with a particular infection. These assays provide faster turnaround times, often delivering results in approximately one hour depending on the platform. Many panels also include detection of antimicrobial resistance markers that can guide early therapeutic decisions.

Syndromic testing is particularly valuable in hospitalized or critically ill patients, where rapid identification of the causative organism can affect treatment decisions and infection control measures. In cases such as hospital-acquired pneumonia or severe respiratory infections, testing multiple pathogens individually can delay treatment and increase the risk of complications. Syndromic testing allows clinicians to quickly identify the responsible pathogen and initiate targeted therapy.

Several diagnostic companies offer syndromic testing platforms. bioMérieux's BIOFIRE system is one of the most widely used platforms and provides pathogen-specific results in approximately one hour. The system offers multiple syndromic panels, including the BIOFIRE Respiratory Panels, BCID2 Panel, Gastrointestinal Panel, Meningitis/Encephalitis Panel, Pneumonia Panel, and Joint Infection Panel, which simultaneously detect numerous pathogens and resistance markers associated with specific infections.

QIAGEN markets the QIAstat-Dx syndromic testing platform, which includes panels for respiratory infections, gastrointestinal pathogens, and meningitis/encephalitis. The QIAstat-Dx Respiratory Panel can detect more than twenty viral and bacterial respiratory pathogens in a single cartridge. QIAGEN is also expanding its syndromic testing portfolio with the QIAstat-Dx Rise system, a higher-throughput platform designed to increase laboratory testing capacity and automation.

Hologic's PANTHER Fusion system offers modular syndromic respiratory testing through a menu of assays that can be run individually or combined from a single specimen. The system allows laboratories to expand respiratory testing capabilities by adding assays for influenza, RSV, adenovirus, parainfluenza viruses, and other respiratory pathogens.

Becton Dickinson's BD MAX system provides automated real-time PCR testing and includes syndromic assays for healthcare-associated infections, enteric pathogens, and sexually transmitted infections. The platform automates nucleic acid extraction, amplification, and detection within a single instrument and supports both commercial assays and laboratory-developed tests.

Multiplex molecular testing has also expanded significantly since the COVID-19 pandemic. Numerous assays now allow simultaneous detection of SARS-CoV-2, influenza A/B, and RSV from a single patient sample. These multiplex assays help clinicians differentiate respiratory infections with similar symptoms and support appropriate patient management.

Examples of multiplex respiratory assays include Cepheid's Xpert Xpress CoV-2/Flu/RSV test on the GeneXpert system and QIAGEN's QIAstat-Dx Respiratory Panel Plus. Several companies also offer point-of-care molecular or antigen tests capable of detecting multiple respiratory viruses simultaneously.

Point-of-care multiplex molecular systems are also expanding. Visby Medical markets a disposable handheld PCR respiratory test capable of detecting SARS-CoV-2 and influenza A/B with results available in about 30 minutes. Nuclein's DASH Rapid PCR system provides rapid molecular detection of SARS-CoV-2 and influenza A/B at the point of care with results in approximately 15 minutes. Pfizer markets the Lucira by Pfizer COVID-19 & Flu Home Test, an over-the-counter molecular test that can detect both SARS-CoV-2 and influenza A/B in about 30 minutes.

A number of antigen-based multiplex tests are also available for home or clinical use. These include ACON Laboratories' Flowflex Plus COVID-19 and Flu A/B Home Test and the Healgen Rapid Check COVID-19/Flu A&B Antigen Test, which provide rapid qualitative detection of respiratory viruses in approximately 15 minutes.

Additional advances include the development of PCR-based point-of-care analyzers such as Spindiag's Rhonda system, which uses microfluidic technology to detect respiratory pathogens, including influenza, RSV, and SARS-CoV-2. The platform is designed to expand to larger multiplex panels capable of detecting numerous pathogens from a single sample.

Syndromic multiplex testing is a growing component of modern infectious disease diagnostics. These tests help laboratories manage increasing testing demand while reducing hands-on time and improving diagnostic accuracy. As laboratory staffing shortages and workflow pressures continue, multiplex testing platforms that require fewer reagents, less manual processing, and faster turnaround times are expected to see continued adoption across hospital, reference, and point-of-care settings.

High-Consequence Infectious Disease Threats

The downside of globalism is the spread of unwanted conditions. There have been many examples of previously unknown or rare pathogens that have spread and become major global problems. This can happen rapidly as people travel by air around the world.

Table 11-4: Selected Companies Marketing Products Addressing High-Consequence Infectious Disease Threats

Company	Location	Technology	Target	Details
Abbott Diagnostics	U.S.	mol	TB	RealTime MTB RIF/INH Resistance, on m2000
Abbott Diagnostics	U.S.	mol	Zika	Real Time Zika
Advanced Biological Lab (ABL Diagnostics)	Luxembourg	mol	TB	TB sequencing with DeepChek software
Advanced Biological Lab	Luxembourg	mol	TB	TB by NGS
Altona Diagnostics	Germany	mol	Ebola	RealStar Ebolavirus RT-PCR
Altona Diagnostics	Germany	mol	Zika	RealStar Zika RT-PCR
Atomo Diagnostics	Australia	POC	malaria	AtomoRapid Malaria, Pf/PAN
Atomo Diagnostics	Australia	POC	panel	AtomoRapid dengue and chikungunya
Biocartis	Switzerland	mol	Ebola	Ebola test with Janssen Diagnostics on Idylla
BioInnovation Solutions	Switzerland	mol	Ebola	filoviruses, such as Ebola and Marburg
Bioneer Corp	Korea	mol	Ebola	AccuPower EBOV real-time RT-PCR
Bioneer Corp	Korea	mol	Zika	AccuPower ZIKV Multiplex Zika, dengue, CHIKV
Bioneer Corp.	Korea	mol	Ebola	AccuPower EBOV real-time RT-PCR
Cepheid	U.S.	mol	TB	Xpert MTB/RIF, TB & rifampin-resistance
Cepheid	U.S.	mol	TB	Xpert XDR-TB, extensive drug resistance, PCR
Cepheid	U.S.	mol	Ebola	Xpert Ebola, PCR
Chembio Diagnostics	U.S.	POC	malaria	DPP Malaria

Company	Location	Technology	Target	Details
Co-Diagnostics HBDC	U.S.	mol	TB	LogixSma-RT TB Kit
Coris BioConcept	Belgium	mol	chagas	T. cruzi satDNA OligoC-TesT, PCR
CTK Biotech	U.S.	POC	CHICKV	OnSite Chikungunya IgM Combo Rapid Test
Epistem Holdings	UK	POC	TB	Genedrive TB and resistance
Fio Corporation	Canada	POC	lassa	Corgenix ReLASV Lassa virus antigen on Deki Reader
Fio Corporation	Canada	POC	micro	Deki Reader Malaria & Dengue, LF
GBDbio	U.S.	POC	TB	TB REaD POC test, fluorescent beta lactamase enzyme
GenArraytion (Nephros)	U.S.	mol	zika	MultiFlex Mosquito-borne Panel, zika etc.
Globavir Biosciences	U.S.	mol	dengue	PanGlob RT-PCR Dengue
Hain Lifescience	Germany	mol	TB	GenoType MTBDRsl, colonies & sputum
Thermo Fisher Scientific	U.S.	mol	flu	CDC's influenza A (H7/N9) virus
Luminex (Diasorin)	U.S.	mol	panel	GenArraytion MultiFlex Mosquito-borne Panel-Zika, CHICKV, Dengue
Lumora	UK	mol	malaria	malaria test, LAMP, with FIND and Eiken
Medical Innovation Ventures	Malaysia	POC	dengue	ProDetect Dengue tests
Meridian Biosciences	U.S.	mol	TB	illumigene Mycoplasma Direct assay, improved
Meridian Biosciences	U.S.	mol	dengue	TruQuik
Meridian Biosciences	U.S.	mol	malaria	illumigene Malaria
Qiagen	Netherlands	mol	panel	Altona Diagnostics' RealStar Filovirus RT-PCR Kit
Quest Diagnostics	U.S.	mol	Zika	Focus Diagnostics Zika Virus RNA RT-PCR test
Rheonix	U.S.	POC	zika	Zika virus, Rheonix CARD cartridge & Encompass Optimum
Roche Diagnostics	U.S.	mol	Ebola	TIB Molbio's LightMix Ebola Zaire rRT-PCR Test

Company	Location	Technology	Target	Details
Thermo Fisher Scientific	U.S.	mol	MERS	Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
TIB MOLBIOL GmbH	Germany	mol	Ebola	LightMix Ebola Zaire rRT-PCR Test
TwistDx	UK	POC	Ebola	Solar-powered Diagnostics-in-a-Suitcase Ebola Assay
TwistDx	UK	POC	TB	TwistAMP with colorimetric signal, visual
Ubiquitome	New Zealand	POC	Ebola	Freedom4, battery operated
Vela Diagnostics	Singapore	mol	Zika	Zika in Sentosa Tropical Infections Panel, Dengue, CHICKV
Veredus Laboratories	Singapore	POC	panel	VereTrop, a test to detect 15 tropical diseases

Source: Kalorama Information

Tickborne Diseases (TBDs)

Ticks carry more than just Lyme. There are 19 bacteria, protozoa, and viruses implicated in tick-borne diseases, and as the full range is rarely tested, TBDs are likely quite underdiagnosed. Three million clinical specimens are tested for tick-borne diseases annually, with diagnoses primarily made using ELISA, indirect immunofluorescence assays, and Western blots. Lyme disease, in particular, is tested by ELISA, then by Western blot. However, because ticks can carry multiple pathogens, additional testing will be needed.

Tick-borne diseases, such as Rocky Mountain spotted fever, anaplasmosis, ehrlichiosis, Powassan virus, and babesiosis, are on the rise, and prevention should be on everyone's mind, particularly during the spring, summer, and early fall when ticks are most active. From May through July, people will get more tick bites and tick-borne diseases than at any other time of year in the United States.

Southern tick-associated rash illness closely resembles Lyme disease and occurs in individuals who have not traveled to Lyme-endemic areas. The actual cause of this infection is unknown at the moment, and the diagnosis is made clinically.

In many cases, a lone star tick infection may cause a somewhat delayed allergic reaction after eating red meat, such as beef, pork and even lamb, according to Bassett. The serious and potentially life-threatening allergic reaction to red meat is caused when a lone star tick carries a substance called alpha-gal and injects it into a person via the bite. The reaction is often accompanied by hives and can occur up to 12 hours after ingestion of red meat.

ID-FISH Technology offers the iDart Lyme IgG ImmunoBlot Kit, a standalone test for detecting IgG antibodies against Borrelia, the bacterium that causes Lyme disease.

TB and Other Infectious Diseases

Abbott Diagnostics markets molecular assays for tuberculosis on its m2000 molecular testing platform, including the Abbott RealTime MTB and RealTime MTB RIF/INH Resistance assays. These nucleic acid amplification tests detect Mycobacterium tuberculosis complex DNA and identify mutations associated with resistance to rifampin and isoniazid, helping clinicians rapidly identify drug-resistant tuberculosis and guide appropriate treatment decisions.

Advanced Biological Laboratories (ABL Diagnostics), provides next-generation sequencing–based workflows for tuberculosis testing. The company's DeepChek platform, combined with BacterioChek-TB analysis software, enables targeted sequencing and bioinformatic analysis to identify drug-resistance mutations in Mycobacterium tuberculosis. These tools are used in clinical and research laboratories for genomic analysis and antimicrobial resistance surveillance.

Several companies offer molecular assays for emerging viral infections. Altona Diagnostics markets its RealStar RT-PCR kits for pathogens such as Ebola virus and Zika virus. These assays are commonly used by public health and reference laboratories for molecular detection of viral RNA during outbreak investigations and surveillance programs.

Bioneer Corporation of South Korea provides molecular assays for mosquito-borne and emerging infectious diseases through its AccuPower real-time RT-PCR test portfolio. Products include assays for Ebola virus as well as multiplex panels capable of detecting Zika virus, dengue virus, and chikungunya virus simultaneously.

Cepheid, a Danaher company, offers rapid molecular testing for tuberculosis and emerging infectious diseases on its GeneXpert platform. The Xpert MTB/RIF Ultra assay provides

rapid detection of Mycobacterium tuberculosis complex and rifampin resistance, while the Xpert MTB/XDR assay expands resistance detection to include additional mutations associated with extensively drug-resistant tuberculosis. Cepheid also developed the Xpert Ebola assay for rapid molecular detection of Ebola virus in outbreak response settings.

Co-Diagnostics develops molecular PCR assays for infectious diseases using its proprietary primer design technology. The company markets the Logix Smart MTB assay, a molecular test for the detection of Mycobacterium tuberculosis DNA in clinical samples.

Several companies also develop molecular diagnostics for tropical diseases. Coris BioConcept markets the OligoC-TesT Trypanosoma cruzi PCR assay for the detection of T. cruzi, the causative agent of Chagas disease. CTK Biotech offers the OnSite Chikungunya IgM Combo Rapid Test, a point-of-care immunoassay designed for qualitative detection of IgM antibodies against chikungunya virus.

Hain Lifescience, part of the Bruker group, provides molecular diagnostic assays for tuberculosis drug resistance. Its GenoType MTBDRsl line probe assay detects resistance to second-line tuberculosis drugs directly from clinical samples or culture isolates, supporting management of multidrug-resistant tuberculosis.

Reference laboratories also perform molecular testing for emerging infectious diseases. For example, Labcorp offers RT-PCR testing for viruses such as Zika virus in specialized laboratory settings when testing is required for surveillance or clinical diagnosis.

Multiplex molecular detection technologies are also used for mosquito-borne pathogens. Luminex, now part of Diasorin, offers multiplex testing using its xMAP technology platform, enabling simultaneous detection of pathogens such as Zika virus, dengue virus, and chikungunya virus on systems including the MAGPIX instrument.

Other molecular technologies continue to be explored for infectious disease detection. Lumora has developed LAMP-based molecular assays for malaria, designed to provide rapid nucleic acid detection in laboratory and field settings.

All these molecular diagnostic technologies demonstrate the expanding role of nucleic acid testing, multiplex PCR, and sequencing-based methods for the detection of emerging and tropical infectious diseases, supporting rapid diagnosis, surveillance, and outbreak response worldwide.

Chagas

Chagas disease is caused by the protozoan parasite Trypanosoma cruzi, which is transmitted primarily by triatomine insects ("kissing bugs") that are found throughout the Americas. The disease is also known as American trypanosomiasis. Transmission occurs when infected insects deposit parasite-containing feces near the bite site and the parasites enter the body through broken skin or mucous membranes. In addition to vector transmission, infection may occur through blood transfusion, organ transplantation, congenital transmission from mother to child, contaminated food or drink, or laboratory exposure.

Chagas disease is endemic in Latin America, particularly in rural areas where housing conditions favor the triatomine insect vector. The World Health Organization estimates that approximately 6–7 million people worldwide are infected, primarily in 21 endemic countries in Latin America. Because many infections remain asymptomatic for years, it is estimated that a large proportion of cases remain undiagnosed. Chronic infection can lead to severe complications, including Chagas cardiomyopathy, digestive tract enlargement (megacolon or megaesophagus), and neurological disorders. Approximately 20–30% of infected individuals eventually develop serious chronic disease, often decades after the initial infection.

Although historically associated with Latin America, migration has led to an increasing number of cases in non-endemic regions, including the United States, Europe, and parts of Asia Pacific. In the United States, the Centers for Disease Control and Prevention (CDC) estimates that roughly 300,000 people are living with Chagas disease, most of whom acquired the infection in Latin America. Autochthonous (locally acquired) transmission is rare but has been documented in the southern United States, where triatomine insects are present.

Chagas disease is considered one of the neglected tropical diseases (NTDs) due to limited awareness, underdiagnosis, and historically limited treatment options. Two antiparasitic drugs—benznidazole and nifurtimox—are currently available for treatment. Both drugs have been used for decades and are most effective during the acute or early stages of infection. In the United States, benznidazole and nifurtimox are now FDA-approved therapies, although access and diagnosis remain challenges.

Diagnosis of Chagas disease typically relies on serologic testing for antibodies to T. cruzi, particularly during the chronic stage of infection. Molecular tests such as PCR may also be used in acute infections or congenital cases. Several in vitro diagnostic companies provide assays for the detection of T. cruzi infection.

A number of IVD vendors offer tests for Chagas disease. Meridian Bioscience has marketed rapid diagnostic tests under the TruQuick line, which includes assays targeting infectious diseases such as dengue, malaria, and Chagas disease for use in international markets. Chembio Diagnostics developed the Chagas STAT-PAK assay, a rapid immunochromatographic test that detects antibodies to T. cruzi, uses a small sample volume, and requires minimal laboratory infrastructure.

Other manufacturers provide laboratory-based immunoassays. Diasorin offers Chagas testing on its LIAISON automated immunoassay platform, while Roche Diagnostics markets the Elecsys Chagas assay, which uses recombinant antigens to detect antibodies to T. cruzi. InBios International produces the Chagas Detect Plus Rapid Test, an immunochromatographic strip assay for qualitative detection of IgG antibodies to T. cruzi in serum, plasma, or whole blood.

Additional diagnostic products are available from companies such as Wiener Lab, which offers serologic tests for Chagas disease used in Latin America and other endemic regions. These tests include ELISA-based assays and other immunodiagnostic formats used in blood screening programs and clinical diagnosis.

Despite the availability of diagnostic tests, Chagas disease remains underdiagnosed in many regions. Expanded screening programs improved diagnostic access and increased awareness among healthcare providers and are considered important steps toward reducing the burden of this neglected parasitic infection.

Dengue

Dengue fever has increased significantly in recent years, becoming one of the most rapidly expanding mosquito-borne viral diseases worldwide. According to the World Health Organization (WHO), global dengue activity has surged due to factors such as climate change, urbanization, increased international travel, and expanding mosquito habitats. In 2024, more than 7.6 million dengue cases were reported globally, surpassing the previous record of approximately 4.6 million cases reported in 2023. By mid-2025, more than 3.6 million cases and roughly 1,900 deaths had already been reported worldwide. Several countries in Southeast Asia and Latin America have experienced significant outbreaks; for example, the Philippines reported a more than 200% increase in cases compared with the same period in 2024.

Laboratory diagnosis of dengue relies on a combination of molecular tests, antigen detection assays, and serologic immunoassays, depending on the stage of infection. Serologic tests that detect anti-dengue antibodies (IgM and IgG) are widely used, particularly in resource-limited settings. However, antibody-based assays may exhibit cross-reactivity with other flaviviruses, including yellow fever virus, West Nile virus, Japanese encephalitis virus, and St. Louis encephalitis virus, complicating interpretation in regions where multiple flaviviruses circulate.

IgM antibody capture assays, particularly MAC-ELISA (IgM antibody capture enzyme-linked immunosorbent assay), are among the most commonly used tests for diagnosing dengue infection during the acute and early convalescent phases, typically beginning about 5 days after symptom onset when IgM antibodies become detectable. In later stages of infection, IgG immunoassays are frequently used to confirm past exposure or infection. In cases of secondary dengue infection, IgG antibodies often rise rapidly and may be detectable during the acute phase, making IgG assays useful for identifying repeat infections.

Another important diagnostic approach involves the detection of the non-structural protein 1 (NS1) antigen, which can be identified in patient blood samples from the first day of symptoms through the early acute phase of the disease. NS1 antigen tests are widely used as rapid diagnostic tests and ELISA assays, allowing earlier detection before antibody responses develop.

Molecular diagnostic tests, particularly reverse transcription polymerase chain reaction (RT-PCR) assays, are also widely used for dengue diagnosis during the early stage of infection when viral RNA is present in blood. These nucleic acid amplification tests provide high sensitivity and specificity and can identify the specific dengue virus serotype. Commercial molecular test kits are available globally, and the CDC dengue RT-PCR diagnostic panel has received FDA authorization for use in qualified laboratories.

Several companies have developed diagnostic tests for dengue infection. For example, Bio-Rad has marketed dengue diagnostic assays based on technology originally developed by Globavir Biosciences, designed to detect all four dengue virus serotypes with improved specificity relative to other flaviviruses. These assays have received regulatory approvals in various international markets.

Research continues to explore new approaches to dengue diagnostics and disease severity prediction. In 2022, researchers at Stanford Medicine reported identifying an eight-gene

immune expression signature that may help predict which patients are at risk of developing severe dengue, potentially enabling earlier clinical intervention and monitoring.

International public health organizations continue to refine diagnostic recommendations as dengue incidence increases. Updated WHO guidance released in 2025 emphasizes the use of NAATs and NS1 antigen assays for early detection, followed by IgM ELISA testing during later stages of infection. Diagnostic algorithms are also being adapted to reflect regional differences in circulating dengue serotypes, co-circulating arboviruses, and local epidemiology.

Ebola

Ebola virus disease was first identified in 1976, when outbreaks of a severe viral hemorrhagic fever occurred in northern Zaire (now the Democratic Republic of the Congo) and Sudan. The outbreak in Zaire involved 318 reported cases and 280 deaths, making it one of the earliest documented outbreaks of the disease. The illness presented initially with nonspecific symptoms such as fever, fatigue, sore throat, and headache, but often progressed to severe symptoms including abdominal pain, vomiting, diarrhea, rash, and, in some cases, hemorrhage. Laboratory investigations determined that the causative agent was a previously unknown virus related to Marburg virus, which had been identified in 1967. The new virus was named Ebola virus after the nearby Ebola River.

Ebola virus belongs to the genus Ebolavirus within the Filoviridae family. Several species of the virus are known to cause disease in humans, including Zaire ebolavirus, Sudan ebolavirus, Bundibugyo ebolavirus, and Taï Forest ebolavirus, while Reston ebolavirus has been shown to infect primates and pigs but does not cause disease in humans. Since their discovery, these viruses have been responsible for more than 30 outbreaks, primarily in sub-Saharan Africa. Case fatality rates vary by virus species and outbreak conditions, ranging from approximately 25% to over 80%.

Until the mid-2010s, Ebola outbreaks were generally limited to relatively small, localized events in rural areas of Central and East Africa or laboratory exposures. This changed in 2014, when the largest Ebola outbreak in history began in Guinea and spread to Sierra Leone and Liberia. The outbreak ultimately resulted in more than 28,000 reported cases and over 11,000 deaths, highlighting the global threat posed by emerging infectious diseases and prompting significant international investment in diagnostics, vaccines, and therapeutics.

Ebola virus disease continues to be closely monitored by public health authorities and remains an area of active research and diagnostic development. In 2022, an outbreak of Ebola virus disease caused by the Zaire strain occurred in the Democratic Republic of the Congo, while Uganda experienced an outbreak of Sudan ebolavirus beginning in September 2022, which resulted in more than 160 confirmed cases and dozens of deaths before it was declared over in early 2023. In the same year, Ghana reported its first outbreak of Marburg virus disease, a related filovirus infection that causes a similar hemorrhagic fever.

More recently, Uganda reported another outbreak of Sudan ebolavirus in early 2025, which lasted until April 2025. This outbreak involved 14 confirmed cases and 4 deaths, representing a smaller but closely monitored event. The outbreak was successfully contained through rapid surveillance, isolation measures, and international collaboration.

Research institutions and diagnostic companies continue to develop new tools for the detection of Ebola virus and related filoviruses. For example, scientists at Washington University School of Medicine in St. Louis have explored emerging diagnostic technologies such as optical microring resonator biosensors, which may enable rapid detection of viral pathogens, including Ebola. These technologies are part of broader efforts to improve rapid molecular diagnostics, point-of-care testing, and outbreak surveillance systems for highly pathogenic viruses.

Advances in vaccines and therapeutics have also improved outbreak response. Vaccines such as rVSV-ZEBOV (Ervebo) are now used in outbreak settings to protect against Zaire ebolavirus, and several monoclonal antibody treatments have been developed for infected patients. Despite these advances, Ebola virus disease remains a serious public health threat, particularly in regions with limited healthcare infrastructure and ongoing zoonotic exposure to wildlife reservoirs.

Chikungunya

Chikungunya virus infection is characterized by acute fever, rash, and particularly severe joint pain. While the disease is rarely fatal, the joint pain can be debilitating and may persist for months or even years in some patients, resulting in chronic arthritis-like symptoms and long-term disability. Treatment is generally supportive and focuses on relieving symptoms through rest, hydration, and pain management. Historically, there was no vaccine available for chikungunya prevention; however, recent developments have changed the prevention

landscape. The first chikungunya vaccines were approved in the mid-2020s, providing new options for individuals at risk, particularly travelers and populations in endemic regions.

Public health agencies continue to monitor chikungunya activity through global surveillance networks. Organizations such as the CDC's Global Disease Detection Operations Center and regional partners, including the Pan American Health Organization, track outbreaks and coordinate response efforts. Surveillance is important because chikungunya is transmitted by Aedes mosquitoes, the same vectors responsible for dengue and Zika virus transmission, allowing the virus to spread rapidly in tropical and subtropical regions where these mosquitoes are present.

Diagnostic testing for chikungunya includes molecular assays in the early stage of infection and serologic tests that detect IgM and IgG antibodies in the later stages. Several companies provide immunoassay-based tests for chikungunya infection. For example, bioMérieux markets VIDAS Anti-Chikungunya IgM and IgG assays, which are automated immunoassays used in clinical laboratories for the detection of antibodies against the virus. Rapid diagnostic tests are also available for point-of-care use. Chembio Diagnostics developed the DPP Zika/Dengue/Chikungunya multiplex rapid test system, which uses a small fingerstick blood sample and can provide results within approximately 15 minutes when used with the company's portable reader.

Chikungunya activity has increased in several regions in recent years. In 2025, outbreaks were reported in parts of Asia and Latin America. China reported a surge of cases in certain provinces, while Brazil continued to report the largest number of cases globally, with more than 140,000 reported infections during the year. These outbreaks highlight the ongoing risk of chikungunya transmission in areas where Aedes mosquito populations are established.

In response to growing demand for diagnostic tools during outbreaks, manufacturers have expanded the availability of rapid tests. For example, Beijing Hotgen Biotech developed a Chikungunya IgG/IgM Rapid Test that detects antibodies in approximately 15 minutes. Such rapid tests are particularly useful in outbreak settings and in regions with limited laboratory infrastructure, where timely diagnosis is critical for surveillance and patient management.

Overall, chikungunya remains an important emerging infectious disease due to the expanding geographic distribution of its mosquito vectors and the potential for explosive outbreaks in previously unaffected populations. Continued improvements in surveillance, diagnostic

testing, and vaccination strategies are expected to play a key role in controlling the impact of this virus in the coming years.

Middle East Respiratory Syndrome-Coronavirus (MERS-CoV)

Middle East Respiratory Syndrome (MERS) is a viral respiratory illness caused by the Middle East respiratory syndrome coronavirus (MERS-CoV). The disease was first identified in Saudi Arabia in 2012 and is primarily associated with exposure to infected dromedary camels or with transmission in healthcare settings. Symptoms can range from mild respiratory illness to severe pneumonia and respiratory failure, typically presenting with fever, cough, and shortness of breath. Individuals with underlying health conditions are at higher risk of severe disease. In the United States, the public health risk remains very low. Only two imported cases have ever been confirmed, both identified in May 2014 in healthcare workers who had traveled from Saudi Arabia.

Globally, MERS continues to occur sporadically, particularly in the Middle East. Since its discovery, more than 2,600 laboratory-confirmed cases and nearly 1,000 deaths have been reported worldwide. Most infections have been reported from countries in the Middle East and North Africa, particularly Saudi Arabia, though travel-associated cases have occasionally been detected in Europe and Asia. Small clusters continue to occur, often linked to healthcare exposure or contact with infected camels. For example, Saudi Arabia reported a small number of additional cases during 2025, including infections associated with hospital exposure and camel contact.

Laboratory diagnosis of MERS is primarily based on nucleic acid amplification testing, especially real-time reverse transcription polymerase chain reaction. In the United States, most state public health laboratories can test for MERS-CoV using a molecular assay developed by the Centers for Disease Control and Prevention. This assay has been authorized for use under emergency regulatory provisions because there are no widely marketed FDA-cleared commercial diagnostic tests specifically for MERS-CoV. Syndromic respiratory diagnostic panels used in many laboratories may also include targets for MERS-CoV detection.

Marburg

Marburg virus disease is another highly pathogenic viral hemorrhagic fever caused by Marburg virus, a member of the filovirus family closely related to Ebola viruses. The disease was first recognized in 1967 when laboratory workers in Germany and Yugoslavia developed severe hemorrhagic fever after exposure to tissues from infected African green monkeys imported for research. The natural reservoir of the virus is now known to be the Egyptian fruit bat, which can transmit the virus to humans directly or indirectly.

Diagnosis of Marburg virus disease relies on several laboratory methods. Molecular techniques such as PCR are the primary diagnostic tools during the acute stage of infection. Antigen detection tests and IgM antibody capture assays can also help confirm infection shortly after symptom onset. Later in the course of the disease or after recovery, IgG antibody tests can be used to identify prior infection. Because of the high risk associated with handling the virus, laboratory testing must be conducted in specialized high-containment facilities using strict biosafety procedures.

Recent years have seen several Marburg virus outbreaks in Africa. Ghana reported its first outbreak in 2022. Additional outbreaks have occurred in multiple countries since then, highlighting the continued emergence of filovirus diseases. Rwanda reported its first outbreak in 2024, involving dozens of confirmed cases and multiple deaths. In early 2025, Tanzania declared a Marburg virus outbreak that resulted in several confirmed and probable cases before containment measures were implemented. These outbreaks have underscored the importance of rapid diagnostic testing, surveillance, and international cooperation in responding to highly pathogenic viral diseases.

SARS-CoV-2 (COVID-19)

Diagnosis of viral infections generally relies on two primary methodologies: molecular nucleic acid amplification testing, such as real-time reverse transcription PCR and serologic immunoassays that detect virus-specific antibodies (IgM and IgG) or viral antigens. Molecular testing directly detects viral RNA and remains the most sensitive approach for detecting active infection, particularly during the early stages of disease, when viral replication is highest. During the COVID-19 pandemic, RT-qPCR became the reference method for detecting SARS-CoV-2 because of its high analytical sensitivity and specificity.

However, molecular detection can be affected by several factors, including specimen type, the timing of collection relative to symptom onset, and the patient's viral load. If viral RNA levels in the specimen are low, such as very early or late in infection or due to inadequate sample collection, molecular tests may yield false-negative results. For this reason, specimen quality, proper handling, and testing during the appropriate clinical window remain critical for accurate RT-qPCR results.

Serological testing provides another diagnostic approach by detecting the host's immune response to infection rather than the virus itself. Immunoassays that detect IgM and IgG antibodies can identify individuals who have mounted an immune response following viral exposure. Antibodies tend to be more stable than viral RNA and can often be detected even after the acute infection has resolved. Serology is therefore useful for identifying prior infection, supporting epidemiologic surveillance, and evaluating immune response in vaccinated or previously infected individuals.

Combining molecular and serologic testing can improve overall diagnostic insight, particularly when the timing of infection is uncertain. RT-qPCR or other NAAT methods are most useful during the acute phase of infection, when viral RNA is present in respiratory specimens. Serologic assays become more informative during the later or convalescent phase, when antibody production has developed. For diseases such as COVID-19 and other viral infections, the complementary use of molecular detection and antibody testing can help clinicians better determine infection status, disease stage, and past exposure.

Monkeypox

Mpox (formerly commonly called monkeypox) is a viral disease caused by the monkeypox virus, an orthopoxvirus in the same family as smallpox. Clinical illness may include fever, swollen lymph nodes, fatigue, and a characteristic rash that progresses to vesicles and pustules. Although often self-limited, severity varies by viral clade, patient age, immune status, and access to care. Transmission occurs through close contact with an infectious rash or body fluids, prolonged face-to-face exposure involving respiratory secretions, and contact with contaminated materials. Sexual contact has been an important transmission route in many outbreaks, but mpox is not limited to sexual transmission.

From 2024 through 2026, mpox epidemiology has been defined by two parallel realities: continued low-level clade II circulation in multiple regions and more concerning clade I activity in parts of Africa, including outbreaks driven by clade I sublineages that spread into

areas with limited prior exposure. WHO declared a Public Health Emergency of International Concern in August 2024 in response to the upsurge in Africa and cross-border spread; by September 2025, WHO determined the emergency designation could be lifted because of sustained declines in key hotspots, while emphasizing that mpox remained a public health concern requiring ongoing surveillance, testing access, and preparedness.

Diagnostic capacity has expanded rapidly and is centered on PCR-based detection of MPXV DNA from lesion swabs, the preferred clinical specimen type for confirmation. During the 2022 outbreak response, the CDC's Laboratory Response Network scaled testing using a CDC-developed orthopoxvirus PCR approach, and U.S. health authorities began shipping CDC orthopoxvirus testing materials to major commercial laboratories, including Aegis Sciences, Labcorp, Mayo Clinic Laboratories, Quest Diagnostics, and Sonic Healthcare, to increase national testing capacity and improve access.

IVD manufacturers also moved quickly to support decentralized and higher-throughput mpox testing. BD collaborated with CerTest Biotec to validate the VIASURE Monkeypox assay on the BD MAX platform using the system's open reagents, enabling automated sample-to-result PCR workflows on an installed base already used for other infectious disease assays. Roche offers a high-throughput cobas MPXV real-time PCR assay for the cobas 6800/8800 systems, using a dual-target design suitable for large clinical laboratories processing many specimens. Abbott markets the Alinity m MPXV assay for automated real-time PCR testing on Alinity m platforms. Cepheid offers the Xpert Mpox on GeneXpert systems, supporting near-patient or rapid-turnaround testing models with on-demand operation in many settings.

Thermo Fisher Scientific developed multiple PCR tools to support mpox testing workflows, including the Applied Biosystems TaqPath Monkeypox/Orthopox Virus DNA Kit, which is designed to detect MPXV and screen for non-variola orthopoxviruses using common real-time PCR laboratory infrastructure. Thermo Fisher also supports mpox detection through targeted microbe-detection assay options that laboratories can incorporate into validated workflows.

A number of organizations pursued smaller-footprint or point-of-care nucleic acid approaches as well. Ustar Biotechnology advanced its EasyNAT Monkeypox Virus Assay, a cartridge-based NAAT approach intended for more decentralized testing models, and the assay has been evaluated for emergency procurement pathways in global health settings. Applied DNA Clinical Labs developed laboratory-developed testing services for mpox and subsequently expanded capability to address both clade I and clade II, reflecting the changing

epidemiology and the need for clade-aware confirmation in some contexts. T2 Biosystems publicly explored the development of a rapid molecular mpox test during the early outbreak period; however, this was communicated as development intent rather than a widely deployed commercial assay.

Market Analysis

Traditional microbiology, molecular microbiology, and mass spectrometry tests are commonly performed in microbiology laboratories. Infectious disease immunoassays are frequently performed in the core laboratory on fully automated analyzers that often perform both chemistry and immunochemistry tests. These core laboratory platforms and tests are not a significant focus of this chapter. However, infectious disease immunoassays represent a significant segment of the overall microbiology market, and they are competitive methods for identifying certain pathogens. All four major segments (traditional microbiology, immunoassays, molecular microbiology, and mass spectrometry applications in microbiology) are included in the microbiology market analysis discussed in this chapter.

Traditional culture-based microbiology methods have been used for many years in microbiology laboratories.

Microbial identification and ID/AST by traditional culture-based methods require a long time to complete, and physicians need answers quickly to use the information when making treatment decisions. As a result, culture-based testing faces considerable competition from other, faster methods to identify which microbial pathogen is present. However, culture-based traditional microbiology will remain an important segment of the overall microbiology market.

Infectious disease immunoassays represent the largest segment of the microbiology market. As previously mentioned, many infectious disease immunoassays are now performed on large, automated immunochemistry analyzers in the core laboratory, rather than in microbiology laboratories.

Molecular microbiology is also a well-established market, with $6.9 billion in revenues in 2025 (excluding the $1.8 billion COVID-19 market). However, technological advances are making this market more rapidly growing and dynamic. Examples of advances that have already reached the market include syndromic testing and rapid molecular assays for detecting specific pathogens.

The global microbiology market can also be segmented by geographical regions. The bulk of the market is in developed regions, with North America accounting for 44% and Europe accounting for 35%. Asia Pacific represents about 13% of the market, with the remaining 8% generated in RoW.

Table 11-5: Global Microbiology Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	44%
Europe	35%
Asia Pacific	13%
RoW	8%
Total	**100%**

Source: Kalorama Information

The market analysis in the chapter looks more in depth at the microbiology market segments (traditional microbiology, immunoassays, molecular microbiology, and mass spectrometry). In the tables that focus on these segments, it can be seen that testing for pathogens such as HIV, hepatitis viruses, and respiratory pathogens (both bacterial and viral pathogens) are significant parts of multiple segments of the microbiology market.

Market Analysis - Traditional Microbiology ID/AST

The traditional microbiology market focuses on microbial identification followed by antibiotic susceptibility testing (ID/AST). This traditional area of microbiology remains a gold standard for infectious disease confirmatory testing and its growth will persist with ID/AST's advantages in terms of accommodation of high testing volumes and relatively low testing costs.

Companies reported mixed performance for ID/AST technologies. For instance, Becton Dickinson reported slower growth in its product lines due to supply disruptions and slow returns to "prior levels." While not all news and performance were negative, bioMérieux received FDA 510(k) Clearance for its VITEK COMPACT PRO test during the first half of 2025, which is positioned to drive new growth in the segment; while Abbott Laboratories continued to perform well in the segment with mid-single digit growth.

Table 11-6: Global Microbiology ID/AST Market, by Segment, 2025-2030 ($ million)

[Blood Culture; Chromogenic Media; ID/AST Auto; ID/AST Panels; Rapid Microbiology]

Segment	2025	% Mkt	2030	% Mkt	CAGR
ID/AST Auto	1,790	32%	2,170	34%	4%
Chromogenic Media	1,315	24%	1,380	22%	1%
Blood Culture	1,167	21%	1,340	21%	3%
Rapid Microbiology	876	16%	943	15%	2%
ID/AST Panels	438	8%	481	8%	2%
Total	**5,586**	**100%**	**6,314**	**100%**	**3%**
Supplies	*1,994*	--	*2,154*	--	*2%*

Note: Percentages rounded

Source: Kalorama Information

The global market for microbiology ID/AST is estimated at $5,586 million in 2025. With 2.5% revenue growth, it will reach $6,314 million in 2030. Traditional microbiology includes culturing clinical specimens and also testing the resulting culture samples. Following culture

of the sample, pathogen identification can be accomplished using fluorogenic and chromogenic substrates that react in the presence of a particular genus or species in the culture or cultured sample.

Antibiotic susceptibility or resistance of bacteria is typically determined by exposing cultured organisms to graduated or variable drug concentrations. Visual examination, optical scanning, fluorogenic/chromogenic substrates or other reagents may be used to determine the growth or lack of growth of the bacteria exposed to antibiotics in individual wells, plates, or plate areas.

Kalorama Information organizes the microbiology ID/AST market into the following product categories:

- Microbial ID/AST Systems, and Panels and reagents for ID/AST systems
- Chromogenic media
- Rapid tests done on colonies selected from culture media
- Blood culture bottles and systems

While the markets for each of these product categories continue to grow, they are mature markets that, despite innovation, record sales growth a bit slower than the molecular microbiology or mass spectrometry markets, which are discussed below.

The overall market leader for ID/AST systems and reagents is bioMérieux, but competitors abound where stable revenue growth is seen. bioMérieux is estimated to compete for the leading position with Abbott Diagnostics and Becton Dickinson.

The rise of molecular microbiology, alongside the dominant immunoassay segment, was initially expected to drive the gradual replacement of traditional methods for identification and antimicrobial susceptibility testing in infectious disease diagnostics. However, this transition has progressed more slowly than anticipated, and ID/AST is expected to remain a stable and essential part of the market through 2030. While culture-based methods have long turnaround times, ranging from a day to several weeks, and require significant laboratory labor, they continue to play a critical role in clinical decision-making. Molecular assays offer advantages in speed and accuracy, but they are generally more expensive both in terms of reagents and overall testing costs compared to high-throughput, automated ID/AST systems,

which continue to provide cost-effective and scalable solutions for routine microbiology testing.

Culture-based traditional microbiology will remain an important segment of the overall microbiology market, expected to increase at 2.5% CAGR by 2030. Immunoassays and molecular assays can determine whether a known pathogen is present. However, a negative result only means that the specific microbial pathogens being tested are not present, and it is possible that the patient is infected by a different microorganism. Molecular assays also rely on probes and primers that remain vulnerable to changing microbial genetics. Traditional susceptibility testing may more conclusively demonstrate a pathogen's resistance and vulnerability than detecting one or two specific gene markers. However, in particularly critical or time-sensitive microbiology workups, such as inpatient infections, ID/AST has lost volume to molecular and other rapid alternative systems that enable clinicians to quickly initiate informed treatment.

North America is the largest region for ID/AST testing worldwide (34%), particularly for automated systems. Asia Pacific held steady at 29% in 2025, while the European market remained at 27% market share.

Antimicrobial resistance and nosocomial infections represent leading infectious disease threats for the developed world and will be addressed in significant part by ID/AST testing, particularly in the treatment of outpatient infections. Remaining growth will be found in relatively undeveloped markets where ID/AST capacities have yet to be built out among clinical laboratories.

Table 11-7: Global ID/AST Testing Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	34%
Asia Pacific	29%
Europe	27%
RoW	10%
Total	**100%**

Source: Kalorama Information

Traditional ID/AST

The global market for microbial identification and antimicrobial susceptibility systems is valued at $3.4 billion in 2025 and is projected to reach $4.0 billion in 2030. ID/AST systems can be divided into panels and reagents performed by manual, semi-automated, or automated systems. Panels account for about 20% of the market, while automated systems account for the larger share of sales, at 80%.

Table 11-8: Global ID/AST Testing, Distribution by Systems, (%)

[Auto, Panel]

System	% Mkt
Auto	80%
Panels	20%
Total	**100%**

Source: Kalorama Information

Specific Technologies offers the Reveal Rapid Susceptibility Testing System. The system provides quantitative determination of antibiotic efficacy within hours of positive blood culture. The Reveal antibiotic susceptibility testing (AST) system offers phenotypic MIC matching CLSI gold standard results within an average of 5 hours from positive blood sample, while greatly simplifying workflow, at a cost low enough to prompt widespread adoption.

Blood Culture

Blood culture testing continues to evolve as microbiology laboratories adopt faster diagnostic workflows designed to improve the detection and management of bloodstream infections. Blood culture bottles and automated incubation systems are used to detect bacteremia (the presence of bacteria in the bloodstream) and fungemia (bloodstream infections caused by yeasts or other fungi). Physicians typically order blood cultures when patients present with symptoms suggestive of sepsis, including persistent fever, chills, hypotension, or other signs of systemic infection. Once a blood culture becomes positive, laboratories often employ rapid

identification and resistance testing to accelerate clinical decision-making and guide targeted antimicrobial therapy.

Blood cultures are most commonly performed in hospitalized patients with persistent fever of unknown origin or suspected sepsis. Although blood culture systems may also be used in specialized circumstances to support testing for disseminated mycobacterial infections such as tuberculosis, dedicated mycobacterial culture systems are generally used for routine TB diagnostics. The ongoing burden of sepsis worldwide continues to drive demand for blood culture systems and associated consumables, as rapid identification of bloodstream infections remains critical for reducing morbidity and mortality in hospitalized patients.

The blood culture instrumentation and consumables market continues to grow steadily as hospitals invest in automated microbiology workflows and rapid diagnostic technologies. The market is largely dominated by two major suppliers—Becton Dickinson (BD) and bioMérieux—whose systems are widely installed in hospital microbiology laboratories worldwide. BD markets its BACTEC family of blood culture instruments, while bioMérieux offers the BacT/ALERT line of systems. Together, these platforms represent the majority of installed blood culture instrumentation globally.

bioMérieux's BacT/ALERT VIRTUO is a fully automated, continuously monitoring blood culture system designed to streamline workflow in laboratories of varying sizes. The system allows laboratory staff to load blood culture bottles at any time, reducing manual handling and improving efficiency. Automated unloading, visual alerts, and integration with laboratory information systems through middleware solutions support faster reporting and improved laboratory productivity.

BD complements its BACTEC blood culture platforms with laboratory informatics tools, such as the BD Synapsys solution, which integrates microbiology workflow data and provides laboratories with operational insights to improve turnaround time and performance. BD also provides specialized culture media used for platelet quality control testing, enabling laboratories and blood banks to detect bacterial contamination in platelet units before transfusion, thereby helping reduce the risk of transfusion-associated sepsis.

In addition to traditional blood culture incubation systems, molecular diagnostic companies are introducing rapid, multiplex assays that identify pathogens directly from positive blood cultures. DiaSorin, for example, markets multiplex assays on its LIAISON PLEX platform. The LIAISON PLEX Blood Culture Yeast Assay detects a panel of fungal pathogens

commonly associated with bloodstream infections, while the LIAISON PLEX Gram-Negative Blood Culture Assay identifies multiple gram-negative bacteria along with important antimicrobial resistance markers. These assays are designed to accelerate pathogen identification following positive blood cultures, enabling clinicians to initiate appropriate therapy earlier and improve patient outcomes.

Table 11-9: Selected Advanced Techniques in Positive Blood Culture

Company	Location	Technology	Details
Accelerate Diagnostics	U.S.	Rapid ID + phenotypic AST	Accelerate Pheno system with Accelerate PhenoTest™ BC Kit for organism ID plus rapid phenotypic AST directly from positive blood cultures (menu dependent on Gram stain workflow)
Abbott	U.S.	Protein/immuno (culture isolate)	BinaxNOW™ PBP2a (for MRSA marker detection from cultured isolates; not a direct-from-blood-culture multiplex panel)
Becton Dickinson	U.S.	Mycobacterial liquid culture	BACTEC™ MGIT™ systems for mycobacterial culture
BioFire Diagnostics	U.S.	MSLDI-TOF	BIOFIRE® Blood Culture Identification 2 (BCID2) Panel: broad target menu (bacteria + yeasts + key resistance genes) run from positive blood culture bottles
bioMérieux	France	mass spec	assays for Knome sequencing platform
bioMérieux	France	mass spec	VITEK MS, ID/AST on Shimadzu mass spec
bioMérieux	France	ID/AST	BacT/ALERT VIRTUO, 15 min result
Bruker Biosciences	U.S.	mass spec	MALDI Sepsityper Solution, positive blood culture
Bruker Biosciences	U.S.	mass spec	integrate MALDI Biotyper with BD Phoenix
Bruker Biosciences	U.S.	mass spec	MALDI Biotyper
Bruker Biosciences	U.S.	mass spec	MALDI Biotyper CA System, gram neg
Cepheid	U.S.	PCR	Xpert MRSA/SA Blood Culture (BC)
Miacom Diagnostics	Germany	FISH	hemoFISH, blood culture ID, 15 minutes
Specific Technologies	U.S.	PCR	SpecID, metabolomic fingerprint, bacterial ID during growth

Source: Kalorama Information

Chromogenic Media

Once a sample arrives in the microbiology laboratory, use of organism-specific culture media can reduce the time for sample work-up by encouraging the growth of specific organisms and also coloring them with stains that they absorb as they grow. This makes the organisms visible on the culture plate.

Culture media are available in two major categories. General-purpose products such as blood agar and broths are used as the first step in culturing bacteria from specimens such as swabs, sputum, and urine. Selective or organism-specific chromogenic (coloring) media for organisms such as enterics, Salmonella, Shigella, E. coli, strep B, Staphylococci, Candida, hospital-acquired infections, and urinary tract infections – can also be used on selected specimens.

Chromogenic media supplement traditional ID/AST in a manner analogous to lateral flow tests, compared with laboratory immunoassays. In 2025, chromogenic media was worth approximately $1,315 million, increasing by 1.0% to $1,380 by 2030. Identification results are more easily obtained and interpreted through media color change, but at the expense of optimal accuracy and plate-test specificity (negative results can rule out a critical pathogen, but do not identify the infectious organism).

Rapid Tests Performed on Colonies from Culture Media

In the microbiology segment, rapid tests refer to manual tests performed on colonies picked from growth media or swabbed plates. This differs from the rapid point-of-care or near-patient tests used directly on patient samples to detect specific pathogens. In 2025, rapid microbiology is estimated to be valued at $876 million and will grow at a 1.5% CAGR to $943 million in 2030.

Many traditional microbiology rapid tests (performed following culture) have been replaced by analyzer-based immunoassays in developed countries but are still important tools for small labs and in developing regions.

Supplies

The segment is made up of microbiology supplies such as transport and prepared media, sample collection devices and stains

These are high-margin, low-service products sold primarily by catalog and direct marketing.

Transport and culture are an important first step in the imperative for faster test turnaround times and especially for the new generation of molecular assays. The role of these collection and transport products is to ensure that sufficient numbers of live microorganisms survive to provide a true assessment of their presence in the patient. Thus, the role of these supplies

will always be integral to microbiology, supporting both routine and advanced methods. A sample carrying a pathogen has to reach a lab somehow.

COPAN Diagnostics, Inc. is a leading supplier of and innovator in collection and transport systems. COPAN has been supplying bacteriology swabs, viral transport media and molecular systems since 1994.

Organism-specific transport media help maintain the viability of the targeted organism in a medium or on a swab. The media also limit the growth of other flora that could crowd out the targeted organism.

Market Analysis - Microbiology Immunoassays

Infectious disease immunoassays are frequently performed in the core laboratory on fully automated analyzers that often perform both chemistry and immunochemistry tests. These core laboratory platforms and tests are not a significant focus of this chapter. However, infectious disease immunoassays represent a significant segment of the overall microbiology market, and they are competitive methods for identifying certain pathogens.

Immunoassays are an important segment of diagnostic testing in which antibodies react with a target analyte found in biological fluids such as blood, urine, or saliva. The analyte is often a protein but can be a small molecule such as a drug or toxin. In some immunoassays, a purified antigen may be used to detect an antibody analyte. There are many different immunoassay formats that cannot all be reviewed in detail within the scope of this chapter. The major types of immunoassays discussed here are traditional rapid assays and enzyme immunoassays.

It has often been speculated that molecular tests would replace infectious disease immunoassays. This has not proven to be the case; a number of molecular tests have become very popular, but immunoassays are less expensive, more automatable, and readily available to labs of any size. Historically, the evolution of molecular tests slowed growth in the immunoassay sector. However, the rapid adoption of COVID-19 antigen and serology-based tests has shifted some of the market growth back to the immunoassay segment.

The combination of Abbott Diagnostics with Alere has created a powerhouse in immunoassays for infectious diseases. The world market for infectious disease immunoassays has been dominated by Abbott Diagnostics since the 1980s. The company's strength lies in a broad menu of tests and assay systems. Abbott further consolidated its position with the release of a number of FDA-cleared assays.

Abbott has built a strong immunoassay portfolio. The company provides a variety of instrumentation to meet all levels of ELISA testing, from complete walk-away automation to microplate readers and washers. Abbott also provides immunofluorescence assays, with a menu of IFA and DFA tests that includes kits for autoimmune diseases, infectious diseases and sexually transmitted diseases. Abbott’s strength, however, was as the leader of rapid immunoassays (discussed below).

Improvements in Microbiology Immunoassays

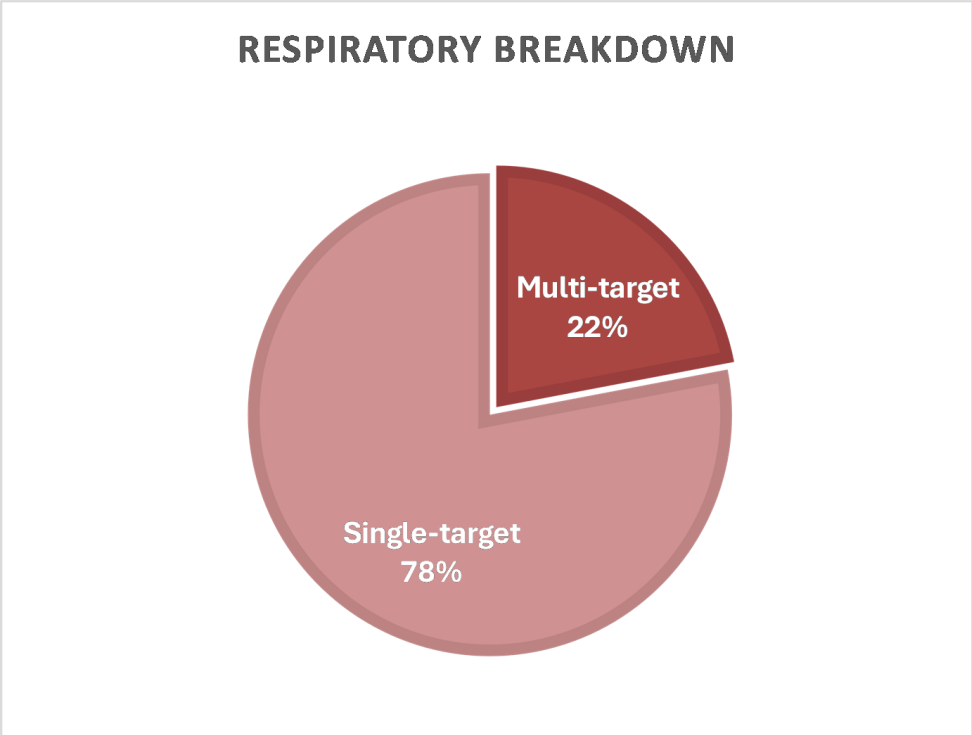
Recent improvements in microbiology immunoassays reflect significant advances in speed, sensitivity, automation and multiplexing. Many clinical laboratories perform a very large number of immunoassays every day, and test automation has been essential. Historically, a common approach with immunoassays was to use a 96-well microtiter plate. Diagnostic companies worked to gradually automate these assays, using automated pipetting devices, microtiter plate washers, and microtiter plate readers, eventually developing automated analyzers based on microtiter plate technology.

Single-target and multi-target panels are found in both respiratory and non-respiratory segments of the immunoassay market. The immunoassay respiratory market for targeted testing is focused on single-target testing, but the multi-target testing is growing.

Immunoassay multi-target panels are increasingly used because they offer several advantages over traditional single-target tests. The primary advantage of immunoassay multiplex panels is their ability to reduce time to diagnosis compared with traditional methods such as culture or sequential testing. Immunoassay multi-target panel testing consolidates multiple single tests into one high-confidence assay, enabling faster and more accurate clinical decision-making.

Figure 11-1: Immunoassay Respiratory Testing, by Target Pathogens, 2025 (%)

[Multi-Target, Single-Target]



Source: Kalorama Information

Table 11-10: Selected Infectious Disease Immunoassay Innovations

Company	Location	Target	Details
Abbott Diagnostics	U.S.	HIV	ARCHITECT HIV Ag/Ab Combo assay
Ceres Nanosciences	U.S.	lyme	Nanotrap Lyme Antigen (LA) Test
Curetis/Ares Genetics	Germany	Sepsis/AMR response	Acumen's AcuSept panel, sepsis immune response
Diasorin	Italy	campy	LIAISON Campylobacter stool test
Diasorin	Italy	GI	Liaison bacterial stool-testing panel
Diaxonhit	France	inf	avidity portfolio active vs older infections
Diaxonhit	France	sepsis	BJI InoPlex test staph antibodies in blood
Dynamiker Biotechnology	China	fungi	ELISA invasive fungal disease
EKF Diagnostics	UK	sepsis	Stanbio LiquiColor Procalcitonin, automated analyzers
Genalyte Inc.	U.S.	Ebola	Ebola antigens and IgM/IgG antibodies
Global BioDiagnostics	UK	TB	TB, Reporter Enzyme Fluorescence
Gold Standard Diagnostics	U.S.	syphilis	AIX1000 Rapid Plasma Reagin (RPR) Automated
MBio Diagnostics (Light Deck Diagnostics)	U.S.	malaria	LightDeck Malaria cartridge
MBio Diagnostics	U.S.	instr	LightDeck, multiplexed immunoassay platform, cartridge
MeMed Diagnostics	Israel	response	ImmunoXpert pathogen immune response proteins
Nanologix	U.S.	instr	Nanologix N-Assay, ELISA
Pearl Diagnostics	U.S.	Resp	MycoMEIA Aspergillus Immunoassay
Quansys Biosciences	U.S.	resp	14-plex Pneumococcal Array
Quidel	U.S.	resp	Sofia RSV Fluorescent Immunoassay
Quidel	U.S.	resp	Sofia Strep A+ Fluorescent Immunoassay
Response Biomedical	Canada	sepsis	RAMP Procalcitonin
Singulex	U.S.	pathogens	single molecule counting technology

Company	Location	Target	Details
Transasia Bio-Medicals	India	STD	ErbaLisa Syphilis
U. of California, Irvine	U.S.	HCV	HCV-AGS EIA acute HCV in urine
ViroCyt	U.S.	sample	ViroTag & Virus Counter 3100

Source: Kalorama Information

Most immunoassays performed in large, centralized laboratories today are done on fully automated, random-access analyzers that are not based on 96-well microtiter plates. Diagnostic companies that offer fully automated, random-access analyzers include Abbott, Beckman Coulter, Bio-Rad Laboratories, bioMérieux, Grifols, Eiken Chemical, QuidelOrtho, Roche, Siemens Healthineers, Tosoh Bioscience, and many others.

The major categories of strength for immunoassay testing are hepatitis, HIV, sexually transmitted disease, infectious diseases and respiratory diseases.

Table 11-11: Global Clinical Laboratory-Based Microbiology/Infectious Disease Immunoassay Market, by Pathogen, 2025($ million)

[HAIs/Sepsis; Hepatitis; HIV; Lyme Disease; Mycology; Parasitology; Respiratory; STDs; ToRCH; Other]

Pathogen/Disease Indication	2025 Sales	% Mkt
Respiratory	2,991	23%
Hepatitis	2,100	16%
HAIs/Sepsis	1,755	13%
HIV	1,685	13%
STDs	1,350	10%
ToRCH	1,335	10%
Parasitology	224	2%
Lyme Disease	172	1%
Mycology	73	<1%
Other*	1,480	11%
Total	**13,165**	**100%**

Note: *includes immunoassays for EBV, Chagas, Dengue, Malaria, etc.

Note: Percentages rounded

Source: Kalorama Information

North America is the largest geographical segment of the microbiology/immunoassay market, followed by Europe.

Table 11-12: Global Laboratory-Based Microbiology/Infectious Disease Immunoassay Market Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	52%
Europe	30%
Asia Pacific	11%
RoW	7%
Total	**100%**

Source: Kalorama Information

Hepatitis Testing

The term "hepatitis" means inflammation of the liver. Many things can cause the liver to become inflamed including drugs, toxins, excessive alcohol, and infections by certain bacteria and viruses. Several viruses can cause hepatitis including hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), Hepatitis D virus (HDV), hepatitis E virus (HEV), and hepatitis G virus (HGV). The most common types in the United States, and the focus of much of the hepatitis immunoassay testing, are HAV, HBV, and HCV.

Hepatitis has been increasingly important due to new guidelines suggesting testing for all Baby Boomer-aged results.

The first immunoassays for hepatitis B virus became available in the 1970s. Enzyme immunoassays are now available for several HBV markers including:

- HBsAg – Hepatitis B surface antigen
- Anti-HBs – Antibody to hepatitis B surface antigen
- HBcAb or Anti-HBc – Hepatitis B core antibody

- HBeAg – Hepatitis B e antigen
- HBeAb or Anti-HBe – Antibody to hepatitis e antigen

Hepatitis C remains a significant challenge for the medical community. According to the CDC, around 3.9 million people in the United States have a chronic HCV infection or nearly 1% of the population. An estimated 2 million people in the United States have a chronic HBV infection. Worldwide an estimated 58 million people have chronic hepatitis C with about 1.5 million new infections every year.

Both qualitative and quantitative tests are available for HBsAg, as well as HBsAg confirmatory tests. Together, results from these assays can be used to differentiate between acute or chronic hepatitis B infection and whether a person has been infected with HBV in the past.

Immunoassays HBV markers for anti-HAV IgG, anti-HAV IgM, and anti-HCV are also available from many companies, including on the major immunoassay analyzers and integrated systems of the major diagnostic companies. In addition, many companies that market lateral flow tests, especially companies who market their products in countries such as China and India, market assays for HBV and HCV. This reflects the importance of hepatitis B diagnostic tests in these markets.

Abbott received CE Mark for the Determine HbsAg 2 test for use with serum, plasma, or whole blood. The test is a rapid lateral flow test that enables the identification of those with hepatitis virus infection and facilitates linkage to care. It is now commercially available in Europe, Africa, Asia Pacific and Latin America. It has received CE Mark, and data have been submitted for WHO prequalification.

The guidelines have fueled a surge in hepatitis testing, and this is a large market as a result.

Selected commercially available immunoassay and molecular IVD tests for hepatitis include:

- Abbott RealTime HCV Genotyping II molecular assay (Abbott)
- ADVIA Centaur HBsAgII Assay (Siemens)
- ADVIA Centaur HCV Assay (Siemens)
- Aptima HBV Quant Assay (Hologic)
- Aptima HCV Quant Assay (Hologic)

- COBAS AmpliPrep/COBAS TaqMan HBV Test (Roche)
- COBAS AmpliPrep/COBAS TaqMan HCV Test (Roche)
- cobas DPX Test (Roche)
- cobas MPX Test (Roche)
- cobas TaqScreen DPX Test (Roche)
- cobas HBV Test (Roche)
- DeepChek HBV RT real time PCR genotyping and DR assay (Advanced Biological laboratories)
- DeepChek HBV Core/PreCore Assay based on real-time PCR (Advanced Biological Laboratories)
- Dual Probe HCV (Roche)
- Elecsys HBsAg II Assay (Roche)
- Elecsys HBsAg II assay (Roche)
- Elecsys Anti-HCV II Assay (Roche)
- GS HBsAg EIA (Bio-Rad)
- HBV Sequencing Assay (Abbott)
- INNO-LiPA HBV Genotyping assay (Fujirebio Diagnostics)
- INNO-LiPA HBV Multi-DR reverse hybridization line probe assay (Fujirebio Diagnostics)
- INNO-LiPA HBV PreCore reverse hybridization line probe assay (Fujirebio Diagnostics)
- LIAISON Anti-HAV chemiluminescence immunoassay (Diasorin)
- LIAISON HBsAg chemiluminescent immunoassay (Diasorin)
- LIAISON HCV Ab chemiluminescence immunoassay (Diasorin)
- MONOLISA Anti-HAV EIA (Bio-Rad)
- MONOLISA Anti-HBc EIA (Bio-Rad)
- MONOLISA Anti-HBs EIA (Bio-Rad)

- MUREX HBs Ag ELISA test (Diasorin)
- MUREX anti-HBc ELISA test (Diasorin)
- MUREX anti-HCV ELISA test (Diasorin)
- MUREX HCV Ag/Ab ELISA test (Diasorin)
- ORTHO HCV Version 3.0 ELISA Test System (Ortho-Clinical Diagnostics)
- TruQuick HBsAg/HCV Combo Test
- TruQuick HEV IgG/IgM Test (Meridian Bioscience)
- UltraGene HBV Assay based on real-time PCR (Advanced Biological Laboratories)
- VITROS Anti-HAV Assay (QuidelOrtho)
- VITROS Anti-HBe Assay (QuidelOrtho)
- VITROS Anti-HBs Assay (QuidelOrtho)
- VITROS Anti-HCV Assay QuidelOrtho)

Roche markets the Elecsys HCV Duo immunoassay test. The assay is the first available immunoassay to simultaneously determine hepatitis C virus antigen and antibody status from a single sample. This test enables earlier diagnosis of active hepatitis C virus infection, which can lead to earlier intervention for patients.

Fujirebio offers the INNO-LiPA HCV 2.0 genotyping assay is a line probe assay designed for the qualitative detection and identification of Hepatitis C genotypes 1 to 6 and subtypes a and b of genotype 1.

Sepsis

Sepsis syndrome is the 11th-highest cause of death in the United States, and its incidence has increased consistently over the past 20 years. Worldwide, sepsis is responsible for over 4.5 million deaths, making sepsis one of the world's fastest-growing healthcare problems.

The IVD industry can rightly take some credit for the current focus on sepsis. It is not a disease that is obvious from symptoms alone, and many hospital deaths previously written off have been attended to because of better testing protocols and technology. This is one of the reasons the disease is called "the invisible killer." The main test for sepsis has been blood

culture, which does not provide a definitive answer for at least 24 hours and requires a significant concentration of bacteria in the blood to yield a quick, definitive result. The hunt, therefore, was on for earlier, more efficient markers of sepsis.

The diagnosis of sepsis has been greatly improved by biomarker discovery. Procalcitonin (PCT) was identified as a sensitive biomarker for systemic bacterial infections about 15 years ago. It is a peptide precursor of the hormone calcitonin, which is involved in calcium homeostasis. Procalcitonin may sometimes be ordered, along with other tests such as a C-reactive protein, blood culture, and complete blood count to help detect or rule out sepsis or detect/rule out bacterial pneumonia in those who are seriously ill and in children with a fever of unknown origin.

In response to bacterial infections, nearly all tissues in the body release PCT, especially the lungs. In normal metabolism, procalcitonin is produced in the thyroid gland and helps regulate the calcium and phosphate balance in the body. In Europe, PCT is commonly used to determine a bacterial-infection immune response from viral infections or an inflammatory response not linked to a pathogen.

Procalcitonin testing is commonly used in hospitals to help assess patients admitted with suspected significant bacterial infection, particularly in suspected sepsis and lower respiratory tract infections, and to support antibiotic stewardship decisions. PCT can rise within roughly 6–12 hours after a systemic bacterial inflammatory response begins, and serial measurements are often used to track response to therapy. Many hospital pathways obtain an initial PCT on admission and repeat testing every 24–48 hours to evaluate trends, with decreasing values supporting clinical improvement and, in appropriate cases, earlier antibiotic de-escalation or discontinuation.

Thermo Fisher Scientific's 2009 acquisition of B.R.A.H.M.S established a leading position in sepsis-related biomarker testing. B.R.A.H.M.S-branded PCT assays are among the most widely used and clinically validated PCT methods in Europe and are also available in the U.S. on selected platforms. Through partnerships and assay implementations, PCT testing aligned with B.R.A.H.M.S methods has been available on major immunoassay systems, including bioMérieux VIDAS, Roche cobas e/Elecsys, and, depending on country-specific registrations, selected Siemens and Abbott immunoassay platforms. Fujirebio also offers a procalcitonin assay on its LUMIPULSE immunoassay platform, providing another automated option for measuring this bacterial-infection–associated biomarker in clinical laboratories.

Through agreements with third-party immunoassay companies, the B.R.A.H.M.S/Thermo Fisher assay or assay technology is available on the following platforms:

- bioMérieux VIDAS immunoanalyzers
- Siemens Healthineers' ADVIA Centaur CP immunoanalyzers (outside of the United States)
- Abbott Diagnostics ARCHITECT i and ci integrated chemistry and immunoanalyzers (outside of the United States)
- Roche Diagnostics cobas e and Elecsys instruments
- Diasorin LIAISON instruments

Fujirebio Diagnostics is also in the game, offering the procalcitonin assay for testing on its LUMIPULSE platform. Procalcitonin is an interesting biomarker specific to bacterial infections, and its levels are proportional to the patient's risk of developing sepsis.

In the U.S., vendors of the procalcitonin test received FDA clearance to market the test for expanded use that follows the protocol used in Europe. Based on a recent study, monitoring PCT levels over 4 days can help doctors determine which septic patients are at the greatest risk of death, enabling them to adjust or intensify the medical care for those patients.

One traditional and commonly used clinical biomarker for sepsis is blood lactate. Elevated levels of lactate, fever and elevated white blood cell counts can serve as early inclusion criteria for sepsis. Elevated lactate is associated with increased morbidity and mortality in sepsis, but only when using a high cut-off value that excludes patients with developing sepsis or those still in need of intervention. Lactate levels can also produce false positives, as elevated results can also be observed in patients without sepsis. As a fast yet imperfect screening biomarker for sepsis, lactate is bound to be supplemented by other biomarkers to improve the accuracy and sensitivity of sepsis screening. Kalorama information does not include lactate as a sepsis biomarker within the scope of this report; lactate assays are most often performed on blood gas analyzers, which are included under the non-infectious critical care POC IVD segment.

The global lab-based microbiology immunoassay sepsis market is estimated at $1,566 million in 2025. Innovation in PCT methods has fueled growth in recent years, generating a market worth about $478 million in 2025 and, with a 3% growth rate, reaching $548 million by 2030.

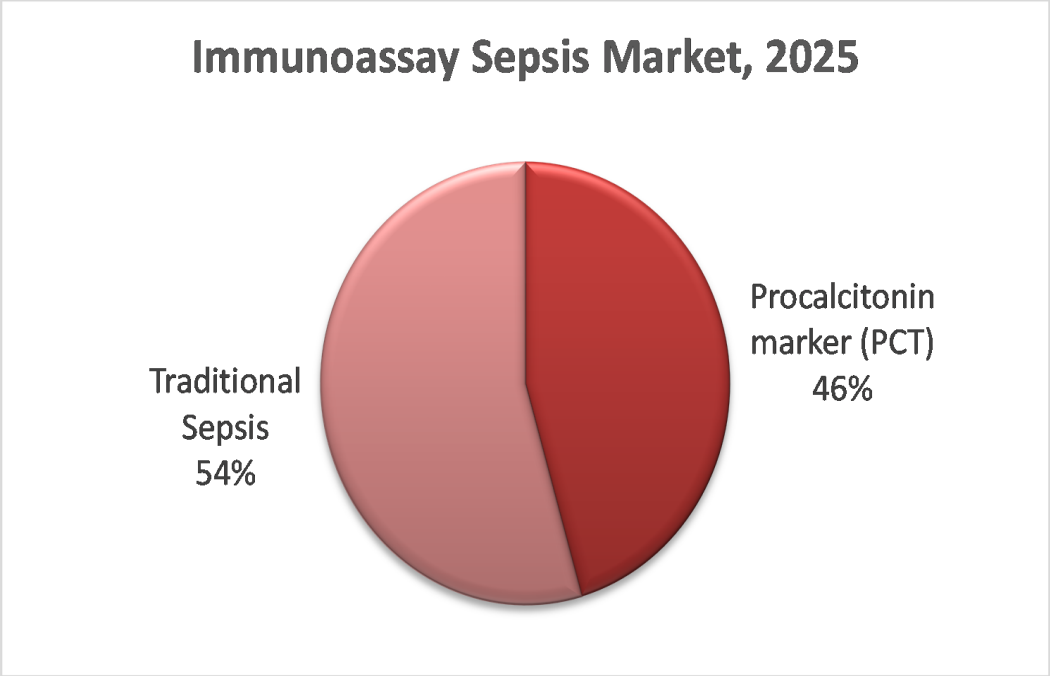
The global lab-based microbiology immunoassay sepsis market is divided into two areas:

- Traditional testing
- Procalcitonin marker testing

The traditional testing for sepsis totaled 54% of the market and the newer PCT marker testing totaled 46% of the sepsis market. The PCT marker testing will likely continue to make inroads.

Figure 11-2: Global Lab-based Microbiology Immunoassay Sepsis Market Distribution, by Type, 2025 (%)

[PCT, Traditional]



Source: Kalorama Information

HIV Immunoassay Testing

HIV testing has been available since the mid-1980s and remains a cornerstone for screening blood and blood products as well as diagnosing infection. HIV exists as two main types, HIV-1 and HIV-2, with multiple subtypes of HIV-1 identified. Over time, blood tests have evolved

to detect antibodies to both HIV-1 and HIV-2, along with a broad range of subtypes. Continuous improvements in assay sensitivity have shortened the time from infection to detection. Current fourth-generation immunoassays combine detection of HIV-1 p24 antigen with antibodies to HIV-1 and HIV-2, enabling earlier identification of infection than antibody-only tests.

Globally, approximately 40 million people are living with HIV, and annual deaths remain in the hundreds of thousands, although both incidence and mortality have declined over time due to improved access to testing and treatment. HIV/AIDS continues to represent a major healthcare challenge, particularly in sub-Saharan Africa, where the burden of disease remains highest and access to diagnostics and treatment can be limited in some regions. Expanding access to testing, early diagnosis, and treatment remains critical to reducing transmission and improving outcomes.

Modern laboratory testing is characterized by high-throughput immunoassay platforms such as the Elecsys HIV combi PT from Roche, a widely used fourth-generation assay that detects both HIV-1 p24 antigen and HIV-1/2 antibodies in a single test. This dual-detection approach shortens the diagnostic window and improves the identification of early infection. These assays are routinely incorporated into laboratory testing algorithms and are commonly run alongside other infectious disease screens on automated analyzer systems to support efficient, high-volume workflows.

As HIV diagnostics have become faster and more standardized, many health systems have adopted routine “opt-out” screening, in which HIV testing is offered as a standard part of care rather than limited to high-risk populations. This approach has helped normalize testing, reduce stigma, and increase early detection, supporting earlier treatment initiation and lowering transmission rates. The continued expansion of routine screening programs and the streamlining of laboratory workflows remain key drivers of HIV testing volume worldwide.

Commercially available IVD tests for AIDS/HIV include:

- ADVIA Centaur CHIV Assay (Siemens)
- Aptima HIV-1 Quant Assay (Hologic)
- COBAS AmpliPrep/COBAS TaqMan HIV-1 Test (Roche)
- Determine HIV-1/2 Ag/Ab Combo Test (Abbott)
- Elecsys HIV combi PT assay - 4th generation (Roche)

- Geenius HIV 1/2 Supplemental Assay (Bio-Rad)
- GS HIV Combo Ag/Ab EIA (Bio-Rad)
- GS HIV-1 Western Blot (Bio-Rad)
- INNO-LIA HIV I/II Score line immunoassay - Fujirebio Diagnostics
- UltraGene HIV real-time PCR Assay (Advanced Biological Laboratories)
- Uni-Gold Recombigen HIV-1/2 (Trinity Biotech)
- ViroSeq HIV-1 Genotyping System (Abbott)
- VITROS HIV Combo Test (QuidelOrtho)

Hologic received CE marking for its Aptima HIV-1 Quant Dx assay, a nucleic acid amplification test performed on the fully automated PANTHER system for the detection and quantitation of HIV-1 RNA. The assay is widely used for viral load monitoring and plays an important role in the clinical management of patients infected with HIV-1, helping guide treatment decisions and assess response to therapy. While earlier positioning suggested broader applications, viral load assays are not typically used as primary diagnostic or confirmatory tests for HIV infection; instead, diagnosis relies on antigen- and antibody-based testing algorithms. The Aptima HIV-1 Quant Dx assay may be used alongside clinical presentation and other laboratory markers to support disease monitoring and prognosis but claims regarding use for early infant diagnosis or as a dual-purpose diagnostic are not broadly supported in current clinical practice.

OraSure offers its OraQuick HIV Self-Test for HIV-1 and HIV-2 in Europe. The test is available in six European countries, including the United Kingdom, Germany, France, Italy, Spain, and Portugal. The company also offers the OraQuick Advance HIV 1-2 Rapid Antibody Test and the OraQuick In-Home HIV Test.

Chembio offers several HIV tests, including its DPP HIV-Syphilis assay, which is a multiplex single-use test. Chembio also offers the HIV1/2 STAT-PAK assay, THE Sure Check HIV 1/2 Assay, Sure Check HIV Self-Test and the STAT VIEW HIV 1/2.

Bio-Rad offers a line of next-generation HIV multiplex flow immunoassays. Products include the BioPlex 2200 HIV Ag-Ab multiplex immunoassay, and the GS HIV Combo Ag/Ab EIA kit paired with the EVOLIS system. It also offers the Geenius HIV 1/2

Supplemental Assay. The Geenius HIV 1/2 Supplemental Assay is the only FDA-approved test for the confirmation and differentiation of antibodies to HIV-1 and HIV-2.

Cepheid markets its X-pert HIV-1 Viral Load XC and Xpert HIV-1 Qual XC. Both tests are next-generation, extended coverage tests for HIV testing. Xpert HIV-1 Viral Load XC adds a second target for HIV-1 detection that provides extended strain coverage to improve performance and address the risk of false negative results due to gene mutations or deletions. Xpert HIV-1 Viral Load XC is intended to assess viral load levels, which are used to monitor the effectiveness of antiretroviral treatment.

Xpert HIV-1 Qual XC also adds a second target for early identification of HIV-1 infections up to 7-10 days before seroconversion. The test has been cleared for use with infants, adolescents, and adults in both laboratory and near-patient testing environments. With all reagents on board in one fully integrated cartridge, Xpert HIV-1 Qual XC facilitates dried blood spot (DBS) sample processing and a simplified workflow. Finally, Xpert HIV-1 Qual XC does not contain guanidinium thiocyanate (GTC), making cartridge disposal simpler and more environmentally friendly.

Table 11-13: Selected HIV Assays

Vendor	Product	Format
Abbott	ARCHITECT HIV Ag/Ab Combo	CMIA
Abbott	PRISM HIV Ag/Ab Combo	ChLIA
Abbott	Alinity HIV -1/2 Ag/Ab Combo	Immunoassay
bioMérieux	VIDAS HIV DUO Ultra	N/A
Bio-Rad	Genetic Systems	ELISA
Bio-Rad	Genetic Systems HIV-1/HIV2 Peptide	ELISA
Bio-Rad	Genetic Systems HIV-1/HIV-2 Plus O	ELISA
Bio-Rad	GS HIV-1 Western blot	Western blot
Bio-Rad	BioPLex 2200 HIV Ag-Ab	Multiplex flow
Bio-Rad	GS HIV Ag/Ab Combo EIA	EIA
Diasorin/Murex Diagnostics	Murex SUDS hIV-1	Rapid ELISA
Roche	Elecsys HIV combi PT	Immunoassay
Siemens Healthineers	ADVIA Centaur HIV Ag/Ab Combo	Microparticle chemiluminometric immunoassay

Source: Kalorama Information

Sexually Transmitted Diseases (STDs)

Sexually transmitted diseases (STDs) include hepatitis B, hepatitis C, and HIV, which have already been discussed. Two additional STDs that are important for immunoassay testing worldwide are syphilis and chlamydia. Immunoassay testing revenues for the remaining STD segments are estimated at $1.4 billion for 2025.

Syphilis is a significant global public health concern. Management of symptomatic cases of syphilis is not sufficient. The World Health Organization estimated there were over 8 million new cases of syphilis worldwide. This is important because syphilis infection during pregnancy results in 70,000 fetal and neonatal deaths, 115,000 cases of infant congenital

disease, and 55,000 cases of premature birth/low birth weight each year, according to the WHO.

Most cases of syphilis worldwide are outside of the United States. In 2022, the CDC reported that 207,000 people in the United States contracted syphilis. In addition, the U.S. Preventive Services Task Force recommends that all pregnant women be screened for syphilis infection. In 2022, there were 3,755 babies born with syphilis in the U.S., which reflects a 937% increase in the past decade. However, syphilis is also an important problem in developing countries.

Sexually transmitted diseases are passed from one person to another through intimate physical contact, such as heavy petting, and from sexual activity, including vaginal, oral, and anal sex. STDs are very common. In fact, the CDC estimates 20 million new infections occur every year in the United States.

The traditional algorithm for serological syphilis testing starts with a non-treponemal assay, such as the VDRL (Venereal Disease Research Laboratory) or RPR (Rapid Plasma Reagin) tests, to screen patients, with reactive samples followed by a Treponema-specific method. Immunoassays have been developed and are now available on many automated analyzers. In developing countries, rapid tests for syphilis are often used.

Chlamydia and gonorrhea were two of the first infectious disease targets for commercialized clinical molecular tests and have since been joined by a suite of other molecular sexually transmitted disease assays. Chlamydia is a common target for rapid STD screening and is often now multiplexed with gonorrhea in molecular assays for improved screening coverage from a single test, due to the lack of other rapid screening methods available for gonorrhea. Chlamydia and gonorrhea are also commonly screened due to a lack of early symptoms and a related high number of unknown cases.

In the United States, STDs have been problematic from a public health standpoint, and sustained screening has been necessary for the elimination of certain diseases or to otherwise reverse growing incidences.

With consistent national reporting, it has become apparent that STDs have rebounded from reported historical lows and have been resilient to eradication goals.

Commercially available selected IVD tests for syphilis include:

- Alere Determine Syphilis TP immunoassay (Abbott)
- Captia Syphilis IgG EIA (Trinity Biotech)
- Elecsys Syphilis Assay (Roche)
- INNO-LIA Syphilis Score line immunoassay (Fujirebio Diagnostics)
- LIAISON Treponema Screen chemiluminescence immunoassay (Diasorin)
- RPR Quicktest (EKF Diagnostics)
- SERODIA TP•PA agglutination test for Treponema pallidum (Fujirebio Diagnostics)
- Trep-Sure Syphilis Total Antibody EIA (Trinity Biotech)
- TruQuick Syphilis Test (Meridian Bioscience)

Roche markets the Treponema pallidum assay, a fully automated assay for the detection of antibodies to Treponema pallidum for use on all Roche immunoassay systems for low-, mid-, and high-volume testing environments, including the cobas e 411, cobas e 601, cobas e 602, and MODULAR ANALYTICS E170 analyzers. The Treponema pallidum assay is intended as an aid in the diagnosis of syphilis infection on an automated analyzer.

Siemens Healthineers offers an FDA-cleared menu of Atellica infectious disease immunoassays, including: HIV Ag/Ab Combo (CHIV), HBsAg II, HCV, and Syphilis. The HBsAg II SMART algorithm and the hot zone help reduce repeat testing and decrease turnaround time.

Bio-Rad offers its BioPlex 2200 Syphilis Total & RPR assay, a novel one-step universal testing method to aid in the diagnosis of syphilis infection. The BioPlex 2200 Syphilis Total & RPR (rapid plasma reagin) assay offers laboratories the first fully automated Treponemal/non-Treponemal dual assay, which simultaneously detects antibodies to T. pallidum and reagin antibodies as well as RPR titer (the level of antibody) determination for effective treatment monitoring.

Chembio offers several HIV tests, including its DPP HIV-Syphilis assay, which is a multiplex single-use test.

ToRCH

ToRCH is an acronym for a group of infectious diseases that can cause illness in pregnant women and may cause birth defects in their newborns. The test is generally part of the traditional screen for pregnant women in developed countries. It is a common test area, and many companies compete in a market valued at about $1.3 billion in 2025. Roche, Diasorin, Siemens Healthineers, and Zeus Scientific (Sebia) are among many ToRCH panels available.

Toxoplasma gondii is the most commonly used part of the ToRCH panel. It is a ubiquitous intracellular parasite that can affect virtually all warm-blooded vertebrates. Infections usually lead to lifelong persistence of the protozoan in muscle and nerve tissues. According to rough estimates 25% – 50% of the global human population carry the parasite, with pronounced geographical and regional differences. Typical sources of infection are the consumption of raw or undercooked meat and the uptake of free spores released by cats into the environment. The TORCH panel includes tests for antibody levels to cytomegalovirus (CMV), herpes simplex virus type 1 (HSV-1), herpes simplex type 2 (HSV-2), and rubella. Differentiation between IgG and IgM is important to distinguish between maternal antibodies and IgM antibodies being produced by the newborn because of infection.

Bio-Rad markets its BioPlex 2200 ToRC IgM Assay. The automated and multiplexed panel, which complements the company's BioPlex 2200 ToRC IgG Assay, is designed to detect IgM-class antibodies to congenital disease-associated pathogens, including Toxoplasma gondii, rubella, and cytomegalovirus.

Randox provides its serology ToRCH controls for newborn infectious disease testing. The controls for ToRCH, a blood test screening for infectious diseases including toxoplasmosis, rubella, cytomegalovirus, and herpes simplex, are available from Randox Laboratories and are used to ensure accurate ToRCH test results and system performance.

Lyme Disease

In light of the increasing importance of this disease, this year's edition expands segment reporting to include Lyme Disease. Ticks (Ixodes scapularis and I. pacificus) transmit Borrelia burgdorferi, the most common cause of Lyme disease. Since the late 1990s, the number of reported cases of Lyme disease in the United States has tripled and the number of counties in the northeastern and upper Midwestern United States that are considered high-risk for Lyme disease has increased by more than 300%. One explanation for this trend is

that the ticks that can transmit Lyme disease have expanded their geographic range and are now being found in places they weren't seen 20 years ago.

Lyme disease is spread by four species of bacteria and accounts for an estimated 1.2 million new cases per year, occurring mostly in the temperate climates of the Northern Hemisphere. Borrelia burgdorferi and Borrelia mayonii are the main causes of the infection in the United States, while Borrelia afzelii and Borrelia garinii account for most afflictions in Europe and Asia. Lyme disease is transmitted to humans via the bite of infected blacklegged ticks. Its common symptoms include fever, fatigue, headache, and a skin rash known as erythema migrans. Although not usually life-threatening, Lyme disease is curable with antibiotics and preventable with a commercially available vaccine. However, if untreated, the infection can lead to a number of debilitating complications, including Bell's palsy, chronic joint inflammation, heart arrhythmias, memory disorders, meningitis, and neuropathy.

Lyme testing represents an area where IVD has contributed. Patients who previously thought they suffered from another disease have been properly identified with the aid of immunoassay testing.

The Centers for Disease Control and Prevention recommends a two-step process when testing blood for evidence of antibodies to the bacteria that cause Lyme disease, and both steps can be performed using the same blood sample. The first step uses an enzyme immunoassay (EIA) or immunofluorescence assay. If the initial result is negative, no further testing is recommended. If the result is positive or indeterminate, a second test is performed. Traditionally, this second step has been an immunoblot (Western blot) test, and the result is considered positive only when both steps are positive. More recently, an alternative approach using two sequential EIAs has also been adopted in many laboratories, eliminating the need for a Western blot while maintaining comparable or improved performance.

Lyme disease can be challenging to diagnose, particularly in the early stages of infection when antibody responses may not yet be detectable. As a result, test sensitivity is lower early in the disease and improves as the infection progresses. IgM-based immunoblot results are more prone to false positives, especially when used outside the appropriate clinical context, leading to more careful interpretation and increased use of newer testing algorithms.

Commercially available selected IVD tests for Lyme disease include:

- Captia B. burgdorferi IgG/IgM EIA (Trinity Biotech)

- LIAISON Borrelia IgG chemiluminescent immunoassay (Diasorin)
- LIAISON Borrelia IgM Quant chemiluminescent immunoassay (Diasorin)
- LIAISON Borrelia IgM II chemiluminescent immunoassay (Diasorin)
- MarDx B. burgdorferi IgG Marblot Western Blot (Trinity Biotech)
- MarDx B. burgdorferi IgM Marblot Western Blot (Trinity Biotech)
- Sofia Lyme FIA (QuidelOrtho)
- Sofia 2 Lyme FIA (QuidelOrtho)

The Bio-Rad Anti Borrelia (Lyme) EIA is used for the qualitative and/or semi-quantitative detection of IgG, IgM, and IgA antibodies to Borrelia burgdoferi in human serum. This assay is highly sensitive and specific for Lyme borreliosis and is used as an aid in diagnosing Lyme disease. Its improved sensitivity combines purified Bb lysate and recombinant p39 proteins as antigens. For higher specificity, serum is absorbed in a blocking solution containing E. coli proteins.

QuidelOrtho's Sofia Lyme Fluorescent Immunoassay (FIA) uses advanced immunofluorescence-based lateral-flow technology to provide rapid differential detection of human IgM and IgG antibodies to Borrelia burgdorferi from serum and plasma specimens from patients suspected of B. burgdorferi infection. Sofia Lyme FIA, with the Sofia 2 or Sofia analyzer, provides automated, objective results in 10 minutes, enabling Lyme testing in near-patient settings.

Bio-Rad markets its BioPlex 2200 Lyme Total Assay, a multiplex test method to aid in the diagnosis of Lyme disease. The Assay can simultaneously detect multiple targets. The release of the BioPlex 2200 Lyme Total assay is the latest offering in Bio-Rad's infectious disease menu for the BioPlex 2200 System, an automated multiplex technology platform.

Researchers from multiple institutions—including the Center for Infection and Immunity at Columbia University, the U.S. Centers for Disease Control and Prevention (CDC), the National Institute of Allergy and Infectious Diseases (NIAID), Roche Sequencing Solutions, Farmingdale State College, and Stony Brook University—collaborated to develop a multiplex serologic assay known as the TBD-Serochip. The development of this technology reflects ongoing challenges in diagnosing tick-borne diseases (TBDs), including variable performance of existing tests, inter-laboratory differences in results for pathogens such as Anaplasma, Babesia, Ehrlichia, and Rickettsia, and the absence of widely available

diagnostics for several emerging tick-borne pathogens. These limitations have become more significant as the number and geographic spread of tick-borne infections in the United States continues to increase.

The TBD-Serochip is a high-density peptide microarray designed to detect antibodies to a wide range of tick-borne pathogens using a single patient sample. The platform screens immune responses against more than 170,000 peptide fragments derived from tick-borne pathogens, enabling simultaneous detection of antibodies associated with infections such as Anaplasma phagocytophilum, Babesia microti, Borrelia burgdorferi, Borrelia miyamotoi, Ehrlichia chaffeensis, and Rickettsia rickettsii, as well as viral agents including Powassan virus and Heartland virus. Because the platform is built on a flexible peptide array design, new pathogen targets can potentially be incorporated relatively quickly as additional tick-borne pathogens are discovered or characterized.

The TBD-Serochip remains primarily a research or advanced development tool rather than a routinely deployed clinical diagnostic assay. Additional clinical validation, regulatory review, and workflow optimization are still required before it can be implemented widely in clinical laboratories. Another limitation of serologic approaches such as this is that antibody detection may reflect previous exposure rather than active infection, which means the assay would likely need to be interpreted alongside established diagnostic algorithms—such as the two-tiered Lyme disease testing strategy or pathogen-specific molecular testing—to help distinguish current infections from past exposures.

Despite these limitations, multiplex serologic technologies such as TBD-Serochip demonstrate the potential for broad-spectrum surveillance and improved differential diagnosis of tick-borne diseases, particularly in patients with complex or atypical presentations where multiple pathogens may be possible. Further development of these platforms may eventually support more comprehensive testing strategies as the landscape of tick-borne infections evolves.

Market Analysis - Molecular Microbiology

Over the past 25 years, PCR-based infectious disease testing has exploded into a highly competitive market. There are three companies, Cepheid, Roche, and bioMérieux, that provide a significant share of molecular microbiology test sales. A diverse set of other major players compete in the field, each with its own niche in instrumentation, assays, or integrated workflows. Other major companies in the molecular microbiology market include Hologic, Beckman Colter, Thermo Fisher, QIAGEN, BD, Abbott, Diasorin, and Siemens Healthineers.

The molecular microbiology market has grown rapidly over the past decade, reaching $6.9 billion in 2025 (excluding specific COVID-19 testing, which is valued at $1.8 billion for the year. The market is expected to grow to $10.6 billion by 2030, demonstrating a CAGR of 4.2% over the forecast period.

Molecular microbiology tests are expensive compared to traditional microbiology or immunology, and the largest geographical markets for molecular microbiology tests are currently in developed regions such as North America (44%) and Europe (35%), Asia Pacific (13%). Indeed, use of molecular technology continues to be a function of a developed world but is only 8% of the molecular microbiology testing market.

Table 11-14: Global Molecular Microbiology Sales Distribution by Region, 2025 (%)

[Asia Pacific, Europe, North America, RoW]

Region	% Mkt
North America	44%
Europe	35%
Asia Pacific	13%
RoW	8%
Total	**100%**

Source: Kalorama Information

Cost is an important issue in all clinical laboratories. Microbiology has been undergoing significant changes for many years now. It is certainly not surprising that technologies with advantages in speed and quality of results are also more expensive than traditional microbiology.

Traditional microbiology remains viable, and its reagents are inexpensive compared to many other technologies now used in the microbiology laboratory. However, traditional microbiology is very labor-intensive and can take days to generate results. Many laboratories have invested in equipment to automate some or all of the traditional microbiology methods.

Immunoassays are relatively inexpensive and can be performed on automated analyzers. They can also generate results relatively quickly. However, immunoassays that detect organisms or their antigens are typically less sensitive than molecular methods.

The major pathogens/disease indications targeted by companies in this market are hepatitis, HIV, healthcare-acquired infections and sepsis, respiratory pathogens, and sexually transmitted diseases/women's health.

Table 11-15: Global Molecular Microbiology Market, by Pathogen/Disease Indication, 2025-2030 ($ million)

[Blood Bank Screening; GC/Chlamydia; HAI; Hepatitis; HIV; Mycobacteria/TB; Organism ID; Respiratory; Others]

Pathogen	2025	% Mkt	2030	% Mkt	CAGR
Respiratory (including COVID)	3,408	39.3%	4,103	38.6%	4%
HAI	1,772	20.4%	2,090	19.7%	3%
Hepatitis	1,419	16.4%	1,932	18.2%	6%
HIV	946	10.9%	1,060	10.0%	2%
GC/Chlamydia	465	5.4%	544	5.1%	3%
Mycobacteria/TB	270	3.1%	410	3.9%	9%
Organism ID	200	2.3%	225	2.1%	2%
Others	192	2.2%	267	2.5%	7%
Total	**8,672**	**100%**	**10,631**	**100%**	**4%**
Blood Bank Screening	1,330	--	1,790	--	6%

Note: Percentages rounded

Source: Kalorama Information

The table above represents the market for molecular microbiology tests. The market is estimated at $8,672 million, with an additional $1,330 million representing blood bank screening. With 4% growth, the segment is expected to reach $10,631 million in 2030. Molecular blood bank screening will likely make moderate gains, reaching $1,790 in 2030.

Molecular diagnostics demonstrated their value during the COVID-19 pandemic, accelerating adoption across microbiology laboratories and reinforcing the role of nucleic acid amplification technologies in infectious disease testing. The widespread deployment of molecular testing during the pandemic highlighted its ability to deliver high sensitivity, rapid turnaround times, and scalable testing capacity. As a result, molecular methods have become increasingly integrated into routine microbiology workflows and continue to influence the direction of the diagnostic market. Recent advances in molecular microbiology, including

multiplex PCR panels, syndromic testing, and decentralized testing platforms, have the potential to further transform how infectious diseases are diagnosed and managed.

These advances are particularly relevant in areas such as community-acquired pneumonia, where traditional diagnostic approaches often have limited sensitivity and may take days to produce actionable results. Studies examining diagnostic challenges in pediatric conditions have emphasized the limitations of conventional microbiological methods and the growing importance of rapid molecular testing. Rapid detection of the specific pathogen responsible for pneumonia, whether bacterial, viral, or mixed infection, can significantly improve clinical decision-making, allowing clinicians to target therapy more effectively and reduce unnecessary antibiotic use.

One of the most important developments in recent years has been the emergence of true rapid molecular tests designed for near-patient or point-of-care use. These systems combine simplified sample preparation, automated nucleic acid amplification, and rapid detection in compact platforms suitable for decentralized healthcare settings. Several diagnostic companies have commercialized molecular platforms that deliver results in under an hour and have achieved CLIA-waived status for selected assays, enabling their use in physician offices, urgent care clinics, pharmacies, and other point-of-care environments.

Companies such as Roche, Cepheid (Danaher), Abbott, Sekisui Diagnostics, and QuidelOrtho have introduced rapid molecular diagnostic systems targeting respiratory infections and other infectious diseases. These platforms support point-of-care detection of pathogens such as SARS-CoV-2, influenza, RSV, and Group A Streptococcus. The continued development of rapid molecular diagnostics, combined with the increasing availability of CLIA-waived assays, is expected to expand access to accurate testing at the point of care and further reshape the clinical microbiology testing landscape.

Lab Automation and Molecular Diagnostics

The foundations of clinical molecular diagnostics began to take shape in the 1960s with early work in nucleic acid analysis and molecular biology. The modern era of molecular testing, however, began with the invention of the polymerase chain reaction by Dr. Kary B. Mullis in the 1980s while working at Cetus Corporation in Emeryville, California. PCR provided a method for amplifying extremely small amounts of DNA, enabling the rapid and highly sensitive detection of genetic material. In 1991, Cetus sold the PCR intellectual property rights to F. Hoffmann-La Roche Ltd. for approximately $300 million. At the time, the price

was widely viewed as excessive, but PCR ultimately became the core technology underlying modern molecular diagnostics, proving to be one of the most influential innovations in clinical laboratory medicine.

During the early expansion of molecular diagnostics, Roche introduced PCR-based platforms such as the Amplicor and LightCycler systems, which became widely adopted in molecular laboratories. These instruments helped establish PCR as a routine diagnostic tool for detecting infectious diseases, genetic mutations, and other molecular targets. Over time, molecular testing evolved toward greater automation, higher throughput, and integrated workflows.

Roche is one of the leading suppliers of molecular diagnostic systems through its cobas portfolio of fully automated PCR platforms. Systems such as the cobas 5800, cobas 6800, and cobas 8800 support high-throughput molecular testing and are widely used in clinical laboratories for infectious disease diagnostics, viral load monitoring, blood donor screening, and other nucleic acid–based assays. These automated platforms integrate sample preparation, amplification, and detection in a single workflow, reflecting the continued evolution of PCR from a research technique into a cornerstone of modern clinical diagnostics.

Table 11-16: Selected Automated Molecular Test Instrument Platforms

Company	Location	Technology	Details
Abbott Diagnostics	U.S.	PCR	Alinity m molecular
Abbott Diagnostics	U.S.	PCR	Plex-ID platform
Abbott Diagnostics	U.S.	PCR	Abbott m2000 RealTime System
Becton Dickinson	U.S.	SDA	BD ProbeTec ET System and Viper
Biocartis	Switzerland	PCR	Fast-Track oncology assays on Idylla
bioMérieux/BioFire	U.S.	PCR	FILMARRAY Torch platform, random access multiplex PCR
Cepheid	U.S.	PCR	SmartCycler and GeneXpert
Diasorin	Italy	PCR	LIAISON MDX disc platform
GeneSTAT Molecular Diagnostics	U.S.	PCR	RT-PCR GeneSTAT platform, RNA, DNA
GenMark Diagnostics (Roche)	U.S.	PCR	ePlex sample-to-answer system, PCR
Genomica	Spain	platform	CLART (Clinical Array Technology) platform
Hologic	U.S.	TMA	Aptima reagents on Tigris and PANTHER instruments
Luminex (Diasorin)	U.S.	PCR	Verigene SP System, automated inf dis testing
Meridian Bioscience	U.S.	PCR	Revogene infectious diseases
Meridian Bioscience	U.S.	LAMP	Alethia (illumigene)
Qiagen	Netherlands	PCR	QIAsymphony RGQ MDx system for clinical labs
QuidelOrtho	U.S.	HDA	Solana molecular system
Revvity	U.S.	platform	Applied Biocode 96 well
Roche Diagnostics	U.S.	PCR	cobas 6800 system
Roche Diagnostics	U.S.	PCR	cobas Liat PCR system, CLIA waived
Siemens Healthineers	U.S.	PCR	VERSANT kPCR Molecular System
Thermo Fisher Scientific	U.S.	PCR	Ion Torrent line

Source: Kalorama Information

Molecular technology is making a valuable contribution to clinical diagnostics on many fronts. Commercially available kits are used for a variety of conditions, including infectious diseases, primarily hospital-acquired infections, tuberculosis, hepatitis, gonorrhea, HIV, and chlamydia; coagulation gene mutations; HLA tissue typing; hereditary and chronic diseases; and a slew of cancers. In most cases, the information provided by these tests will affect the choice of therapy and the aggressiveness of the therapeutic strategy to be taken.

In light of the extraordinary times we are living through as a result of the COVID-19 pandemic and other infectious disease epidemics, the remainder of this section will focus on molecular testing in microbiology and virology. Molecular diagnostic tests directly target infectious agents, such as bacteria and viruses, by using DNA and RNA probes that recognize their genetic signatures.

The menu of molecular diagnostics has expanded since the 1990's introduction of PCR tests for tuberculosis, HIV and Chlamydia Trachomatis/Neisseria Gonorrhoeae by Roche Diagnostics, Gen-Probe (now part of Hologic) and Becton Dickinson.

The first PCR-based instruments performed tests as unique entities. Now molecular platforms from companies such as Abbott Diagnostics, Luminex (Diasorin), bioMérieux's BIOFIRE's Film Array, Roche Diagnostics and others can run panels of up to 30 targets, and in less than 1 hour in some cases. They are also leading the way to random access rather than batch testing, which, while commonplace with immunoassays, has been slower coming to microbiology. This is because traditional microbiology has a history of treating each sample in a unique process.

The anticipated demand for molecular infectious disease tests has encouraged the commercialization of molecular instrumentation for microbiology and virology testing. Thus, microbiology companies continue to expand their product portfolios and upgrade their systems, primarily by automating microbiology test procedures across all areas of the test segment. The result is the development of a variety of new platforms that bypass the traditional ID/AST first step by enabling direct testing of blood, urine, nasal swabs, sputum, etc. Note that mass spectrometry analysis is performed on a bacterial culture colony.

In an era of rapid automated test results, microbiology still has a lot to do. The imperative for the 21st century is to determine as quickly as possible if a person has an infection, decide whether to treat or not to treat and then select a method of treatment. All too often, patients have been given antibiotics when not required. This has contributed to the current problem

of antibiotic resistance in bacteria. It can be argued that efficient rapid tests in hospitals, clinics, physician offices and other care sites would have solved many issues related to infectious disease diagnostics.

Yet challenges remain in seeing the new methods developed completely, past regulatory hurdles, and integrated successfully in clinical practice. Further, the main advantages culture has over newer methods are its comparatively low cost and proven antimicrobial susceptibility testing.

Several trends are evident as the field of molecular infectious diseases evolves:

- integrated sample to answer test systems respond to the need for easy-to-use molecular tests for all sizes of labs
- random access sample processing on instrumentation
- direct tests from the sample without time-consuming sample pretreatment for DNA extraction
- tests for high-demand pathogens are coming to market including: C. difficile, TB, respiratory infections, and STDs
- companies are beginning to develop sequencing systems for a wide variety of targets
- CLIA moderate molecular test instruments provide smaller labs the opportunity to run molecular tests in-lab without having to send them out

Molecular Respiratory Infection Testing

Respiratory infections are a major public health problem. Patients who present with these infections may have similar symptoms, but it is important to identify the causative virus to select appropriate therapy. Here, molecular is an advantage. The importance of screening for many respiratory diseases as a panel is evident by the number of molecular respiratory pathogen panels that have been introduced in recent years.

Respiratory tract infections were responsible for tremendous morbidity and disease burden. Recent flu seasons have taken a toll in the United States, justifying the use of advanced systems for detection

- 2025: Between October 1, 2025 and April 11,2026, there have been 31-54 million cases of flu with between 23,000 and 78,000 deaths (preliminary)
- 2024: Between October 1, 2024 and June 15, 2025, there have been 20-35 million cases of flu with 13,000 deaths
- 2023: Between October 1, 2023 and June 15, 2024, there have been 35-65 million cases of flu with 21,000 deaths
- 2022: Between October 1, 2022 to April 30, 2023, there have been 27-54 million cases of the flu and 19,000 -58,000 deaths from the flu.
- 2021: Approximately 8 million to 13 million people were sickened with the flu between October 1, 2021 and June 11, 2022 for this flu season.
- 2020: Approximately 39 million to 56 million people were sickened with the flu between Oct. 1, 2019, and April 4, 2020, according to CDC's last in-season influenza burden estimate for this flu season.
- 2019: CDC estimates that the burden of illness during the 2018–2019 season included an estimated 35.5 million people getting sick with influenza, and 34,200 deaths from influenza.
- 2018: one of the more severe flu seasons. The overall burden of influenza for the 2017-2018 season was an estimated 45 million influenza illnesses and 61,000 influenza-associated deaths

Respiratory illness leads to mortality in vulnerable populations such as children, the elderly, and immunocompromised individuals. The WHO has indicated that respiratory tract infections are among the top four causes of morbidity and mortality worldwide.

Molecular tests were not historically common in flu testing, but due to their sensitivity and advances in technology, there has been an uptake. Kalorama has estimated the market for molecular respiratory infections at $1,645 million in 2025 and, with 7.2% growth, will reach $2,325 million in 2030. For the 2024-2025 season, COVID-19 infections led to increased testing for other respiratory diseases to confirm or rule out COVID-19. Major vendors reported that the segment delivered above-average revenue growth in flu testing. Over the past couple of years, major vendors have noted an increase in system installations during severe influenza seasons or in response to testing demands from the previous year. The rapid identification of respiratory pathogens is particularly important for vulnerable populations such as hospitalized patients, the elderly, and individuals with compromised immune

systems. Early detection of the causative organism and any associated antimicrobial resistance markers helps guide appropriate treatment decisions and supports antimicrobial stewardship efforts. Multiplex molecular panels that can simultaneously detect multiple viral and bacterial pathogens have therefore become an important component of modern respiratory diagnostics.

One of the most widely used systems is the BIOFIRE FILMARRAY Respiratory Panel, marketed by bioMérieux. The current Respiratory Panel 2.1 (RP2.1) detects multiple viral and bacterial pathogens in a single test, including influenza viruses, respiratory syncytial virus, SARS-CoV-2, adenovirus, parainfluenza viruses, human metapneumovirus, rhinovirus/enterovirus, and several bacterial targets such as Mycoplasma pneumoniae, Chlamydia pneumoniae, and Bordetella pertussis. The system provides results in approximately one hour and is widely used in hospital laboratories and near-patient testing environments.

Multiplex molecular testing for respiratory infections has also been pursued by other companies. The Unyvero platform, originally developed by Curetis, included lower respiratory tract and pneumonia panels that could detect numerous pathogens and antibiotic resistance markers directly from clinical specimens. The technology is now associated with OpGen, and while development and regulatory activities have continued in some markets, adoption has been more limited than that of leading syndromic PCR systems.

Several additional manufacturers now offer multiplex respiratory diagnostic panels, including Cepheid, Roche, QIAGEN, Seegene, Luminex/Diasorin, and others. These platforms provide rapid, sample-to-answer molecular testing that can identify a broad range of respiratory pathogens and, in some cases, key antimicrobial resistance markers. The continued expansion of multiplex respiratory testing reflects the growing need for rapid pathogen identification, improved patient management, and more targeted antibiotic use in respiratory infections.is still a flurry of multi-pathogen tests hitting the market.

Diasorin markets its LIAISON PLEX system, including its first panel of tests, the LIAISON PLEX Respiratory Flex Assay. The LIAISON PLEX is a new multiplexing platform that enables test customization, providing flexibility for infectious disease syndromic diagnostics. The LIAISON PLEX Respiratory Flex Assay tests for 19 pathogens, including 14 viral and 5 bacterial targets.

Roche offers its breakthrough TAGS technology. Roche markets the cobas Respiratory flex test, with TAGS (temperature-activated generation of signal) technology. The technology uses multiplex PCR testing combined with color, temperature, and data processing to identify 15 pathogens in a single PCR test. The cobas Respiratory flex test can detect up to 12 common respiratory viruses, including influenza A, B, RSV, and SARS-CoV-2, in a single sample. The cobas Respiratory flex test runs on the cobas 5800,6800, and 8800 systems.

The Respiratory Trio – Flu, Strep, RSV

The success of molecular systems opens opportunities for distinguishing a possible influenza result from other diseases. Other than flu, the most promising respiratory conditions treated are RSV and Strep A. RSV is a very common cause of respiratory tract infection, especially in young children. RSV is a member of the Paramyxoviridae family of viruses. There are two types of RSV, A and B, and many strains. RSV has an RNA genome that encodes 10 viral proteins. The virus has a lipid envelope containing viral glycoproteins involved in viral entry into cells and fusion of the viral envelope with cell membranes. Much of the pathology caused by RSV is related to damage to the lining of the small airways of the respiratory tract.

Group A Streptococci (GAS) are responsible for most cases of streptococcal pharyngitis, although other groups, such as C and G, may also cause disease. Strep throat affects all age groups but is most common in children between the ages of 5 and 15 years. Strep throat has an incubation period of 2-4 days. Classic symptoms include the abrupt onset of sore throat accompanied by fever, malaise and headache.

QIAGEN markets its QIAstat-Dx syndromic testing system and respiratory assay panel for the detection of multiple respiratory viral and bacterial pathogens. The panel provides simultaneous testing for more than 20 pathogens. Syndromic testing using molecular diagnostics can identify illnesses that present with a set of symptoms of uncertain cause, such as influenza or pneumonia. QIAGEN said it expects to release numerous diagnostics for infectious diseases, oncology, and other areas. Additional respiratory pathogens targeted in molecular POC assay development include Bordetella pertussis, S. pneumoniae, viruses such as adenovirus, rhinovirus, human metapneumovirus (hMPV), parvovirus, and parainfluenza.

A new emerging opportunity in molecular microbiology is DNA and RNA sequencing. The first sequencing-based microbiology test, Abbott's ViroSeq HIV-1 Genotyping System (which is based on Sanger sequencing technology), has been on the market for several years. Abbott currently markets two infectious disease assays based on Sanger sequencing. The

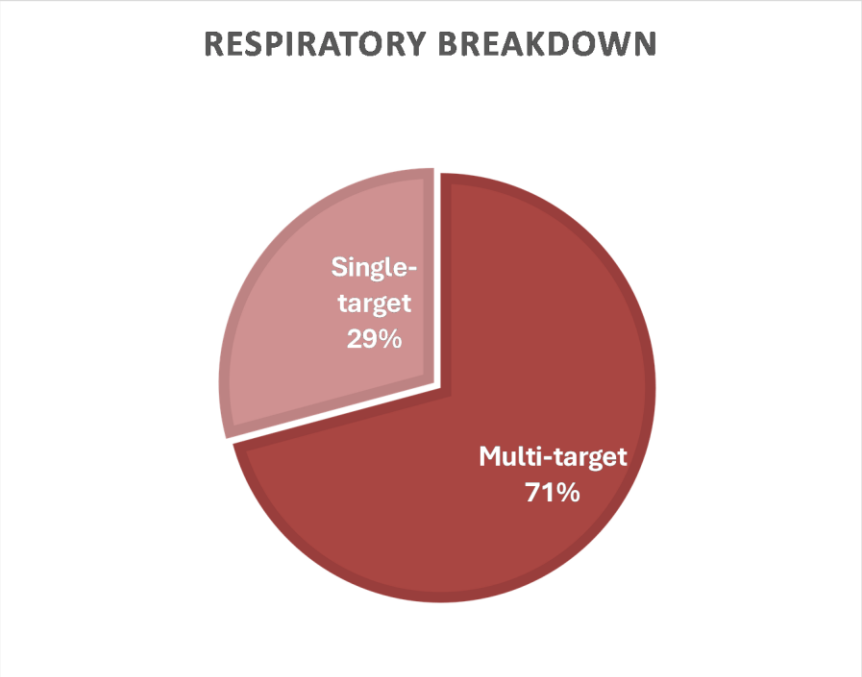
ViroSeq HIV-1 Genotyping System is intended for use in detecting HIV genomic mutations that confer resistance to specific types of antiretroviral drugs, as an aid in monitoring and treating HIV infection. It is available in the United States and internationally. In addition, the HBV Sequencing Assay is available outside the U.S.

Sanger sequencing is both slow and expensive, and this technology has not gained widespread use in clinical microbiology. Next-generation sequencing builds upon the basic strategy of Sanger sequencing. Some companies currently offer laboratory-developed next-generation sequencing-based tests and sequencing-based IVD tests.

The sequencing-based microbiology tests and development activities discussed here are likely to be just the start of a new era in molecular microbiology testing.

Figure 11-3: Molecular Respiratory Testing, by Target Pathogens, 2025 (%)

[Multi-Target, Single-Target]



Source: Kalorama Information

Molecular Testing for Sexually Transmitted Diseases

Sexually transmitted diseases are a foundational area of sales for the molecular testing market for GC and Chlamydia, and Kalorama estimates the market at $465 million in 2025 and growing to $540 million in 2030 at a CAGR 3% per year. The first FDA-cleared PCR-based test was developed by Roche for the detection of Chlamydia trachomatis, and the sexually transmitted disease market remains a major segment of the infectious disease molecular diagnostic market. Many of the chlamydia tests available today are combination tests that detect both Chlamydia trachomatis and Neisseria gonorrhea.

The first clinical test for human papillomavirus (HPV) was developed by Digene, which was later acquired by QIAGEN. Initially, HPV testing was limited to abnormal Pap smear samples. Use of HPV tests as part of cervical cancer screening has expanded, and HPV tests are now used together with Pap smears as women are screened. The market for HPV testing expanded but then faced pressure as guidelines changed, recommending Pap smear and HPV testing every 3 years. Four years ago, the FDA approved the use of the cobas HPV test for first-line primary screening for cervical cancer and high-risk HPV infection with or without a Pap smear. In 2018, that was expanded for women under 25 as well. Roche's HPV test remains the only FDA-cleared test for primary screening for cervical cancer. Other companies, including Hologic, also offer HPV tests now. (HPV revenues are covered in Chapter 13).

The Hologic PANTHER system remains widely used for high-throughput molecular testing, particularly for sexually transmitted infection diagnostics, including Chlamydia trachomatis and Neisseria gonorrhoeae. The platform supports primary tube sampling and continuous random-access loading, allowing laboratories to add samples, reagents, and consumables without interrupting workflow. Multiple assays can be performed from a single specimen, enabling efficient multiplex testing and high productivity in centralized laboratories. The PANTHER system is designed with a relatively compact footprint and automated workflow, making it suitable for high-volume clinical laboratories.

Hologic expanded the PANTHER platform with the PANTHER Fusion module, which adds real-time PCR capability to complement the company's Aptima transcription-mediated amplification assays. The Fusion module enables modular syndromic testing, particularly for respiratory infections, allowing laboratories to run individual or multiple respiratory assays from a single patient sample. The PANTHER component is optimized for high-volume liquid-reagent assays, while the Fusion module supports cartridge-based PCR testing suited

to lower-volume or specialized assays. PANTHER Fusion respiratory assays include tests for influenza A/B, RSV, parainfluenza viruses, adenovirus, rhinovirus, and human metapneumovirus, with additional menu expansion over time.

Seegene offers the Allplex STI Essential Assay, a multiplex real-time PCR test that simultaneously detects multiple sexually transmitted pathogens in a single reaction. The assay targets organisms including Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, Mycoplasma hominis, Ureaplasma urealyticum, and Ureaplasma parvum. The test uses Seegene's proprietary DPO (Dual Priming Oligonucleotide) and MuDT (Multiple Detection Temperature) technologies, which enable the simultaneous detection and quantification of several targets while reporting individual Ct values for each organism.

Roche Diagnostics offers molecular assays for sexually transmitted infections on its cobas 6800 and cobas 8800 systems, including the cobas TV/MG assay, which detects Trichomonas vaginalis and Mycoplasma genitalium DNA in symptomatic and asymptomatic individuals. These high-throughput systems are widely used in large laboratories for infectious disease testing, including blood-borne viruses and women's health applications.

QIAGEN has also expanded its automated molecular testing portfolio through the NeuMoDx 96 and NeuMoDx 288 systems, which support random-access PCR testing. These platforms provide automated sample preparation, amplification, and detection, allowing laboratories to run multiple assays simultaneously. The test menu includes assays for sexually transmitted infections, hepatitis viruses, HIV, respiratory pathogens, and transplantation-related monitoring, as well as the ability to run laboratory-developed tests.

Hologic has further broadened its women's health testing portfolio with assays such as Aptima BV and Aptima CV/TV, which detect pathogens associated with bacterial vaginosis, Candida infections, and trichomoniasis. The Aptima Multitest Swab Specimen Collection Kit allows clinicians to collect a single specimen for testing multiple infections, including bacterial vaginosis, Candida species (including Candida glabrata), trichomoniasis, chlamydia, gonorrhea, and Mycoplasma genitalium. These assays are performed on the PANTHER system using Hologic's Aptima sample transport tubes.

Another approach to multiplex STI testing is offered by Randox, whose Sexually Transmitted Infection Multiplex Array uses a combination of multiplex PCR and biochip array hybridization to detect multiple bacterial, viral, and protozoan pathogens simultaneously.

This system can identify primary infections as well as co-infections, providing a broader diagnostic profile for sexually transmitted disease testing.

BD markets its Onclarity HPV assay for self-collection. The new approval of self-collected samples will provide more individuals with access to cervical cancer screening.

Molecular Hepatitis Testing

The two most significant molecular hepatitis tests by revenue are for hepatitis B virus (HBV) and hepatitis C virus (HCV), which together account for the majority of the molecular hepatitis diagnostics market. In 2025, the global molecular hepatitis testing market is estimated at approximately $1.4 billion, driven primarily by viral load monitoring and ongoing disease management rather than initial diagnosis alone. Historically, key intellectual property for molecular hepatitis diagnostics originated with the Novartis Diagnostics business, which Grifols acquired in 2013. This acquisition helped shape the competitive landscape, and today the market is dominated by major core laboratory suppliers, including Abbott, Roche Diagnostics, Siemens Healthineers, and Hologic, all of which offer integrated molecular platforms for high-throughput viral testing.

Molecular testing plays an important role in the diagnosis and clinical management of HBV and HCV infections. Nucleic acid amplification tests are used to confirm infection and, more importantly, to quantify viral load, which is essential for monitoring treatment response and guiding therapy decisions. Quantitative viral load assays remain the backbone of hepatitis management in clinical laboratories. Increasingly, reflex testing algorithms are being implemented, in which a positive antibody screen is automatically followed by molecular viral load testing, improving diagnostic rates and streamlining workflows. While genotyping was historically important, particularly for HCV, its role has declined with the widespread adoption of pan-genotypic antiviral therapies. For example, Siemens Healthineers' VERSANT HCV Genotype 2.0 assay (LiPA) was once widely used for genotype determination, but demand has decreased as treatment approaches have evolved.

High-throughput molecular platforms continue to dominate centralized testing. Hologic offers HBV and HCV viral load assays on its PANTHER system, enabling parallel testing of multiple infectious diseases, including HIV, HBV, and HCV, on a single automated platform. Abbott and Roche Diagnostics similarly provide comprehensive viral load menus integrated into their core laboratory molecular systems. Sequencing-based assays, once used for

genotyping and resistance detection, have become less common in routine practice, although they may still be used in specialized settings.

Point-of-care and near-patient molecular testing has emerged as a complementary segment, particularly for expanding access in decentralized and resource-limited environments. Cepheid offers HCV and HBV molecular assays on its GeneXpert platform, providing relatively rapid results and enabling testing closer to the patient. In emerging markets, companies such as Molbio Diagnostics have developed portable molecular systems, such as the Truenat platform for HBV testing, to support broader screening and monitoring initiatives. Regional manufacturers, including Shanghai Kehua Bio-Engineering, continue to supply PCR-based hepatitis assays tailored to local markets. In addition, alternative sample-collection approaches, such as dried blood spots and plasma separation cards, are being used to simplify logistics and expand access in remote settings.

The molecular hepatitis testing market is mature and increasingly shaped by global screening and elimination efforts, particularly for HCV. Growth is being driven by expanded testing programs, improved access to care, and integration with other infectious disease workflows, especially HIV, where multi-disease testing platforms improve efficiency and utilization. The trend is toward broader access, decentralized testing, and streamlined clinical pathways rather than the introduction of entirely new standalone assays.

Molecular HIV Testing

The market includes molecular testing such as genotyping, quantitative and qualitative for HIV. A sizable market can be expected based on HIV-positive patient populations in the United States and major international markets for HIV care in Latin America, Africa, and Asia. Available parameters for HIV patient populations were used to estimate viral load (VL) test volume. Available indicators were used to adjust HIV VL to actual market demand (i.e., how much demand is instead met by CD4 or p24 antigen testing options for patients on antiretroviral therapy.

Molecular HIV testing is fairly mature, generating $946 million in 2025, with most innovation and growth relating to antiviral therapy, including testing for viral load, viral tropism, and drug resistance. Clinical approaches to HIV in the United States, Europe and other developed countries emphasize molecular testing as a tool for the management of chronic infection and achieving viral suppression. The focus of innovation among molecular

HIV test vendors is to improve their relevance to antiretroviral therapy and to tap opportunities in the developing world with simple, affordable tests.

Rapid HIV screening tests and other advanced diagnostic lab tests are already widely available in many developing countries at concessional or discounted prices through centralized procurement programs. Molecular HIV diagnostics for viral load testing will require similar concessional pricing in order to implement antiretroviral treatment (ART) worldwide. Ruggedness, simple operation (integrated test performance), and low-cost reagents will be critical features of any molecular HIV diagnostic product intended for widespread deployment in the developing world. Currently, molecular tests are very rarely used for HIV screening outside of at-risk infants. Detection of HIV DNA is used for early infant detection as it bypasses false positives from maternal anti-HIV antibodies. The long-term development of the molecular HIV test market will depend on improved availability of antiretroviral therapy.

The widespread availability of rapid and laboratory-based immunoassays, which are significantly less expensive than molecular methods, continues to limit the growth of qualitative molecular HIV testing. In contrast, market growth in HIV diagnostics is largely driven by quantitative assays for viral load monitoring and genotyping tests that guide antiretroviral therapy (ART) decisions. Advances in antiretroviral drugs have set new standards for treatment effectiveness, allowing for near-complete suppression of viral replication in many patients. Effective management of HIV requires a combination of testing approaches: genotypic assays identify mutations associated with drug resistance, while phenotypic assays assess how well the virus replicates at specific drug concentrations.

The majority of the molecular POC HIV test market would be for quantitative or VL assays performed at points of care. Global HIV programs are expected to influence progress from earlier campaigns for HIV screening to treatment coverage and viral suppression. As a result, the global number of patients on ART is expected to grow significantly, driving demand for viral load tests. Without access to testing facilities, many ART patients in low-resource areas will rely on rugged, rapid molecular systems used in near-patient settings. Linking ART patients to routine VL testing is expected to be one of the primary challenges in the HIV testing market.

In terms of new test launches, several qualitative home-based HIV self-tests have been commercialized and continue to generate increasing demand, particularly as public health programs expand access to decentralized screening and self-management. Most currently

marketed home HIV self-tests remain non-molecular lateral flow immunoassays, since these offer simplicity, affordability, rapid turnaround, and no instrumentation requirements. Examples include Atomo HIV Self-Test developed by Atomo Diagnostics and OraQuick In-Home HIV Test from OraSure Technologies. Atomo's device has expanded through international public health procurement channels, while OraQuick remains one of the most established over-the-counter HIV self-tests globally.

Molecular HIV testing still does not offer the same level of convenience and consumer simplicity as lateral flow self-tests, although point-of-care molecular HIV testing remains a strategic priority for several molecular diagnostics companies because of its superior analytical sensitivity and ability to support viral load monitoring. Cepheid continues to offer qualitative HIV detection and viral load assays on the GeneXpert System platform, including Xpert HIV-1 Qual and Xpert HIV-1 Viral Load assays, delivering results in approximately 90 minutes with minimal hands-on time. The self-contained cartridge design reduces the risk of contamination and eliminates liquid waste handling, making the system suitable for decentralized laboratories and near-patient settings.

Several other companies have also expanded near-patient molecular HIV testing. Molbio Diagnostics continues to market Truenat HIV-1, a chip-based real-time PCR assay run on the portable Truenat platform. The system is designed for decentralized, resource-limited settings and has gained traction for combining portability, battery operation, and rapid nucleic acid amplification in a compact format. Molbio has also broadened its Truenat menu across tuberculosis, hepatitis, respiratory infections, and other infectious diseases, strengthening its role in near-patient molecular diagnostics.

The HIV testing market continues to show a dual-track trend: rapid growth in self-testing immunoassays for screening and sustained expansion of portable molecular platforms for confirmatory diagnosis, early infant diagnosis, and viral load monitoring, particularly in low-resource and high-burden regions

Abbott's ViroSeq HIV-1 Genotyping System is intended for use in detecting HIV genomic mutations that confer resistance to specific types of antiretroviral drugs, as an aid in monitoring and treating HIV infection. It is available in the United States and internationally. This assay is based on Sanger sequencing. Next-generation sequencing could make sequencers viable clinical platforms for HIV genotyping. An example of a currently available HIV clinical testing service based on next-generation sequencing is ARUP Laboratories' DEEPGEN test for HIV-1 genotyping and tropism.

Outside developed countries, rapid HIV screening tests and other advanced diagnostic lab tests are already widely distributed at concessional or discounted prices through centralized procurement programs. Molecular HIV diagnostics for viral load testing require similar concessional pricing for use with antiretroviral treatment worldwide. Ruggedness, simple operation and low-cost reagents will be critical features for any molecular HIV analyzer hoping to be widely deployed in the developing world.

Qualitative molecular HIV tests share the market for HIV detection and diagnosis with rapid and lab-based immunoassays. The tests can be used to detect early infections, including those in infants born to HIV-positive mothers. Growth in the HIV market is largely driven by quantitative tests for viral load monitoring and genotyping tests to assess antiretroviral therapy options. Antiretroviral drugs are setting new standards in effectiveness with therapy able to completely suppress viral replication. With over 28 individual drugs from six different classes approved for the treatment of HIV-1 infections, a combination of different phenotypic and genotypic tests is necessary to monitor HIV-infected patients. Genotypic tests identify particular mutations associated with resistance and phenotypic tests measure the ability of a viral infection to grow in the presence of known drug concentrations.

Table 11-17: Innovations in Molecular POC Diagnostics for HIV

Company	Remarks
Abbott	Determine for HIV Early Detect RealTime HIV-1
Atomo Diagnostics	Atomo HIV Self Test
Cepheid, USA (Now a part of Danaher Company)	Xpert HIV-1 Viral load: quantitative molecular test; RNA extraction, purification, reverse transcription and cDNA real time quantitation - integrated
Hologic	Aptima HIV-1 Quant Dx
InSilixa, USA	HIV diagnostic and drug resistance genotyping assays (In development); CMOS biochips technology; aiming at 1-hour sample to answer solutions
Molbio Diagnostics	Truenat HIV-1
QuantuMDx Group Ltd., UK	Q-POC™ device, a portable molecular diagnostic device; provide results in less than 30 minutes
Rheonix, USA	Developed molecular testing solution (microfluidic system and assay); simultaneously detect host anti-HIV antibodies and viral RNA in a single specimen of saliva or blood
Roche	Cobas HIV-1

Source: Kalorama Information

Molecular Tests for Hospital-Acquired Infections (HAIs)

Hospital-acquired infections (HAIs) are infections acquired by patients during hospital treatment. The broader term healthcare-associated infections refer to infections that patients get while being treated at any healthcare facility. HAIs are a major and often preventable problem.

The table below notes the most common general nosocomial infection types.

Table 11-18: Frequency of the Most Common Nosocomial Infections

Infection Site	Incidence: Developed Regions	Incidence: Developing Regions
Urinary Tract Infection	3%-5% of all admissions	25%-30% of all admissions (80% due to device (catheter) use)
Pneumonia	1%-2% of ventilated patients/admissions	10%-15% of ventilated patients
Surgical Site Infection	5%-10% of discharges	15%-20% of wounds
Central Vascular Line	5%-15% of central vascular access patients	15%+ of all patients

Source: Kalorama Information

Assessing the Problem: Nosocomial Infection Statistics

The rise of an aging population presents a major challenge for modern healthcare, particularly due to the growing number of immunocompromised patients who are increasingly vulnerable to healthcare-associated infections. A critical concern is that many HAIs are caused by antibiotic-resistant microorganisms, making them more difficult and costly to treat. Antimicrobial resistance is a growing global threat, affecting not only developing countries but also advanced healthcare systems in regions like the EU and the United States.

In the U.S., HAIs are estimated to cause 100,000 deaths annually, with a nosocomial infection rate of 5% to 10% among hospital admissions. Similarly, the EU reports over 2 million new HAI cases each year, of which more than 400,000 are linked to AMR pathogens, resulting in approximately 30,000 deaths annually. These infections significantly increase healthcare costs, prolong hospital stays, and strain already limited inpatient resources—posing an urgent need for improved infection prevention, rapid diagnostics, and effective antimicrobial management.

Bloodstream infections are considered the most expensive inpatient condition in hospitals, costing more than $20 billion in the U.S. healthcare system and more than £2.8 billion in the United Kingdom. Hospitals have invested heavily in HAI surveillance, control and clinical testing solutions over the past five years in an effort to contain costs. The molecular AMR/HAI testing market is concentrated in the developed world, with the United States and Europe together representing 80% of the market; less- developed healthcare systems continue to rely predominantly on blood cultures and immunoassays for AMR/HAI testing.

Advancements in molecular testing have profoundly changed the landscape of HAI testing. Traditionally, blood cultures have been used to detect inpatient infections and sepsis, but their effectiveness is limited by long turnaround times and the non-specificity of initial results. Molecular diagnostics were first applied to identify pathogens in positive blood cultures through qualitative FISH assays. Without target nucleic acid amplification, FISH assays rely upon the blood culturing step to improve test sensitivity.

At present, molecular testing for HAIs and pathogen AMR is primarily performed using PCR and other molecular assays that amplify target nucleic acids directly from blood, wound sites, respiratory samples, or blood cultures. Nucleic acid amplification tests performed on integrated systems provide rapid and reliable multiplex results even outside of traditional molecular labs. Rapid testing is the primary growth area in the molecular AMR/HAI market, as hospitals seek to implement appropriate care as quickly as possible to save patient lives and reduce antimicrobial misuse.

Patients most at risk from antibiotic-resistant "superbugs" are often those who are already weakened by severe viral lung infections such as influenza, SARS, and COVID-19. These viral infections can compromise the immune system and damage respiratory tissues, creating a vulnerable environment for secondary bacterial infections, including those caused by multidrug-resistant organisms.

In particular, COVID-19 patients frequently experience severe lung inflammation, requiring high levels of oxygen and mechanical ventilation. While life-saving, ventilator use significantly increases the risk of ventilator-associated pneumonia (VAP). In addition to lung damage, patients on ventilators face a heightened risk of long-term cognitive impairment, physical debility, and complications related to sedation and prolonged immobility.

Unlike community-acquired pneumonia, which is more common and generally easier to treat, VAP is often caused by highly resistant bacteria, such *as Pseudomonas aeruginosa, Acinetobacter baumannii, or Klebsiella pneumoniae,* making it more difficult to manage and often resulting in more severe outcomes. It is estimated that up to 15% of ICU patients who require mechanical ventilation develop VAP. Contamination of the ventilator tubing or improper airway management can allow bacteria or secretions to bypass the body's defenses and colonize the lower respiratory tract.

Preventing VAP requires meticulous care by ICU staff, including strict adherence to infection control protocols, regular oral hygiene, proper maintenance of ventilator circuits, and

minimizing sedation to allow earlier weaning from the ventilator when possible. As antimicrobial resistance continues to rise, especially in intensive care settings, the importance of infection prevention, rapid diagnostics, and antimicrobial management cannot be overstated.

There are certain limitations to estimating the frequency and incidence of nosocomial infections. Kalorama Information has attempted to gather data from multiple sources and provide an estimate based on reported data

HAIs of common concern include infections by methicillin-resistant Staphylococcus aureus (MRSA), multidrug-resistant Escherichia coli, carbapenem-resistant Enterobacteriaceae (CRE), vancomycin-resistant Enterococci (VRE), Clostridium difficile (C-diff), and noroviruses. MRSA testing is included in all molecular HAI tests. A multiplex molecular assay is used to identify Staphylococcus aureus and detect its resistance gene. The U.S. CDC estimates that MRSA accounts for about 10% of all HAIs. European countries widely implemented MRSA screening for arriving patients to curb infection rates in the late 1990s.

Clostridium Difficile

Clostridium difficile (CDF/cdf', or 'C. diff') is a species of bacteria of the genus Clostridium, which are Gram-positive bacilli, anaerobic, spore-forming rods (bacilli). C. difficile is the most significant cause of pseudomembranous colitis. Clostridium difficile infection (CDI) can range in severity from asymptomatic to severe and life-threatening and many deaths have been reported, especially among the aged.

C. difficile is a bacterium living in harmony with other bacteria, not in a parasitic relationship, but deriving benefits from one another in the human intestine in a minority of the population. In small numbers, it does not result in any significant disease. Antibiotics, especially those with a broad spectrum of activity, disrupt the normal intestinal flora, leading to overgrowth of C. difficile, which flourishes under these conditions. This leads to pseudomembranous colitis.

Patients who have been staying long-term in a hospital or nursing home are more likely to be colonized by this bacterium. Clostridium difficile acquisition is estimated to be 13% in patients with hospital stays of up to two weeks and 50% in those with hospital stays longer than four weeks.

C. difficile is transmitted from person to person by the fecal-oral route. Because the organism forms heat-resistant spores, it can remain in hospital or nursing home environments for extended periods. It can be cultured from almost any surface in the hospital. Once ingested, spores pass through the stomach unscathed due to their acid resistance. They change to their active form in the colon and multiply.

Toxigenic culture, in which organisms are grown on selective media and then tested for toxin production, remains a highly sensitive and specific method, but it is slow and labor-intensive and is no longer routinely used for frontline diagnosis. Most laboratories now rely on faster molecular assays or multistep testing algorithms to support timely clinical decisions. Current practice generally recommends testing a single appropriate specimen rather than multiple samples, unless there is a strong clinical reason to repeat testing. Modern assays are designed to detect both toxin A and toxin B, or the genes that encode them, reflecting the recognized importance of toxin B in disease. Delays in diagnosis can still occur, but these are more often related to test selection and workflow rather than limitations in detecting specific toxins, and timely, accurate testing remains critical to improving patient outcomes.

Cepheid remains one of the leading companies in the HAI and AMR molecular diagnostics segment. Its Xpert MRSA NxG assay is an important rapid molecular test MRSA surveillance, providing accurate results in approximately one hour. Cepheid also strengthened its AMR menu through expanded FDA-cleared claims for Xpert Carba-R, a rapid molecular assay designed to detect carbapenemase-producing Gram-negative bacteria. The expanded claims include testing of perirectal swab specimens and the use of pure bacterial colonies, allowing laboratories to support both infection-prevention strategies and therapeutic decision-making. Cepheid's cartridge-based, near-patient molecular format continues to make it one of the strongest decentralized AMR platforms globally.

Becton Dickinson continues to hold a strong position in the U.S. HAI and antimicrobial resistance testing market through its combined molecular and microbiology portfolio. The BD MAX system supports assays for MRSA, Staphylococcus aureus, vancomycin-resistant enterococci, and Clostridioides difficile, while the company's broad footprint in hospital laboratories helps support infection control, surveillance, and antimicrobial stewardship efforts. In multiplex molecular screening, bioMérieux remains a key player with its BIOFIRE FilmArray panels, including gastrointestinal and blood culture identification tests. These syndromic panels detect a wide range of pathogens, along with important resistance markers such as mecA/C, vanA/B, and carbapenemase genes, enabling rapid identification of infectious organisms and resistance profiles directly from clinical samples.

Roche Diagnostics continues to offer molecular HAI assays on its laboratory analyzers, including the Cobas MRSA/SA Test for MRSA differentiation and the Cobas Cdiff Test for detection of toxigenic C. difficile. Roche also expanded near-patient HAI testing in Europe through its Cobas Liat System, with CE-marked assays that offer rapid molecular detection of MRSA and C. difficile in patient care settings. Although Roche remains stronger in centralized molecular testing than in decentralized HAI screening, its installed molecular base continues to support hospital microbiology workflows.

Other molecular HAI and sepsis products remain relevant across specialized segments. QIAGEN markets molecular assays for C. difficile, MRSA, and VRE on Rotor-Gene platforms. T2 Biosystems remains important in bloodstream infection testing with the T2Candida Panel and T2Bacteria Panel, which support rapid sepsis diagnosis directly from whole blood. Former products, such as the Verigene blood culture tests originally developed by Luminex Corporation, now part of DiaSorin, still retain some clinical relevance for rapid blood culture organism identification and resistance marker detection.

MRSA

The competitive landscape for healthcare infection testing is fragmented with numerous players. The use of tests makes it difficult to determine market leadership and share, due to their use for non-serious infection testing.

The area of Staphylococcus aureus infection testing, particularly for methicillin-resistant Staphylococcus aureus (MRSA), has expanded significantly over the past decade as hospitals increasingly adopted rapid molecular screening to support infection control and antimicrobial stewardship. Early molecular growth began with platforms introduced by Becton Dickinson and Cepheid, and the market later broadened as additional suppliers introduced assays for rapid MRSA detection, strain differentiation, and resistance marker identification. Although earlier participants such as Luminex Corporation and AdvanDx contributed specialized products, the strongest current commercial positions are concentrated among larger integrated molecular diagnostics companies.

Cepheid remains one of the dominant players in this segment through its Xpert MRSA and next-generation Xpert MRSA NxG assays, both run on the GeneXpert System. These cartridge-based molecular assays provide rapid MRSA detection directly from nasal swabs, with results available in approximately one hour, allowing hospitals to identify carriers quickly and implement isolation protocols sooner. Cepheid's MRSA menu has remained a

cornerstone of hospital infection prevention programs because of its decentralized workflow, rapid turnaround time, and strong installed base worldwide.

Randox Laboratories has expanded rapid molecular MRSA testing through the Vivalytic MRSA/SA assay on the Vivalytic Analyzer platform. This system differentiates MRSA from methicillin-sensitive Staphylococcus aureus in approximately 50–60 minutes and is positioned for near-patient and urgent-care use, helping clinicians accelerate patient isolation and treatment decisions. Roche Diagnostics also remains active with the Cobas MRSA/SA Test, while bioMérieux supports MRSA detection through syndromic molecular and microbiology systems. Becton Dickinson continues to market MRSA assays on the BD MAX System. By 2026, the leading companies in molecular MRSA testing are Cepheid, BD, Roche, bioMérieux, and increasingly Randox, while Abbott has a more limited direct role in dedicated MRSA molecular testing compared with these core competitors.

Molecular TB Testing

Tuberculosis (TB) remains one of the leading causes of death worldwide. According to the World Health Organization, approximately 10.6 million people developed TB in 2023 and about 1.6 million died from the disease. TB is closely linked with HIV infection, as immunocompromised individuals are significantly more susceptible; TB continues to be a leading cause of death among people living with HIV. Drug-resistant TB remains a major global health challenge, with hundreds of thousands of new cases showing resistance to rifampicin, the most effective first-line drug, and the majority of these cases classified as multidrug-resistant TB (MDR-TB). While countries such as China have made progress in reducing TB incidence and mortality, many regions remain off track to meet global elimination targets.

Definitive diagnosis of TB relies on identification of Mycobacterium tuberculosis in clinical specimens such as sputum, typically through microbiological culture or molecular detection. In practice, a combination of diagnostic approaches is often used. Traditional methods include smear microscopy and culture, while imaging techniques such as chest X-ray support clinical assessment but lack specificity. The tuberculin skin test (Mantoux test) has historically been used to detect latent TB infection, but its interpretation is complicated by prior BCG vaccination and cross-reactivity, as well as reduced sensitivity in immunocompromised individuals. As a result, its role has been supplemented in many

settings by interferon-gamma release assays (IGRAs), which provide improved specificity for latent TB infection and are not affected by prior vaccination.

Molecular diagnostics are an important technology for TB detection and management. PCR-based assays enable rapid detection of M. tuberculosis DNA and can simultaneously detect key drug-resistance markers, particularly rifampicin resistance. Cepheid has expanded its TB menu with assays such as Xpert MTB/RIF Ultra, which improves sensitivity over earlier versions, and Xpert MTB/XDR, which extends detection to additional resistance markers. These cartridge-based systems provide results within a few hours and are widely used in both centralized and decentralized settings. Portable molecular platforms such as those from Molbio Diagnostics offer Truenat MTB and MTB-RIF assays designed for near-patient use, particularly in resource-limited environments. High-throughput molecular systems from companies such as Roche Diagnostics support centralized testing in laboratories with available infrastructure.

There is also growing interest in alternative sample types and biomarker-based approaches, including urine-based assays, particularly for patients who are unable to produce sputum, such as children and individuals with advanced HIV infection. Despite these advances, no single test fully addresses all diagnostic needs, and combinations of molecular, immunologic, and microbiological methods are often required.

The intersection of TB and HIV continues to be a critical public health concern. HIV infection significantly increases the risk of progression from latent to active TB, and TB remains the leading cause of death among HIV-positive individuals. As a result, integrated testing and treatment strategies for TB and HIV are a major focus of global health programs.

TB diagnostics are evolving toward faster, more sensitive, and more accessible molecular approaches, with increasing emphasis on early detection, identification of drug resistance, decentralized testing, and integration into broader infectious disease control programs.

The TB diagnostics market is heavily concentrated in high-burden regions, particularly Asia and Africa, where national screening programs drive testing volume. Cepheid continues to dominate global molecular TB testing, while companies such as Molbio Diagnostics have expanded access through portable, decentralized PCR platforms. Recent product development has focused on expanded drug resistance detection and increased use of near-patient systems, rather than the introduction of entirely new diagnostic platforms.

Limitations of Molecular Microbiology Testing

Molecular microbiology has made it possible to detect microorganisms much faster than culturing them. However, there are limitations. If monoplex tests are performed, multiple tests may be required to determine which microorganism is present. Multiplex tests and syndromic test panels reduce the need for multiple tests, but they are more expensive. Negative testNex results do not rule out the presence of a microorganism. Negative results only indicate that, if a microorganism is present, it is not one of the pathogens tested.

Another limitation is that molecular microbiology tests can detect the presence of an antibiotic resistance gene, but these tests do not provide phenotypic information, such as whether the gene is active and whether the bacteria are actually resistant to the antibiotic. How will the bacteria actually react to the presence of that antibiotic?

Also, most molecular microbiology tests available today are not fast enough for point-of-care testing while the patient is still in the physician's office or clinic. Molecular microbiology tests that require only a few hours to perform represent a significant improvement over traditional microbiology in hospitals, where the results can then be used to inform treatment decisions for inpatients.

Some laboratories and diagnostic companies have increasingly incorporated next-generation sequencing into the microbiology laboratory. Sequencing enables the analysis of a large number of genes in a single test and can identify both known and previously unrecognized microorganisms. Its use has expanded in areas such as outbreak investigation, antimicrobial resistance detection, and characterization of complex infections. While sequencing has the potential to further advance microbial identification and resistance profiling, its routine use is still limited by cost, data interpretation requirements, and the need for specialized infrastructure. Turnaround times have improved, but in many settings, they are still longer than the times required for immediate clinical decision-making in physician offices and smaller laboratories. As a result, sequencing is best described as advancing toward broader clinical adoption rather than remaining in an early stage. Researchers and diagnostic companies have made significant progress in bringing new technologies into the microbiology laboratory, but continued innovation is needed to further improve speed, accessibility, and clinical integration.

Rapid Microbiology Tests

Rapid microbiology tests are molecular and immunoassay tests.

Historically, rapid immunoassays have commonly come in two configurations. One configuration is a flow-through assay, which requires several steps, including placing the sample on the device, washing, and adding detection molecules that make the test result visible to the eye. In flow-through tests, the biological fluid passes through a porous material or membrane into an absorbent. With this type of immunoassay, the analyte is captured on the membrane by the capture molecules. This is washed with buffer, and then detection molecules are added to produce a detectable signal on the porous material. These devices are typically encased in a plastic housing, and one sample is tested per cassette.

A second configuration is the lateral flow test, also called an immunochromatographic test. These may be strip tests or housed in cassettes. With lateral flow tests, the biological sample is added to a sample pad located at one end of the strip. The sample flows along the membrane to the conjugate pad, which contains detection molecules consisting of antibodies or antigens that are specific to the analyte. With a dry, unused strip, these detection molecules are immobilized on the conjugate pad. The fluid in the sample solubilizes the detector molecules, which then bind to the analyte if it is present. This analyte/detector mix flows further along the strip to the location of an analyte-capture molecule. If the analyte is present, the analyte/detector combination is captured and can be visualized. This is often a line on the strip, but it can be another shape, such as a "+" or other symbol. A control is also included, and the control line should always be visible upon assay completion. The second line is visible if the analyte is present.

Lab-based immunoassays do not meet the pressing needs for mass screening and diagnostic programs required by public health professionals and clinicians in the developing and developed world. Therefore, there is an increasing demand for reliable, rapid tests for infectious diseases. This enables earlier patient diagnosis and treatment, and saves patients and healthcare plans money, while avoiding costly delays and unnecessary quarantines. Further studies have shown that the majority of individuals seen in clinics do not return to receive their lab test results and therefore remain untreated if positive.

The majority of diagnostic tests currently used for these purposes are rapid immunoassays, chosen for their low cost and convenience. However, one of the key downsides of these rapid

tests is their poor sensitivity. Negative samples are typically re-tested in a central lab with a more sensitive molecular test, delaying time-to-result by many hours.

Table 11-19: Global Rapid Microbiology Testing Market, Sales Distribution, by Pathogen, 2025 (%)

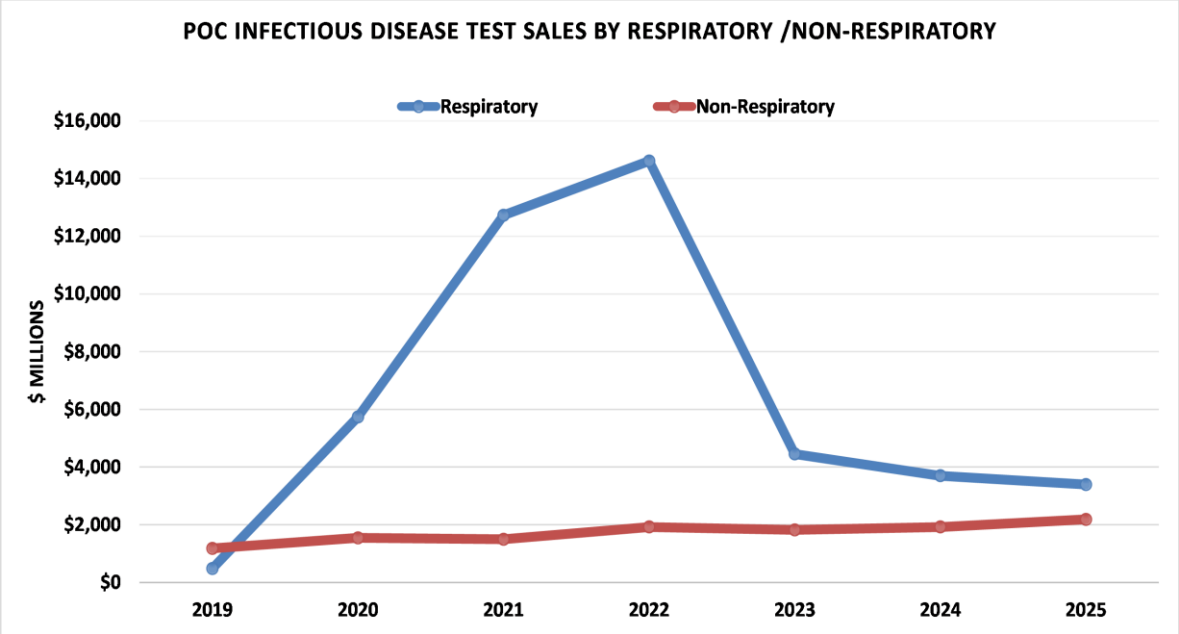
[C. Difficile; COVID-19; E. coli; H. pylori; Hepatitis; HIV; Influenza; Malaria; Other respiratory; STD; Other]

Pathogen	% Mkt
Respiratory	60.8%
STD	6.6%
Hepatitis	5.2%
HIV	5.2%
C. difficile	3.7%
Malaria	3.6%
E. Coli	1.9%
H. pylori	1.7%
Other	11.3%
Total	**100%**

Source: Kalorama Information

POC multi-target panels are increasingly used because they offer several advantages over traditional single-target tests. A key advantage of molecular multi-target panels is their ability to reduce time to diagnosis compared with conventional methods such as culture or sequential testing. By consolidating multiple single assays into a single, high-confidence test, molecular multiplex panel testing enables faster and more accurate clinical decision-making, particularly in high-acuity cases involving sepsis and central nervous system (CNS) infections.

Figure 11-4: Rapid Infectious Disease Test Sales, by Respiratory/Non-respiratory Segments, 2025 (%)

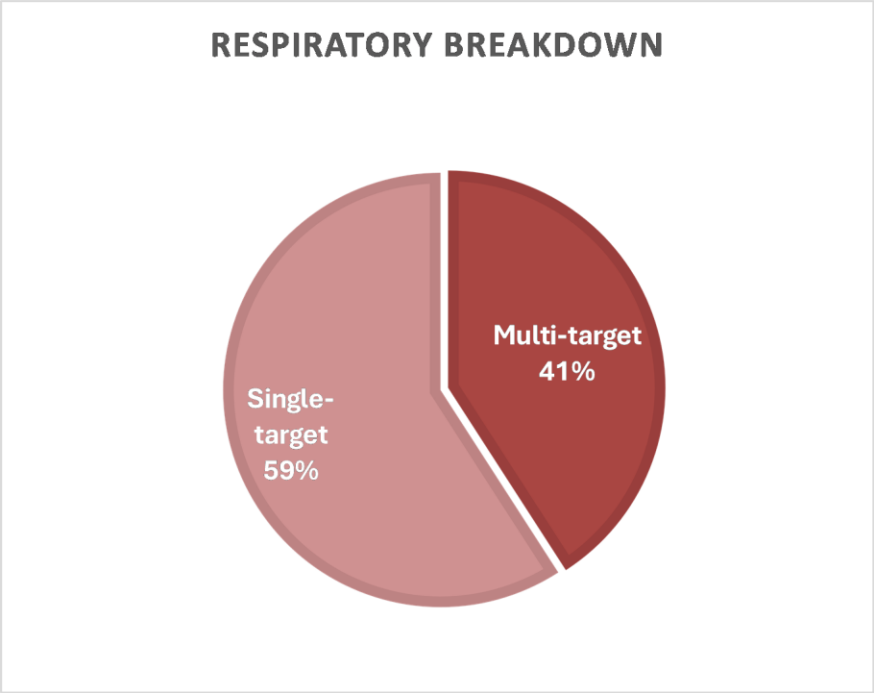


Source: Kalorama Information

Rapid respiratory tests accounted for the largest percentage of cases by pathogen in 2025. Rapid Respiratory tests are further divided into testing for single-target and multi-target from a single specimen. POC IVD respiratory molecular panels generally use PCR or isothermal amplification (NAAT) technologies and are deployed in compact, cartridge-based systems. These systems offer laboratory-level sensitivity while providing rapid turnaround times for results.

Figure 11-5: Rapid Respiratory Testing, by Target Pathogens, 2025 (%)

[Multi-Target, Single-Test]



Source: Kalorama Information

For some diseases, such as COVID-19 and influenza, physicians cannot wait long to start antiviral therapy because available treatments must be initiated within a short window after infection. An example of influenza treatment is Flumadine (rimantadine), which must be administered within 48 hours of the onset of flu symptoms. This has fueled the market for rapid influenza tests.

QuidelOrtho offers the Sofia Influenza A+B Fluorescent Immunoassay (FIA) on its Sofia 2 system. The test uses advanced immunofluorescence-based lateral-flow technology to detect influenza A and influenza B viral nucleoprotein antigens. Positive results can be obtained in as few as 3 minutes, negative results in 15 minutes.

Selected rapid tests for HIV include:

- Abbott Alere Determine HIV-1/2 Combo, mPIMA HIV 1/2 VL

- Standard Diagnostics BIOLINE HIV Ag/Ab Combo.
- Chembio HIV1/2 STAT-PAK Rapid IgG Antibody Lateral-flow, DPP HIV-Syphilis System
- OraSure OraQuick ADVANCE Rapid HIV 1/2 Assay
- Trinity Biotech Uni-Gold Recombigen
- MedMira Reveal Rapid HIV-1

In the United States, HIV testing has evolved beyond earlier mail-in collection systems to include true at-home tests, where individuals can collect a sample, perform the test, and read the results themselves. These self-contained tests have made HIV screening more accessible and convenient, supporting earlier detection and reducing barriers to testing. At the same time, many companies continue to market rapid HIV tests outside of the United States, particularly for use in clinical and community-based settings.

In emerging markets, point-of-care diagnostic tests for diseases such as malaria, HIV, and syphilis play a critical role in improving access to care, especially in areas with limited laboratory infrastructure. These tests enable faster diagnosis and treatment decisions, helping to improve clinical outcomes and support large-scale screening and public health programs.

Diagnostics are not prioritized in global health, as funding has largely focused on developing and delivering therapeutic interventions and vaccines. The lack of quality standards in the evaluation and regulation of diagnostics has also led to the proliferation of low-quality diagnostic tests being sold and used without evidence of effectiveness, discouraging companies with high-quality tests from competing in the same market.

Rapid tests are available for: HIV, gonorrhea, syphilis, chlamydia, herpes, hepatitis, strep A, strep B, tuberculosis, RSV, influenza, legionella, mononucleosis, mycoplasma pneumonia, E. coli, H. pylori, cryptosporidium, giardia, C. difficile, rotavirus, fungal disease, and bacterial meningitis.

NOWDiagnostics received FDA de Novo authorization for OTC and POC diagnostic testing. The First To Know Syphilis Test is the first and only rapid syphilis test in the U.S that provides an in-home result in 15 minutes.

Mass Spectrometry

One of these innovations, increasingly finding a home in microbiology, is mass spectrometry. Mass spectrometry has been used in clinical laboratories for other indications for several years. However, mass spectrometry platforms have become transformative technologies in microbiological applications. Mass spectrometry has quickly emerged as a significant advancement for the rapid detection and characterization of bacterial pathogens following culture. Mass spectrometry can identify the microbial pathogen in minutes, compared to the hours required for traditional ID/AST.

Mass spectrometry instrument systems are expensive, and these platforms are primarily used in developed countries. Once a laboratory has acquired a mass spectrometry system, testing individual samples is relatively inexpensive.

Table 11-20: Selected Companies Marketing Mass Spectrometers and/or Assays for the Clinical Laboratory [CE-Marked and/or 510(k) cleared]

Company	Technology/Product
Agena Bioscience, Inc.	MassARRAY System Diagnostic panels: •MassARRAY Dx Lung Panel • MassARRAY Dx Colon Panel
ALIFAX S.r.l.	Clinical chemistry kits for LC/MS tests for •Endocrinology (hormones) •Homocysteine •Vitamins Clinical pharmacology kits for LC/MS therapeutic drug monitoring of •Antiepileptics •Antiarrhythmics •Immunosuppressants •Antibiotics
Andromas SAS	LT2-Andromas MALDI-TOF mass spectrometer
Beckman Coulter, Inc. (Subsidiary of Danaher Corporation)	MALDI Biotyper (Beckman Coulter distributes the MALDI Biotyper in the U.S.)
bioMérieux SA	VITEK MS
Bruker Corporation	MALDI Biotyper and MALDI CA Biotyper – MALDI-TOF mass spectrometer for microbial identification;
Revvity	NeoBase 2 MS
SCIEX (SCIEX - A Danaher Company)	Clinical mass spectrometers offered by SCIEX include: • 3200MD Mass Spectrometer • 4500MD Mass Spectrometer Clinical assays available from SCIEX include: • Amino Acids and Acylcarnitines in Dried Blood Spots IVD Assay Kit • Immunosuppressants IVD Assay Kit • 25-OH-Vitamin D3/D2 in Serum/Plasma IVD Assay Kit
Thermo Fisher Scientific	Prelude MD HPLC, Endura MD Mass Spectrometer, and ClinQuan MD Software Extent System

Source: Kalorama Information

The Future Outlook for Microbiology

The future of microbiology diagnostics is strongly tied to growth, driven by both technological advancements and the persistent emergence of new infectious diseases. Innovations in microbiology testing, especially in molecular diagnostics, have led to significant expansion, particularly in infectious disease detection. These modern methods offer higher sensitivity and specificity, addressing many previously unmet clinical needs and reshaping the clinical diagnostics landscape.

Molecular techniques have not only transformed traditional microbiology but have also enhanced other IVD segments, including immunodiagnostics, by delivering more accurate and actionable insights. Application areas such as blood screening, POC diagnostics, cytogenetics, and tissue typing have been notably redefined by integrating advanced molecular tools.

Given the ongoing and unpredictable threat of infectious diseases, demand for microbiology testing remains strong and is projected to outpace the broader IVD market in revenue growth. However, despite the clinical necessity, microbiology diagnostics are not immune to economic pressures

Current technologies cannot meet all the needs of the microbiology lab for identification and antibiotic susceptibility testing (ID/AST). The traditional microbiology market will continue to grow, but at a slower pace than certain other segments.

The expanding capabilities and numbers of molecular diagnostic and mass spectrometry-based tests, combined with the need for tests that can deliver faster results than traditional microbiology, will drive growth in these segments. Continued advances in technology will continue to fuel growth in the microbiology market.

The ultimate goal in the microbiology market is rapid tests, less than 30 minutes, for microbial identification and antibiotic susceptibility testing ID/AST. These tests can identify which microbial pathogen is present, either using a panel of major pathogens associated with the syndromic symptoms or a test that can identify unknown pathogens. In addition, these rapid tests would provide antibiotic susceptibility information, informing the physician which antibiotics will be effective in treating the infection.

One company, Specific Diagnostics (part of bioMérieux), offers the SPECIFIC REVEAL Rapid AST System. Molecular-based syndromic tests are available to identify microbial pathogens (including viral and bacterial) if the pathogen is among the microbes included in the panel. In addition, the first truly rapid (less than 20-minute) molecular tests for influenza, RSV, and strep A are on the market and can be used at the POC.

Microbiology labs are improving all the time. The potential has grown in many areas to make faster treatment for certain infections. Please see the following examples:

- Rapid antigen and PCR tests are now available for the laboratory diagnosis of sore throat, with a turnaround time of minutes to a few hours.
- Bacteriology automation, such as Kiestra TLA, can reduce turnaround times for urine cultures to less than a day, and a day and a half for wound swabs.
- Rapid PCR tests for atypical respiratory pathogens (Legionella spp., Mycoplasma pneumoniae, Chlamydia pneumoniae) can mean that macrolide coverage for community acquired pneumonia can be stopped early, or not even started.
- Ultra-fast PCR tests for influenza can prevent any antibiotics being prescribed in patients who present with Upper Respiratory Tract Infection (URTI).
- PCR tests with genotypic antimicrobial susceptibility information can avoid the use of indiscriminate antibiotics and selection pressure for antibiotic resistance.

The molecular market expanded quickly in response to the COVID-19 pandemic, developing tests, reducing result turnaround times, and increasing specificity over a short period. The demand for molecular technology increased during this period. The installation base of molecular analyzers, expanding techniques, and test menus in labs worldwide, grew to meet the demand. Due to this increased demand, more laboratories are now equipped to run molecular testing as part of their routine diagnostic test offerings.

Mass spectrometry in microbiology is promising driven by technological advancements, integration with computation AI tools and increasing demand for rapid, accurate microbial diagnostics.

Chapter 12: Blood Banking Services

Scope

This chapter examines the marketplace for in vitro diagnostic products specifically related to blood banking. Among these are:

- **Blood Grouping and Typing Products**
- **Immunoassays for Pathogen Detection**
- **Molecular Assays for Pathogen Screening**
- **NAT Blood Screening Systems**

The market is mature but there are innovations, particularly in molecular testing and in information technology systems associated with blood banking products.

Overview

Whole blood transfusions are increasingly replaced by blood component therapy, so there is a strong demand for platelets that are used for trauma patients, burn victims, and cancer patients. Other changes have also influenced the market, including:

- new technologies that limit surgical bleeding;
- improved blood management programs at hospitals;
- fewer elective surgeries;
- more sophisticated blood management programs at hospitals. These programs include collecting blood lost during surgery and returning it to the patient, maximizing hemoglobin levels to prevent anemia, and using medications to reduce intraoperative bleeding.

The Current Status of Global Blood Collection

The following statistics regarding blood collection are notable:

- Volunteer Donors Worldwide: According to WHO statistics, 79 countries collect over 90% of their blood supply from voluntary, unpaid blood donors, and 56 of those countries do so for all of their blood supply; however, 54 countries collect more than 50% of their blood supply from family/replacement or paid donors.
- Blood Collected: Around 118.5 million units of donated blood are collected each year globally, with 42% of the blood collected going to middle- and low-income countries, home of 80% of the world's population. About 13,300 blood centers in 169 countries report collecting a total of 106 million donations; the median number of annual donations per center is 25,700 in high-income countries, compared with 4,400 in middle- and low-income countries. This rate boils down to 31.5 donations per 1,000 people in high-income countries, compared to 16.4 per mil in middle-income countries, and 5 in low-income countries.
- Practice Changes in Transfusions: Whole blood transfusions are increasingly being replaced by blood component therapy; there is strong demand for platelets and Type AB plasma. These blood products are used for trauma patients, burn victims, and

cancer patients. Red blood cells are needed for accident and gunshot victims, as well as in elective surgeries.

- United States: According to AABB (formerly American Association of Blood Banks), community-based independent blood centers supply about 60% of the U.S. blood supply, while the American Red Cross supplies about 40%. The number of blood units collected in the United States was 11.6 million in 2023
- Asia Boosts Blood Collection: The WHO Southeast Asia Region estimates 15.9 million units are collected in contingent nations per year, a great improvement over the 9.4 million units collected, as detailed in this report's previous edition. However, with a requirement of 18 million units, they are still short.
- India Improves but Needs More: India, with its huge population of over 1.3 billion, has 2,903 blood banks, of which 1,043 are public and 1,860 are private, including those run by charitable trusts. Together, they collected 14.6 million
- China Update: China's blood supply is collected primarily from voluntary, unpaid blood donors, following reforms that largely eliminated family/replacement donation practices. All donated blood is screened for transfusion-transmissible infections (TTIs), including HIV, hepatitis B, hepatitis C, and syphilis. Although blood donation rates have increased significantly since implementation of the Blood Donation Law, donation levels remain below the 1–3% population donation rate often considered necessary for stable supply. The COVID-19 pandemic negatively affected blood collection activities, and while donation levels rebounded afterward, China continues to face periodic regional and seasonal blood shortages. In 2023, the country recorded approximately 17 million voluntary blood donations.
- Africa - Safety: The WHO believes that the safety of the blood supply is a priority for all countries and a particular challenge in sub-Saharan Africa. In addition to well-known transfusion-transmitted pathogens such as HIV, HBV, HCV, and bacteria, the risk remains high due to pathogens endemic to African countries, such as chikungunya, dengue, malaria, and Leishmania, for which screening assays may not be readily available.
- Africa - Transfusions: While patients in developed countries receive platelet, plasma, or red cell transfusions, in many African countries, whole blood transfusions remain common. Obstetric hemorrhage, sickle cell disease, and childhood anemia are among the many conditions in Africa requiring transfusion as a critical life-saving

intervention. The African blood supply is also challenged by transfusion-transmitted diseases endemic to the region, including malaria, dengue, chikungunya, and yellow fever. At the same time, local blood donors have significant rates of well-known infectious agents such as HIV, HTLV, and hepatitis, all of which can also be transmitted via transfusion.

- Saudi Arabia: Saudi Arabia has an estimated population of 33.3 million; 10.1 million of which are registered foreign expatriates, and an estimated 5 million illegal immigrants. There are 185 blood banks run by the Ministry of Health, with approximately 800,00 donors in 2024. All blood units are tested for: HIV 1/2, HBsAg, anti HBc, anti HBs, anti HCV, HTLV I/II, syphilis, and malaria. All done by ELISA except syphilis, which is done by Rapid Plasma Reagin (RPR). The Ministry of Health started using nucleic acid testing (NAT) in 2010 with tests supplied by Roche Diagnostics.
- Latin America: The blood collection environment in Latin America and the Caribbean has shown measurable progress in recent years. Total blood donations across the region rose by 15.5% from 2020 to 2023, reflecting a stronger donor recruitment and improved collection systems. In 2023, the voluntary, unpaid donors accounted for 56.8% of all blood collected. Screening performance has also strengthened, with approximately 90% of collected blood processed into components rather than whole blood.

Global Blood Safety

Of the 171 responding countries, 113 (66%) reported having specific legislation covering blood transfusion safety and quality, including 79% of high-income countries, 63% of middle-income countries, and 39% of low-income countries. The WHO recommends that all donations be screened for transfusion-transmitted infections—HIV, hepatitis B and C viruses, and syphilis. Of the 165 nations that have responded, 10 are unable to screen all donated blood for one or more of these pathogens, and 4 are unable to screen any donated blood for any of them.

Additionally, some countries report that they screen for Chagas' disease, malaria, and/or human T-lymphotropic virus (HTLV), which can cause adult T-cell leukemia/lymphoma. Blood collection facilities in the United States test 100% of donations for the four pathogens recommended by WHO and for HTLV, and a portion of donations are tested for Chagas' disease.

Table 12-1: Laboratory Screening of Blood Donations for Transfusion-Transmissible Infections, Number of Countries

[Chagas; HBV; HCV; HIV; HTLV I/II1; Malaria; Syphilis]

Disease	Mandatory Screening Policy	Selective Testing Policy	Unanswered
Syphilis	165	3	3
HCV	164	0	7
HBV	156	0	5
HIV	166	0	5
Chagas[1]	20	12	NA
Malaria[1]	20	31	NA
HTLV I/II1	35	15	NA

Note: The data collection form used for the collection of the 2018 data for the African Region did not include this information. Information collected in earlier years (2015 or 2014) was used for the analysis.

Note: [1]Reporting on Chagas, malaria, and HTLV is limited. **This is the most updated information available at this time**

Source: WHO; 2021 Global Status Report on Blood Safety and Availability

The table below illustrates the prevalence of TTIs in blood donations, by countries' socioeconomic statuses.

Table 12-2: Prevalence of TTIs in Blood Donations [Median (Interquartile range)], by Income Group

Income group	HIV	HBV	HCV	Syphilis
High-income countries	0.002% (0-0.01)	0.02% (0.003-0.13)	0.07% (0.002-0.05)	0.02% (0.02-0.11)
Upper middle-income countries	0.10% (0.03-0.23)	0.29% (0.15-0.62)	0.19% (0.06-0.35)	0.35% (0.11-1.08)
Lower middle-income countries	0.19% (0.03-0.77)	1.70% (0.76-5.54)	0.38% (0.03-0.08)	0.69% (0.16-1.25)
Low-income countries	0.70% (0.33-1.66)	2.81% (2.0-4.50)	1.00% (0.50-2.23)	0.90% (0.60-1.81)

Source: World Health Organization; Blood safety and availability fact sheet

Zika Virus

Zika virus is transmitted primarily by the Aedes mosquito. Zika virus can also be spread by sexual contact. Although 4 out of 5 people infected with Zika virus never develop symptoms, when symptoms do occur, they may include fever, arthralgia (joint pain), maculopapular rash (red area with small bumps), and conjunctivitis (red, irritated eyes). In addition, Zika virus infection during pregnancy can cause serious birth defects.

Market growth from these added NAT screens for Zika and other infectious disease threats may ultimately prove marginal in the U.S. market. Major health systems and blood banks often secure contracts at discounted per-test costs offered by IVD companies looking to win accounts in a very tight market. In other words, adding a NAT assay for Zika may add little or no value to the largest and most competitive contracts.

Selected IVD tests on the market in 2025 include

- Roche cobas Zika test
- Vela Diagnostics Sentose ZIKV PCR test
- ARUP Zika RT-PCR test and the Zika IgM MAC-ELISA

Diasorin offers the LIAISON XL Zika Capture IgM II, a fully automated serology assay for Zika virus detection.

Chembio markets its DPP Zika/Dengue/Chikungunya System by ANVISA, Brazil's health regulatory agency. The test is performed using a small drop of fingertip blood and provides quantitative results in approximately 15 minutes when used with the company's handheld DPP Micro Reader.

Blood and Component Collection

The blood collected is processed into three major components: red cells, platelets, and plasma. These blood components are transfused to patients or used to make drugs and diagnostic reagents. Of the blood components, red cells are the most frequently transfused, accounting for 40 million units annually. An estimated 10 million platelet units are transfused each year into patients in North America, Europe and Asia.

The table below presents how blood components are used in the treatment of various conditions.

Table 12-3: Blood Component Usage for Selected Conditions

Condition	Blood Components
Liver Transplant	6-10 units of red blood cell
	20 units of plasma
	10 units of platelets
Adult Open-Heart Surgery	2-6 units of red blood cells
	2-4 units of plasma
	1-10 units of platelets
Automobile Accident	4-40 units of red blood cells
Leukemia	2-6 units of red blood cells
	6-8 units of platelets daily for 2-4 weeks
Sickle Cell Disease	10-15 units of red blood cells for severe cases
Cancer Chemotherapy	1-10 units of HLA-matched platelets
	1-3 units of CMV negative red blood cells

Source: 2000 Nationwide Blood Collection and Utilization Survey conducted by the National Blood Data Resource Center

Reevaluating Blood Transfusions

Blood transfusions have become so commonplace that it is easy to forget that blood is an organ, and the transfusion is akin to an organ transplant and should be performed only when absolutely necessary. This concept has led some hospitals to reevaluate their blood use. They found that some 30%-50% percent of blood transfusions were medically non-beneficial and may even have contributed to clinical complications such as sepsis and myocardial injury.

On the other hand, the need to ensure a safe transfusion service has increased the cost to produce a transfusion-ready unit of blood and other blood products. Therefore, hospitals are encouraged to find a more effective way to manage their blood usage.

Nevertheless, the U.S. is the largest user of blood transfusions: approximately 5 million people in the United States receive blood and blood components through 10.9 million transfusions per year, which is 44% higher than in Canada and 15% higher than in Europe, per capita.

A blood transfusion introduces a multitude of foreign antigens and living cells into the recipient. The result after multiple transfusions, as in the case of some cancer patients, patients with sickle cell anemia, and other conditions, may be alloimmunization, an immune response generated in response to exposure to these foreign elements in subsequent transfusions, resulting in various clinical consequences, including high fever and transfusion-related acute lung injury.

AABB has studied the effects of blood transfusions on patient outcomes and has been promoting more rational blood utilization. Some of the information collected shows the impact of alloimmunization, reinforcing the need to limit the number of transfusions patients receive.

Table 12-4: Impact of Alloimmunization (% of Patients Screening Positive for One or More Antibodies)

Transfusion History	Percent
Never been transfused	<1%
Previously transfused	3%-8%
Multiple transfusions	20%-30%

Source: AABB

A partial solution for the alloimmunization problem is the development of molecular red blood cell genotyping techniques that allow for a more precise and personalized strategy for matching donors and the recipients of multiple blood transfusions, such as cancer patients, severe anemia, and sickle cell disease.

A proposed alternative to blood transfusions, or at least a means to rely on fewer of them, is the concept of patient blood management, which centers on practicing preventative measures to reduce the patient's potential need for a transfusion. Physicians may treat their patients for

anemia in the weeks before surgery and optimize red cell mass, or they may use medications and techniques that minimize blood loss during the operation.

One such technique, acute normovolemic hemodilution (ANH), involves removing one to three units of blood shortly after anesthesia is induced, then maintaining volume with a crystalloid or colloid replacement; this technique reduces the amount of hemoglobin lost during the operation, and the blood previously withdrawn would be infused back into the patient at the procedure's end.

ANH can be practiced as a sole blood conservation method or in tandem with preoperative autologous donation, blood salvage, or both. Other techniques recommended by AABB include intraoperative blood recovery and reinfusion, apheresis, point-of-care testing, deliberate hypotension, appropriate positioning, maintenance of normothermia, topical hemostatics, fibrin sealants, and perhaps most important of all, an overall improvement in surgical technique.

This evidence-based medical research and guidelines issued by country agencies and other programs are beginning to decrease the number of blood transfusions. But this trend may not affect the number of units screened for pathogens because even blood units that are destined to be processed into platelets, coagulation factors, and plasma have to be screened for the presence of infection.

Blood Typing and Grouping Market

The two major components of the blood banking diagnostics market are blood typing and blood testing and screening for pathogen threats. A variety of different methods are currently used to determine blood type. These may be either manual or automated, as discussed below.

Manual Blood Typing Methods

Manual blood typing methods include slide/tile testing, tube testing, and microplate testing, which differ mainly in terms of the surface on which the blood is tested. For each test, blood type is determined by testing for the presence or absence of Rh factor and blood group antigens A and B on the surface of red blood cells. This is accomplished with the addition of anti-A, anti-B and anti-Rh antibodies. The interaction of antibodies with an antigen produces aggregates that result in agglutination and indicate the presence of that antigen in the blood.

Automated Blood Typing and Screening Methods

Automated blood typing systems use well-established immunohematology principles to classify blood groups while replacing manual interpretation and handling steps with instrument-driven processes. These systems typically use microplate or gel card methodologies to determine ABO and Rh types, along with solid-phase red cell adherence assays or column agglutination techniques for antibody screening and IgG crossmatching. Reaction grading and result interpretation are performed using advanced software that applies image analysis and rule-based algorithms, rather than true artificial intelligence, in most routine systems, although newer platforms are beginning to incorporate machine learning to enhance pattern recognition and quality control.

Automation offers clear advantages over manual blood typing in terms of workflow efficiency, standardization, and error reduction. In environments facing ongoing staffing shortages, automated platforms help laboratories maintain throughput with fewer highly specialized technologists, while still requiring trained oversight for exception handling and result validation. Because reactions are interpreted digitally rather than visually by individual technologists, variability and subjectivity are reduced, improving consistency and traceability. In addition, automation supports improved documentation, integration with laboratory information systems, and enhanced quality assurance, all of which contribute to safer transfusion practices and more efficient blood bank operations.

Molecular Methods

Unusual ABO typing results are a frequent challenge in routine blood grouping. Variants in the ABO gene can lead to weak or inconsistent antigen expression, making results difficult to interpret with standard serologic methods. In addition, clinical factors such as transfusion history, malignancy, or transplantation can further complicate testing. To resolve these discrepancies, blood banks increasingly rely on molecular techniques, which provide clearer characterization of underlying genetic variants. These cases are being encountered more often in practice, largely due to more complex patient populations and improved detection methods rather than an actual increase in rare alleles.

PCR-based ABO genotyping is also used in forensic settings to help determine blood group from tissue samples. Broader genotyping platforms that assess single-nucleotide polymorphisms allow faster and more accurate identification of rare donor types across multiple blood group systems. Red blood cells carry a wide range of antigens beyond ABO, and antigen combinations vary significantly among individuals, even within the same primary blood group. This variability, combined with the presence of specific antibodies in recipients and differences in antigen frequency across donor populations, makes locating compatible blood units increasingly complex and reinforces the value of molecular typing in transfusion support.

Table 12-5: Selected Blood Typing and Grouping Innovations

Company	Location	Area	Technology	Details
Agena Bioscience	U.S.	ABO	mass spec	MassArray for blood group genotyping
Axo Science	France	ABO	molecular	HIFI Blood 96
Etab Sang Pyrénées Méditerranée	France	ABO	DNA array	DNA microarray blood group typing
Grifols International	Spain	ABO	gel	DG Gel Cards for blood typing
Grifols International	Spain	ABO	instr	Eflexis and Erytra, blood bank instruments
Grifols International	Spain	RBC typing	array	ID CORE XT, Luminex xMAP
Grifols International	Spain	ABO	reagents	Monoclonal Antisere reagents
Haemokinesis Pty	Australia	ABO	agglutination	STATUS, automated STAT 1 minute
Haemokinesis Pty	Aust.	ABO	agglutination	STARGEL 10-minute Antibody Screening
Haemokinesis Pty	Australia	POC	ABO	Group Legible Immunohematology Format, paper
Immucor	U.S.	RBC typing	mol	PreciseType HEA
Micro Typing Concepts (MTC)	Germany	ABO	agglutination	INVITROGEL TEST-SYSTEM
Micro Typing Concepts (MTC)	Germany	POC	ABO	INVITROFLOW RAPID TEST, lateral flow paper
Grifols/Progenika	Spain	ABO	Luminex xMAP	BLOODchip
Grifols/Progenika	Spain	IT	Luminex xMAP	BLOODchip ID Data Analysis
Grifols/Progenika	Spain	platelet typing	Luminex xMAP	ID HPA XT
Grifols/Progenika	Spain	RBC typing	Luminex xMAP	IDLine
Quotient Limited (AliveDx)	U.S.	ABO	instr	MosaiQ, an automated, multiplexed ABO microarray
Quotient Limited	U.S.	ABO		ALBAcyte Reagent Red Blood Cell products

Source: Kalorama Information

Quotient developed its immunohematology microarray technology for use on the MosaiQ platform, a multiplex transfusion diagnostics system designed to integrate blood grouping, antibody screening, and infectious disease testing within a single automated workflow. While the concept generated significant interest, commercialization of MosaiQ progressed more slowly than expected, and the system did not achieve broad routine adoption. Following financial challenges and restructuring, key assets were acquired by AliveDx, which has since shifted its focus toward selected transfusion diagnostics and specialty assay portfolios rather than large-scale rollout of the MosaiQ platform. As a result, MosaiQ remains more notable as a technically innovative approach to multiplex transfusion testing than as a widely deployed blood bank system.

Haemokinesis offers rapid emergency blood grouping as a key niche within transfusion diagnostics. Its STATUS platform is designed for urgent ABO grouping and limited Rh phenotyping in trauma and emergency settings, delivering results in approximately one to two minutes using whole blood samples. The system is based on rapid serologic agglutination principles rather than traditional column agglutination and is intended to support immediate transfusion decisions at or near the point of care. While it can process multiple samples sequentially, its primary value lies in speed and ease of use in critical situations rather than in high-throughput batch testing. The company has continued to develop additional transfusion-related products, focusing on rapid-response applications, including expanded typing capabilities and decentralized testing support.

Grifols is a leading global supplier of automated immunohematology systems. Its Erytra family utilizes DG Gel card technology with full automation to perform ABO/Rh typing, antibody screening, crossmatching, and investigation of atypical antibodies with minimal hands-on time. The WADiana Compact continues to serve smaller laboratories, while newer platforms such as Erytra Eflexis offer higher throughput and more flexible workflow configurations suited to mid- and high-volume blood banks. Grifols has continued to expand its automation footprint, including the broader rollout of Erytra Eflexis in Asia, where laboratory modernization and increasing transfusion demand are supporting adoption. Growth in automated blood bank systems remains strongest in regions transitioning from manual or semi-automated gel workflows to fully integrated platforms.

The PreciseType platform enables simultaneous identification of dozens of red blood cell antigens, allowing blood centers and transfusion laboratories to improve donor-recipient matching, identify rare antigen combinations, and preserve scarce donor units for highly sensitized patients. Molecular blood typing continues to gain strategic importance as

transfusion medicine increasingly moves toward precision compatibility, especially for chronically transfused populations.

Grifols has also continued strengthening its position in blood bank innovation through growth in automated typing systems and molecular typing support. The launch of Erytra Eflexis in major international markets reflects continued demand for faster, more flexible blood bank automation capable of handling increasingly complex transfusion testing workloads.

Molecular blood group testing has become an important complement to traditional serologic methods in transfusion medicine, particularly as laboratories encounter more complex patient populations. Unusual ABO typing results and weak or variant antigen expression can create challenges for conventional serology, especially in patients who have been recently transfused, those with hematologic malignancies, or individuals with underlying red cell disorders. In these settings, molecular testing is used to resolve discrepancies and provide a clearer understanding of the patient's true antigen profile. The growing use of chronic transfusion therapy and the rising incidence of alloimmunization have further increased reliance on genotyping to support accurate and consistent blood group determination.

PCR-based blood group genotyping and SNP-based platforms play a central role in extended antigen typing, rare donor identification, and selected forensic applications. Because red blood cells express a wide range of clinically significant antigens beyond ABO and Rh, molecular methods allow laboratories to determine extended antigen profiles with greater precision, particularly when serologic testing is limited by reagent availability or interference from circulating antibodies. This capability is especially valuable when patients develop multiple alien bodies or when compatible donor units are difficult to locate due to uncommon antigen combinations within the donor pool.

Genotyping has proven particularly useful in patients with conditions such as sickle cell disease, thalassemia, autoimmune hemolytic anemia, and hematologic malignancies, where repeated transfusions or positive direct antiglobulin tests can interfere with serologic typing. In these cases, molecular characterization of antigen variants enables more accurate donor matching, helping reduce the risk of alloimmunization and improve long-term transfusion outcomes.

Thermo Fisher Scientific has strengthened its position in molecular blood group testing through its transfusion diagnostics portfolio, particularly following the integration of the Immucor molecular business. The company offers PCR-based and array-based genotyping

solutions designed for extended red blood cell antigen typing, rare donor identification, and resolution of serologic discrepancies. Its platforms support detection of clinically significant antigens across multiple blood group systems, enabling laboratories to perform high-throughput genotyping and improve donor–recipient matching in complex transfusion cases. Thermo Fisher's systems are widely used in reference laboratories, blood centers, and specialized hospital settings, where molecular typing is increasingly incorporated into routine workflows for patients with chronic transfusion requirements, multiple alloantibodies, or inconclusive serologic results.

Size and Growth of Typing Markets

This market is mature. The market for blood typing is $1,030 million in 2025. Recovery has stabilized with 1.8% CAGR, it will grow to $1,125 million. Aging of the population, emerging markets, and new typing systems, including molecular, will drive what growth exists in this market.

Table 12-6: Global Blood Typing Market, 2025-2030 ($ million)

Market	IVD Sales 2025	IVD Sales 2030	CAGR
ABO Typing	1,030	1,125	1.8%

Source: Kalorama Information

Blood Typing Market by Geography

The global market for blood typing is driven by sales in North America and Europe, accounting for about 90%. These markets are well established and are common practice in these regions. In developing nations, blood typing is underutilized but also faces barriers to growth, including education, limited procedures and pricing.

Table 12-7: Global Blood Typing Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	59%
Europe	30%
Asia Pacific	7%
RoW	4%
Total	**100%**

Source: Kalorama Information

Blood Testing Market

In developed nations, donated blood is screened for various pathogens. It is a mature market, but growth comes from new technologies, increased volume and increased testing in developing nations.

In the blood bank and plasmapheresis testing markets, dollar volume closely parallels sample volume. Moreover, with the introduction of molecular diagnostics, a significant increase in cost per test is expected with each new method. Part of this cost increase will be due to inflationary effects, but most of it will result from three market conditions for blood bank/plasmapheresis center testing products. The following table represents recent innovations in blood testing.

Table 12-8: Selected Blood Testing Innovations

Company	Location	Details
Grifols International	Spain	Ultrio Elite 4-in-1 assay
Grifols International	Spain	Procleix PANTHER and Ultrio Elite Assay, HIV1/2, HCV, HBV
Grifols International	Spain	Procleix HEV
Grifols International	Spain	Procleix WNV. West Nile
Grifols International	Spain	Procleix Zika Virus Assay
MP Biomedicals LLC	U.S.	HTLV Blot 2.4, Western blot, testing and viral typing
Roche Diagnostics	U.S.	cobas 6800 and 8800 Systems
Roche Diagnostics	U.S.	cobas TaqScreen DPX infectious diseases, cobas s 201 system
Roche Diagnostics	U.S.	cobas TaqScreen DPX, parvo/HAV
Roche Diagnostics	U.S.	cobas TaqScreen MPX Test v2.0, HIV, HBC, and HCV
Roche Diagnostics	U.S.	MPX, HBV, CMV, West Nile on cobas 6800 & 8800
Roche Diagnostics	U.S.	cobas TaqScreen West Nile Virus Test
Roche Diagnostics	U.S.	4-in1 MPX-E assay

Source: Kalorama Information

Preventing Bacterial Infections

Bacterial contamination is one of the most important infectious hazards in transfusion medicine, particularly for platelet components, which must be stored at room temperature and therefore are more susceptible to bacterial growth than other blood products. Although blood centers and transfusion services have made major progress in viral screening, bacterial risk control for platelets continues to require ongoing attention through improved collection procedures, diversion of the initial blood volume, bacterial detection methods, and pathogen reduction technologies. Current blood safety practice does not eliminate the need for donor screening and infectious disease testing, but increasingly relies on layered strategies to reduce transfusion risk.

Platelets are especially vulnerable to contamination because they are stored under conditions that could possibly lead to bacterial proliferation. This is a major concern for patients receiving intensive transfusion support, including those with cancer, leukemia, and other serious hematologic disorders. To reduce risk, blood centers use measures such as improved skin disinfection, diversion pouches that capture the first portion of donated blood, bacterial testing protocols, and pathogen reduction approaches. Regulatory and professional standards continue to require active bacterial risk control for platelet components rather than reliance on any single safeguard.

Pathogen reduction has become one of the most important proactive safety measures in platelet and plasma transfusion. Cerus's INTERCEPT Blood System remains the leading commercial platform in this area, using amotosalen and UVA light to inactivate a broad range of pathogens and donor leukocytes in platelet and plasma components. The system is well established in the United States and many international markets and has supported a broader move away from relying solely on agent-specific testing. Terumo Blood and Cell Technologies continues to market the Mirasol pathogen reduction system outside the United States, using riboflavin and ultraviolet light to reduce the risk of infection in platelets and plasma, with broader international use in select regions.

Immunoassays

Immunoassays for HIV, hepatitis B, hepatitis C, and syphilis have been the routine approach to testing blood units for blood-borne infectious agents. All blood banks in Latin America

and some in the U.S. also screen donated units for Chagas disease. Blood banks in some developing countries also screen for Lyme, Dengue fever and malaria.

The 2025 market for blood screening immunoassays performed by blood transfusion services—public, private and hospital-based has been evaluated at $834 million. The market is fairly mature, expansion is achieved through the introduction of assays to screen for emerging pathogens such as malaria, Dengue, West Nile virus and Chagas disease testing in developed countries. Also, there is a concerted effort in emerging countries to ensure the safety of the blood supply.

Company penetration in this market is designated by geography. Outside Asia, the blood screening market includes Abbott Laboratories and QuidelOrtho.

In Asia, primarily Japan, Thailand, Korea and Taiwan, the majority of blood banks use Fujirebio's RPHA tests.

Abbott Diagnostics, the leader in immunoassay tests, has made a concerted effort to expand its offerings. Abbott has a long history in blood screening. The hallmark of Abbott's blood screening products is the PRISM System. It consolidates testing into a single system, automating many of the manual testing procedures and steps currently used to screen blood for pathogens. The system tracks and monitors each sample throughout the testing process, providing documentation and quality control for testing facilities.

QuidelOrtho offers the Avioq HTLV-I/II Microelisa System assay, a new test developed in partnership with Avioq, Inc. to screen blood and organ donations for antibodies to human T-lymphotropic virus (HTLV) type I and II. The AVIOQ HTLV-I/II Microelisa System assay is fully compatible with the ORTHO Summit System platform

Whole blood donations are screened for a number of different pathogenic agents including HIV, hepatitis B and hepatitis C. Blood banks in some developing countries also test for pathogens associated with Chagas disease, Lyme disease, Dengue fever and malaria. Additionally, in the US, the FDA's Center for Biologics Evaluation and Research has sought to enhance the safety and effectiveness of blood transfusions by imposing limits on the level of leukocytes allowed in cellular components. The reduction or elimination of leukocytes lessens the risk of adverse transfusion reactions, such as the transmission of intracellular viruses.

Nucleic Acid Testing (NAT)

Nucleic acid testing is an important component of blood screening and is widely used to detect infectious agents in donated blood. By directly identifying viral genetic material, it shortens the window period compared to traditional serologic testing and improves overall blood safety. It is routinely used in the United States, Canada, Europe, Japan, Australia, and many other regions. Standard NAT screening panels typically include HIV-1 RNA, hepatitis C virus RNA, hepatitis B virus DNA, and West Nile virus RNA, with additional targets added in some countries based on regional disease patterns. In practice, NAT works alongside immunoassay testing as part of a layered approach rather than replacing it.

Grifols is one of the major global suppliers of NAT-based blood screening systems and continues to support screening programs across Europe, Asia Pacific, and other international markets. Adoption is already well established in developed regions, while ongoing expansion is driven by regulatory requirements, continued focus on blood safety, and the need to address emerging infectious risks.

Size and Growth of the Market

Manufacturers introduce new assay methods in stages, bringing initial versions to market that meet immediate clinical and regulatory needs while leaving room for improvement in automation, throughput, and workflow integration. Earlier versions may rely on semi-automated processes, while more advanced generations offer higher levels of automation, improved sensitivity, and better connectivity with laboratory systems. Blood banks continue to favor increased automation because it improves standardization, reduces manual handling, and lowers the risk of human error.

Competition in blood and plasma testing remains concentrated among a relatively small number of global suppliers, particularly in high-throughput screening and molecular diagnostics. However, the market is not without pricing pressure. While the complexity of instrumentation and regulatory requirements creates high barriers to entry, large blood centers and national screening programs often negotiate long-term contracts that include volume-based pricing, bundled reagent agreements, and service commitments. As a result, pricing is influenced not only by technological advancement but also by purchasing scale and competitive positioning among leading vendors.

There has been a clear shift toward molecular testing as part of routine blood screening, with nucleic acid testing now well established alongside immunoassays. Growth in molecular testing has been driven by its ability to detect infections earlier, while immunoassays continue to play a critical role in broad screening due to their efficiency and cost-effectiveness. Rather than replacing older technologies entirely, laboratories typically use both approaches in combination, and upgrades tend to occur gradually as systems are replaced or expanded.

At the same time, expanding global travel and the spread of vector-borne diseases have increased awareness of emerging infectious risks in the blood supply. This has led to greater interest in proactive safety strategies, such as pathogen-reduction technologies, that can address a wide range of known and unknown agents. However, these approaches are not universally adopted due to cost considerations and operational factors.

The following chart details the blood testing market in 2025 and its projections through 2030. NAT screens are the largest market segment, primarily due to cost per test. An increase in blood testing in the developing world market will likely drive sales in the immunoassay screen segment; while NAT screens will be suppressed due to higher costs in developing countries, it will be partially offset by increased use in developed markets.

Table 12-9: Global Blood Banking Diagnostics Market, 2025-2030 ($ million)

[Immunoassay Screen; NAT Screens]

Market	IVD Sales 2025	% Mkt	IVD Sales 2030	% Mkt	CAGR
ABO Grouping	1,045	33%	1,150	30%	2%
NAT Screens	1,330	41%	1,790	47%	6%
Immunoassay Screen	834	26%	885	23%	1%
Total	**3,209**	**100%**	**3,825**	**100%**	**4%**

Source: Kalorama Information

Lastly, the market for blood banking and plasmapheresis testing reagents is inelastic. Blood banks must use the latest technology and reagents. For example, blood collection centers often utilize equipment that is being studied under an Investigational New Drug (IND)

application pending approval of a Biologics License Application (BLA). Therefore, with limited competition, companies have considerable pricing discretion and can maintain market share once blood banks and plasmapheresis centers have adopted the assays and purchased the necessary instrumentation. Blood banks and plasmapheresis centers also cannot effectively "cherry-pick" their reagents from various molecular diagnostics suppliers, even as new competition appears. Pricing and discounting for reagents and supplies are generally based on total volume; attempts to spread the business around could actually leave the blood bank or plasmapheresis center with less-than-optimal pricing overall.

The market for blood screening immunoassays is estimated at $834 million in 2025, and with 1% growth driven primarily by emerging markets where the technology is still used, the market will be in $885 million by 2030. Due to their lower cost, immunoassays are more frequently used in developing nations, whereas nucleic acid testing is predominantly used in developed countries, although this is changing. The U.S. was the single largest region for immunoassay testing revenue, due mainly to its prominent position in the blood industry, although U.S. nucleic acid revenue is much higher.

Kalorama estimates the market for NAT blood screening at $1,330 million, growing at 6% due to increasing conversions and the strength of the emerging market NAT conversion.

Blood Testing Market by Geography

The following figure demonstrates the market for all blood testing by geography. The United States, Japan, and Germany lead the world market. China and Latin America are significant markets for both immunoassays and nucleic acid test systems.

Table 12-10: Global Blood Testing Market, by Geography, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	30%
Asia Pacific	29%
Europe	26%
RoW	15%
Total	**100%**

Source: Kalorama Information

The Commercial Outlook for Blood Banking Testing

Blood collection declined during the COVID-19 pandemic as lockdowns and reduced mobility disrupted donor access, but volumes have largely recovered as healthcare systems resumed normal operations. Blood bank testing remains a critical function, focused on maintaining a safe and adequate blood supply through infectious disease screening, investigation of transfusion reactions, ongoing evaluation of donor screening practices, and continuous improvement in collection and testing protocols.

The global blood banking diagnostics market is shaped by a combination of demographic and structural factors. Aging populations in developed regions are increasing demand for transfusions, while emerging markets are expanding healthcare infrastructure and access to diagnostic services. At the same time, the introduction of new testing technologies and workflow automation is showing incremental growth in what remains a relatively mature market segment.

Emerging and re-emerging infectious diseases continue to present ongoing challenges for blood safety. While the urgency surrounding certain outbreaks has declined, the experience with agents such as Zika demonstrated how quickly new threats can affect blood collection and screening practices. Established concerns such as hepatitis B and C, HIV, and West Nile virus remain part of routine screening programs, while additional pathogens, including dengue, chikungunya, malaria, and other vector-borne diseases, continue to require monitoring depending on regional risk. Increasing global travel and climate-related shifts in disease patterns are contributing to broader geographic exposure, reinforcing the need for adaptable screening strategies.

Blood systems are increasingly relying on layered safety approaches that combine donor screening, immunoassay testing, molecular testing, and targeted risk-reduction measures. Pathogen reduction technologies are gaining attention as a proactive strategy to reduce infectious risk across a wide range of known and emerging agents, although adoption varies due to cost and operational considerations. These technologies are expected to play a growing role alongside conventional testing rather than replacing it entirely.

Advances in blood typing are also affecting the market, particularly in molecular and extended antigen profiling. These technologies are becoming more important as transfusion practices evolve to support patients with chronic conditions and repeated transfusion needs, where precise matching can reduce complications such as alloimmunization. As a result,

laboratories are gradually incorporating more advanced typing methods into routine workflows.

Efforts to improve the donor experience are also emerging as part of broader strategies to stabilize and grow the donor base. New digital and engagement tools are being introduced to make the donation process more accessible and appealing, particularly to younger donors, although these innovations remain supplementary to the core clinical and operational aspects of blood collection.

Chapter 13: Histology and Cytology

Scope

This chapter concentrates on IVD histology and cytology products, technologies and services used to stain, analyze and diagnose diseases based on the microscopic examination of tissues and cells. This market includes pathology labs, cancer diagnostics and various disease screenings.

Overview

Histology and cytology remain the foundation of tissue- and cell-based diagnostics. Histology focuses on tissue architecture, while cytology examines individual or small clusters of cells. The workflow still centers on preanalytical processing, fixation, embedding, sectioning, and slide preparation, followed by staining and interpretation. Common specimens include biopsied or surgically excised tissue, as well as fluids such as sputum, cervical samples, and synovial fluid. Slides are typically reviewed first by trained technologists, with pathologists making the final diagnosis, especially in cases showing abnormal or suspicious morphology. Essentially all surgically removed tissue undergoes routine histopathologic evaluation.

Cancer diagnosis continues to rely heavily on determining the tissue of origin, although some cases present as cancers of unknown origin. In these situations, pathologists use a broader toolkit that includes immunohistochemistry (IHC), in situ hybridization (ISH), fluorescence in situ hybridization (FISH), and molecular profiling to define classification. IHC, which uses labeled antibodies to detect specific proteins, is most commonly used, while FISH and related methods identify genetic alterations within cells. These approaches are complemented by next-generation sequencing and other molecular techniques that help define tumor subtype, prognosis, and potential treatment pathways.

The role of biomarkers has expanded significantly. Rather than being limited to structural analysis, histology now integrates protein expression, gene alterations, and signaling pathways to guide therapy selection. Companion diagnostics for targeted therapies are routinely performed on formalin-fixed tissue, and multiplex staining techniques enable multiple markers to be evaluated on a single slide. Analysis of circulating tumor cells and cell-free DNA in blood and other body fluids is advancing, although these approaches are still used selectively and continue to evolve.

Automation and digital pathology are reshaping laboratory workflows. High-throughput slide processors, automated stainers, and whole-slide imaging systems are now common in larger laboratories. Digital pathology enables remote review, image sharing, and the application of image analysis algorithms, including artificial intelligence tools that assist with screening, quantification, and pattern recognition. These systems are helping labs manage rising volumes and workforce shortages while improving consistency and turnaround times.

Cytology has also evolved, particularly in cervical cancer screening, where liquid-based cytology and HPV testing have improved detection and workflow efficiency. In addition to oncology, cytology and histology techniques are used in infectious disease detection, chromosome analysis, and evaluation of inflammatory and degenerative conditions. Flow cytometry is used for hematologic malignancies, while mass spectrometry and sequencing are used in complex or ambiguous cases.

While many advanced technologies, such as spatial biology, multiplex imaging, and integrated genomic-proteomic profiling, are gaining traction, their routine clinical use is still expanding. Adoption depends on validation, cost, reimbursement, and demonstrated clinical utility. Laboratory-developed tests offered through specialized reference labs continue to play a major role in bringing new assays to market, particularly in oncology and rare disease diagnostics, where expertise and test complexity limit widespread in-house adoption.

Our 19th edition of ***The Worldwide Market for In Vitro Diagnostic (IVD) Tests*** consolidates all aspects of histology testing into a single chapter and includes a Special Topics section that addresses histology hot spots. The chapter covers:

- Histology/Cytology
- Digital Imaging
- Tissue Microarrays
- Pharmacodiagnostic Histology
- Circulating Tumor Cells
- Flow Cytometry

Special Topics

Histology Automation

Histology slide analysis is highly labor-intensive and subjective. At least this was the scenario for this market segment until the commercialization of automation and digital image analysis. Now histology is following the trend already in action in other test segments and is investing in end-to-end automation of the entire tissue process. From slide preparation through analysis to result reporting, combined solutions enable faster turnaround times while providing standardized results.

The growing number of cancer patients is a major factor, but several technological advancements also contribute to this growth. Sample preparation for histology has always been fairly automated, but companies have invested in improving it with new, faster tissue fixatives and systems that enhance nucleic acid extraction from tissue samples. Of note is new instrumentation to automate RNA detection in fixed tissues. This is important for advanced companion tests.

Automation of histology has become fairly routine in the developed world and will gradually spread to the larger urban centers in developing countries. Automated sample processing and slide stainers have been available for some 10 to 15 years; however, end-to-end automation, digital optics, and the artificial intelligence algorithms and high-capacity computer power necessary to really make these systems work efficiently have only recently become available.

Innovation in immunohistochemistry (IHC) staining has evolved significantly over the last two decades. The process of staining has shifted from labor-intensive, manual techniques to semi-automated instruments with off-line processes such as deparaffinization and antigen retrieval, and now to a new generation of automated, baking-through-staining instrumentation systems that enable standardization, improved staining consistency, and expedited turnaround times.

Agilent Technologies continues to position the Dako Omnis as a high-throughput integrated automation platform for advanced pathology laboratories, large hospital systems, academic medical centers, and reference laboratories. Dako Omnis combines hardware, workflow software, and assay reagents into a fully automated system supporting both IHC and in situ hybridization (ISH) on a single platform. The system enables continuous slide loading, batch

processing, and overnight operation, allowing full patient cases to be processed with strong workflow consistency and traceability. Operator-level documentation of slide handling, reagent use, and maintenance supports quality assurance and regulatory compliance. Developed with engineering support from Tecan Group, the platform remains a core component of Agilent's digital pathology and companion diagnostics strategy. Agilent also continues to support laboratory workflow connectivity through Dako Link for legacy staining systems, although the current emphasis is increasingly on the integrated Omnis workflow architecture and digital pathology interoperability.

Sakura Finetek remains a major leader in pre-analytical tissue processing and histology automation. The Tissue-Tek AutoTEC a120 continues to serve laboratories requiring automated embedding with barcode-based specimen traceability and connectivity to laboratory information systems. The platform processes up to 120 cassettes per hour and uses automated specimen orientation technology to improve block consistency, reduce variability in tissue handling, and enhance patient safety by minimizing orientation errors and specimen loss. Sakura's integrated pre-analytical workflow remains a major differentiator, particularly when combined with its cassette systems, sectioning solutions, and tissue processors.

Sakura also continues to expand its staining menu on the Tissue-Tek Genie Advanced Staining System, with ready-to-use antibody additions that support oncology, hematopathology, and precision medicine marker panels. Current menu development increasingly emphasizes biomarkers linked to targeted therapy selection, multiplex workflow efficiency, and standardized staining performance across decentralized pathology networks.

BioGenex continues to offer automated sample-preparation and staining workflow solutions for formalin-fixed, paraffin-embedded tissue. Its EZ-AR2 Elegance was developed to streamline deparaffinization, hydration, and antigen retrieval into a single-step preparation process for high-throughput IHC laboratories. The system processes approximately 100 slides in about 30 minutes and is designed for integration with BioGenex retrieval and staining platforms, including microwave-assisted and automated systems. BioGenex maintains an extensive antibody portfolio of over 400 markers, supporting broad pathology panel development across oncology, infectious diseases, and research applications.

In March 2025, BioGenex announced a new approach for the retrieval of antigens from FFPE tissues and their subsequent staining by IHC.

The introduction of information technology and smart phone applications has come to histology. Market leader Roche Diagnostics further solidified its position with the introduction of workflow tools that allow pathologists and lab managers to track the progress of a slide from preparation to digitization along with other critical slide information. This facilitates the exchange of information between pathologists and lab managers, resulting in a more streamlined workflow. The table below presents a selection of histology lab automation products.

Table 13-1: Selected Histology Lab Automation

Company	Location	Area	Details
Applied Spectral Imaging	U.S.	full	Automated imaging analysis
Biocare Medical	U.S.	stain	ONCORE Automated Slide Staining, IHC, FISH, ONCORE ProX
BioGenex	U.S.	stain	eFISHiency System, automated histology
BioGenex	U.S.	stain	EZ-AR2 Elegance; one-step FFPE prep
BioView, Ltd.	Israel	analysis	Duet-3 automated imaging; detection, classification, analysis, counting
Cerner Corp. (Oracle Health)	U.S.	full	Oracle Health Copath anatomic pathology system with Labotix lab automation
Dako/Agilent	Denmark	smpl prep	Dako Omnis automation ISH & IHC tissue processing
Diagnostic Biosystems	U.S.	stain	Mosaic 360 System, an automated IHC instrument & kits, multicolor
Leica Biosystems	Germany	analysis	Aperio RNA ISH Algorithm for use with Advanced Cell Diagnostics' RNAscope
Sakura Finetek Europe	Netherlands	smpl prep	Tissue-Tek AutoTEC a120 Automated Embedder
Sakura Finetek Europe	Netherlands	smpl prep	Paraform Sectionable Cassette System
Serosep Limited	Ireland	smpl prep	HistoPot mini, formalin specimen container fine needle biopsies
Ventana Medical/Roche Diagnostics	U.S.	stain	Roche Digital Pathology Dx with Ventana DP 600n slide scanner
Ventana Medical/Roche Diagnostics	U.S.	stain	HE 600 system, a fully automated H&E staining
Ventana Medical/Roche Diagnostics	U.S.	stain	BenchMark Special Stains platform
Ventana Medical/Roche Diagnostics	U.S.	stain	Ventana Gram Stain BenchMark Special Stains instrument
Visiopharm	Denmark	analysis	Biotopix and Oncotopix software modules for digital pathology automation

Source: Kalorama Information, company reports

A major component of histology automation is information technology tools that facilitate sample tracking and also the ability to extract clinically actionable knowledge, thereby yielding more precise diagnoses, disease stratification, and selection of patient-specific treatments. The table below presents a selection of announced information technology tools.

Table 13-2: Histology Information Technology Tools

Company	Location	Details
Barco	Belgium	Barco's slide review display systems
Dako/Agilent	Denmark	DakoLink IT connect Dako's Autostainer and Artisan
Leica Biosystems/Aperio	U.S.	Aperio ePathology NETWORK connectivity solution
Roche Tissue Diagnostics	U.S.	Navify Pathology Lab Advantage

Source: Kalorama Information, company reports

Advanced Analysis Solutions

Technologies such as immunohistochemistry and FISH allow visualization of specific proteins and genetic alterations in fixed tissue, cells, and selected body fluids. These methods are now routinely used in conjunction with molecular techniques, in which targeted cells or regions of interest can be further analyzed by PCR, sequencing, and, in specialized settings, mass spectrometry.

Tumor heterogeneity, both cellular and molecular, is a challenge in oncology and has driven the adoption of broader profiling approaches. Mass spectrometry imaging, including MALDI-based techniques, is gaining traction for mapping molecular distributions within tissue sections and has demonstrated value in tumor classification and biomarker research. While initially limited to fresh or frozen tissue, improvements now support analysis of FFPE samples, although routine clinical use remains limited.

Next-generation sequencing has become an important tool in tumor profiling, providing more comprehensive genomic insight than single-gene methods such as FISH. These approaches improve the detection of actionable mutations and expand access to targeted therapies.

FFPE tissue is the standard in pathology, but formalin fixation introduces cross-linking and fragmentation that can affect nucleic acid quality. Advances in extraction chemistry, library preparation, and assay design have significantly improved the ability to recover usable DNA and RNA from archival tissue, enabling reliable downstream molecular testing.

FFPE-focused workflows emphasize improved nucleic acid recovery, artifact reduction, automation, and compatibility with multiplex genomic testing, reflecting the growing integration of histology with molecular diagnostics.

Liquid biopsy offers a less invasive option for genomic analysis of tumors compared to traditional tissue biopsy. Tumor-derived DNA circulating in the plasma of cancer patients can be analyzed to detect clinically relevant mutations. Because this approach does not require an invasive procedure, it is particularly useful when tissue biopsy is not feasible or when repeated sampling is needed to monitor disease progression or treatment response.

Liquid biopsy is used in clinical practice for selected applications, especially in oncology, where it provides mutation detection and therapy selection. However, it does not replace tissue biopsy, which remains essential for initial diagnosis, tumor classification, and many pathology-based assessments. Instead, liquid biopsy is used alongside tissue analysis as part of a more comprehensive approach to cancer management.

While genetic and expression assays provide important insight into cancer, they do not fully capture the spatial and cellular complexity of the tumor microenvironment. Tumors develop within a dynamic network of epithelial and stromal cells, vascular and lymphatic structures, cytokines, and infiltrating immune cells. The type, distribution, and activity of these immune cells vary by tumor type and play a significant role in disease progression, prognosis, and response to therapy.

Assessment of the immune environment is an important component of cancer diagnostics, particularly in immuno-oncology. Protein- and gene-based assays, including immunohistochemistry and gene expression profiling, are used to assess immune activity and inform treatment decisions, although their predictive value varies by tumor type and clinical context.

Tumor tissue staining continues to provide critical information on tissue design, spatial relationships, and tumor heterogeneity. These insights allow pathologists to identify and isolate regions of interest within a sample, improving the accuracy of downstream molecular

testing. Higher tumor purity enhances sequencing sensitivity and supports more reliable data interpretation.

Microdissection techniques enable the selection of specific cell populations for molecular and sequencing analysis and are used in both research and selected clinical applications where precise tumor enrichment is required. As molecular diagnostics and histology become more integrated, there is increasing emphasis on linking anatomical pathology with genomic analysis through improved sample preparation and workflow coordination.

Advanced techniques, including multiplex spatial analysis and high-parameter tissue profiling, continue to expand and are gradually moving from research into clinical practice, particularly in specialized centers. At the same time, molecular diagnostics companies are entering the histology space, combining genomic expertise with tissue-based analysis to support more comprehensive cancer characterization and treatment planning.

Table 13-3: Selected Advanced Histology Techniques

Company	Location	Area	Details
Abbott Diagnostics	U.S.	PCR	FGFR3 gene mutations, urine, FFPE, bladder cancer; exclusive license for use of biomarkers granted by Institut Curie
Agena Bioscience	U.S.	mass spec	MassARRAY Dx PLUS assays gene-specific mutations, PGx
Agendia	Netherlands	DNA	MammaPrint FFPE breast cancer recurrence test
Amoy Diagnostics	China	DNA	AmoyDx FFPE DNA/RNA, spin column process
Amoy Diagnostics	China	PCR	AmoyDx ROS1 Kit
Amoy Diagnostics	China	PCR	EML4-ALK, PIK3CA, ERCC1 G, BRAF V600 mutations kit
ArcherDx	U.S.	sequencing	Anchored Multiplexed PCR sequencing libraries
Asuragen	U.S.	DNA	QuantideX DNA Assay, copy number in FFPE
Asuragen	U.S.	smpl integrity	SuraSeq DNA Quantitative Functional Index, DNA QC
BioMark Diagnostics	Canada	mRNA	Spermine/Spermidine N-Acetyl Transferase, mRNA
BioNTech Diagnostics	Germany	PCR	MammaTyper, stratify breast cancer, molecular subtyping
Bruker Biosciences	U.S.	mass spec	rapifleX MALDI-TOF/TOF mass spectrometer
Bruker BioSciences	U.S.	mass spec	ImageID MALDI TOF/TOF system
Circulomics	U.S.	smpl prep	Nanobind DNA & RNA extraction from FFPE
Covaris	U.S.	smpl prep	truXTRAC FFPE RNA extraction kit
DxTerity Diagnostics	U.S.	RNA	DxDirect, RNA in FFPE
DxTerity Diagnostics	U.S.	RNA	DxDirect RUO, RNA in FFPE, multiplexed
Epigenomics	Germany	immuno	Epi proLung tissue assay, Septin
HalioDx	France	immuno	Immunoscore Colon, CD3/CD8 T cells
HalioDx (Veracyte)	France	immuno	Immunoscore CR, CD3/CD8 T cells
HTG Molecular Diagnostics	U.S.	qNPA	HTG melanoma signature assays

Company	Location	Area	Details
HTG Molecular Diagnostics	U.S.	RNA	Edge RNA analysis automation, extraction free
Illumina	U.S.	sequencing	TruSeq Amplicon - Cancer Panel, MiSeq
Illumina	U.S.	sequencing	MiSeqDx for FFPE samples, NGS
IncellDx	U.S.	smpl prep	IncellPrep Liquid Biopsy cell suspension: FFPE
IncellDx, Inc.	U.S.	flow	OncoBreast 3Dx, mRNA, DNA cell ploidy, biopsy
IncellDx, Inc.	U.S.	flow	Quantitative Single Cell PD-L1 OncoTect iO Assay
LGC Genomics	Germany	smpl prep	high volume DNA from FFPE
MO BIO Laboratories	U.S.	smpl enrich	BiOstic FFPE Tissue RNA Isolation, PCR & NGS
Mo Bio Labs	U.S.	smpl enrich	BiOstic FFPE Tissue DNA/RNA Isolation Kit
MolecularMD Corporation	U.S.	DNA	PTEN gene, tumor growth
NanoString Technologies	U.S.	platform	nCounter MAX system for clinical labs
Revvity	U.S.	immuno	Mantra Quantitative Pathology Workstation, immune cells
Silicon Biosystems	Italy	smpl enrich	DEPArray tumor cell extraction from FFPE for NGS
Thermo Fisher	U.S.	array	OncoScan CNV Assay
Thermo Fisher Scientific	U.S.	sequencing	Oncomine Solid Tumor DNA panel, FFPE, lung, colon
Transgenomic	U.S.	QC	Horizon's QC products FFPE & genomic DNA

Source: Kalorama Information, company reports

HPV IVD Testing Becomes Main Stream

HPV refers to a group of more than 200 related human papillomaviruses, many of which cause asymptomatic infections. More than 40 types are transmitted through sexual contact and infect the genital tract of both men and women, while other types cause non-genital warts.

Although most HPV infections are resolved spontaneously, persistent infection with high-risk types can lead to cervical, anal, penile, vaginal, and head and neck cancers. HPV types 16 and 18 account for the majority of HPV-related cancers, while types 6 and 11 are responsible for most genital warts.

HPV is the most common sexually transmitted infection worldwide, with millions of individuals currently infected in the United States and millions of new infections occurring each year. The role of HPV in oropharyngeal cancers has grown significantly, particularly in developed countries, further expanding the clinical importance of HPV testing.

Cervical cancer screening relies on both cytology and molecular testing. The Pap test detects cellular abnormalities associated with HPV infection, while HPV testing identifies the presence of high-risk viral nucleic acids. Persistent infection with high-risk HPV is recognized as the central cause of cervical cancer.

QIAGEN, through its acquisition of Digene, played a key role in establishing the link between HPV and cervical cancer and commercialized early HPV testing using hybrid capture technology. Over time, HPV testing evolved from an adjunct to cytology into a primary screening method. Current screening guidelines increasingly support HPV-first strategies due to higher sensitivity for detecting precancerous lesions, with cytology used for triage.

Liquid-based cytology systems such as Hologic's ThinPrep and BD's SurePath enabled the use of a single cervical sample for both cytology and molecular testing, supporting large-scale screening and automation. These systems are used in laboratory workflows and allow seamless integration with molecular platforms for HPV and other sexually transmitted infections.

The HPV testing market now includes a broad range of assays from major diagnostics companies, including Abbott, Becton Dickinson, Cepheid, Hologic, Roche, and QIAGEN. Modern assays incorporate partial genotyping and risk stratification, particularly for HPV types 16, 18, and in some cases 45, enabling more direct clinical decision-making.

Self-collected sampling has emerged as an important advancement, with PCR-based assays demonstrating comparable performance to clinician-collected samples when validated methods are used. This approach is expanding access to screening in underserved populations

and is being incorporated into national screening programs. Self-collection manufacturers include Roche's cobas HPV test, BD's Onclarity HPV assay, Abbott's simpli-COLLECT HPV kit, and QIAGEN.

Globally, HPV-based screening is expanding, endorsed by public health initiatives and the WHO strategy aimed at cervical cancer elimination. Many countries are transitioning from cytology-based programs to HPV-first screening models.

HPV vaccination is now a major factor shaping the future of screening, reducing the prevalence of high-risk HPV types in vaccinated populations and gradually altering screening strategies and disease incidence patterns.

The market in Europe is estimated at 32% or $409 million for 2025, and the market in North America represents 35%, equal to $448 million.

Table 13-4: Global HPV Test Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	35%
Europe	32%
Asia Pacific	22%
RoW	11%
Total	**100%**

Source: Kalorama Information

Growth in HPV screening has significantly reshaped both the technologies used and the competitive landscape for HPV diagnostics. Earlier signal amplification methods, such as hybrid capture and other low-throughput approaches, have largely been replaced by high-throughput automated molecular platforms that provide greater sensitivity, genotype information, and scalability for population-based screening. Most clinical HPV testing is performed using PCR- or transcription-mediated amplification-based systems running on core molecular analyzers rather than slide-based or tissue-oriented methods.

Roche Diagnostics is one of the strongest global suppliers of HPV screening through its cobas HPV test and high-throughput cobas platforms, which detect high-risk HPV with partial genotyping for types 16 and 18. The company has gained a significant share in organized screening programs.

Hologic and QIAGEN remain major participants, particularly through Aptima HPV mRNA testing and QIAGEN's long-established HPV DNA testing portfolio in international markets. Additional suppliers include Abbott Laboratories, Becton Dickinson, Cepheid, Fujirebio, and Seegene, as well as several regional multiplex PCR providers.

Kalorama presents a conservative market estimate that sets HPV testing at $1,270 million in 2025, and with 11.1% CAGR, will reach $2,145 million in 2030. Roughly 67% of the market is held in North America and Europe. It is estimated that in the U.S. 60% of Pap tests are also accompanied by an HPV test. This acceptance level indicates that physicians are increasingly following evidence-based guidelines that support HPV plus Pap testing for women over age 30. However, cost is still a barrier to the implementation and widespread adoption of combination utilization.

There are a number of cervical cancer screening programs in operation worldwide. Japan, Australia, Singapore, Hong Kong, Taiwan, and Korea have national screening programs. In South Korea, the national screening program has about 60% coverage and is showing slow but steady increases in screening rates.

QIAGEN has been promoting HPV testing in low-resource countries and was awarded the CE mark for its careHPV Test to bring HPV testing to public health programs in low-resource, developing countries. In Thailand, Indonesia, Philippines, Vietnam, and Malaysia local non-government organizations and healthcare groups run screening programs, but there is no national screening policy.

In Africa, India, Bangladesh, and China, where a vast number of women live, there are no official screening programs. However, government and non-government organizations have collaborated to provide real data about the prevalence of cervical cancer in these countries. Further, QIAGEN was awarded the CE mark for its careHPV Test, bringing human HPV testing to public health programs in low-resource, developing countries.

The table below presents a selection of HPV tests that use a cervical fluid sample but are not performed as part of the Pap test. A number of companies still use in situ hybridization; other companies, including Enzo Clinical Labs, perform HPV by flow cytometry.

Table 13-5: Selected HPV Test Innovations

Company	Location	Area	Details
Becton Dickinson	U.S.	PCR	Onclarity HPV on BD Viper LT System
Bio-Reference Lab	U.S.	PCR	GenCerv HPV E6/E7 oncogene
Bio-Reference Lab	U.S.	mRNA	InCellDx GenCerv, HPV mRNA quantification
Cepheid	U.S.	PCR	Xpert HPV on GeneXpert System
DiaCarta	U.S.	bDNA	QuantiVirus HPV E6/E7 bDNA test
Diagcor Bioscience	Hong Kong	PCR	GenoFlow HPV Array, PCR Flow-through
Enzo Biochem	U.S.	flow	FlowScript HPV E6/E7 assay
Enzo Biochem	U.S.	flow	IncellDx's HPV OncoTect
Fujirebio Europe	Belgium	array	INNO-LiPA HPV Genotyping Extra II assay
Fujirebio/Autogenomics	Japan	array	INFINITI HPV, HPV Genotyping BioFilmChip Microarray
Hologic	U.S.	mol	TIGRIS DTS System for Aptima HPV & trichomonas
Hologic	U.S.	TMA	Aptima HPV 16 18/45 genotype on PANTHER & Tigris
GeneCell Diagnostics	India	flow	InCellDx's HPV test in India
Genomed	Switzerland	PCR	F-HPV typing
Genomic Vision	France	PCR	HPV cell integration in cervical fluid smears
Genomica	Spain	array	CLART HPV
Greiner Bio-One	Austria	chip	PapilloCheck HPV genotyping
IncellDx	U.S.	flow	OncoTect 3Dx, cervical fluid
Kindstar Global	China	flow	InCellDx's HPV test in China
Luminex	U.S.	PCR array	Luminex HPV
Milford Medical Lab	U.S.	NGS	HPV genotyping
PreTect AS	Norway	NASBA	PreTect SEE, mRNA
PreTect AS	Norway	NASBA	PreTect HPV-Proofer, mRNA

Company	Location	Area	Details
QIAGEN	Netherlands	PCR	digene HPV Genotyping PS Test
QIAGEN	Netherlands	Signal Amp	careHPV Test for developing countries
QIAGEN	Netherlands	PCR	QIAsymphonySP for liquid cytology
Quest Diagnostics	U.S.	RNA	HPV, E6/E7 messenger RNA
Roche Diagnostics	U.S.	PCR	cobas HPV using samples collected in SurePath fluid
Roche Diagnostics	U.S.	PCR	cobas HPV on cobas 4800 System
Roche Diagnostics	U.S.	array	LINEAR ARRAY HPV Genotyping Test
Roche Diagnostics	U.S.	PCR	cobas HPV direct from cytology vial
Roche Diagnostics	U.S.	PCR	cobas HPV Test screen without Pap first
SeraCare Life Sciences	U.S.	QC	ACCURUN HPV mRNA positive
Shanghai Fosun Long March	China	HPV	Multiplex Probe Amplification, HPV closed tube
TrovaGene	U.S.	tr-DNA	urine-based HPV-HR, high risk
Waters	U.S.	Self Collection	Onclarity HPV Self-Collection Kit
Zeesan Biotech	China	HPV	MeltPro High Risk HPV Genotyping Assay

Source: Kalorama Information, company reports

Market Analysis

Total Market

The histology test segment is one of the more consistent sectors in the IVD industry. Though innovation in histology testing appears to focus on cancer, researchers are investigating cellular processes in diabetes, autoimmune diseases, and neurodegenerative conditions, among others. In the next 5-10 years, some of these new assays will come to market.

Histology, cytology and flow cytometry reagents and instruments can be segmented into the main categories shown below. Also included in this market assessment is testing for circulating tumor cells. All of these techniques involve analyzing cells from either surgical or biopsy tissue or body fluids.

- histology/cytology
- traditional tissue stains
- Pap test
- immunohistochemical stains
- in situ hybridization staining

Table 13-6: Global Histology/Cytology Sales, by Type, 2025-2030 ($ million)

[HPV; Immunohistochemistry; in situ hybridization; Pap Tests; traditional non-Pap stains]

Type	IVD Sales 2025	% Mkt	IVD Sales 2030	% Mkt	CAGR %
Immunohistochemistry	2,364	37%	3,180	36%	6.1%
HPV	1,270	20%	2,145	25%	11.1%
Pap Tests	1,110	18%	1,320	15%	3.5%
in situ Hybridization	1,045	17%	1,515	17%	7.7%
Traditional non-Pap Stains	498	8%	582	7%	3.2%
Total	**6,287**	**100%**	**8,742**	**100%**	**6.8%**

Source: Kalorama Information

Regional Market Analysis

Histology and cytology testing have always been phenomenon of the developed world. At least 80% of the world market for histology/cytology products is held by North America, Japan, Western Europe, and Latin America.

Table 13-7: Global Histology/Cytology Sales Distribution, by Region, 2025 (%)

[Asia Pacific; Europe; North America; Rest of World]

Region	% Mkt
North America	39%
Europe	34%
Asia Pacific	22%
RoW	5%
Total	**100%**

Source: Kalorama Information

The global market for diagnostic reagents, stains, and instruments used in histology and cytology is estimated at $6,287 million in 2025. With increasing demand for cancer diagnostics and pharmacogenomics, the market will grow at nearly 6.8% annually, reaching $8,742 million in 2030.

An additional $3,192 million in sales is generated by digital imaging, CTCs, and flow cytometry, which, with conservative annual growth of 7.0%, will reach $4,480 million by 2030.

Recent product development in digital pathology has shifted toward fully integrated, high-throughput systems that combine slide scanning, image management, and artificial intelligence–based analysis within a single workflow. New platforms such as the VENTANA DP series from Roche Diagnostics and expanded Aperio digital pathology solutions from Leica Biosystems reflect a move toward scalable enterprise systems designed for large laboratory networks. These platforms integrate barcode-driven case assembly, laboratory information systems, and secure remote access, allowing pathologists to review slides

alongside case data across locations and devices. At the same time, software providers are introducing clinically validated AI tools for tumor detection, biomarker quantification, and workflow prioritization, with some platforms offering marketplace-style access to multiple algorithms. These developments are accelerating the transition from traditional microscopy to fully digital, data-driven pathology workflows that improve efficiency, standardization, and diagnostic consistency.

The table below presents the revenue history of the major histology companies in traditional histology markets. Note that these revenues represent a wide variety of histology assay technologies, including stains, Pap testing, IHC, and ISH. These companies occupy approximately 60% of the market for histology tests and systems. Numerous other companies market a host of new and improved histology stains. A selection of these is presented in the appropriate subsection below.

Table 13-8: Revenues of the Major Histology Companies, 2018-2025 ($ million, estimated)

Company	2018	2019	2020	2021	2022	2023	2024	2025	YOY '24-'25
Roche	1,147	1,161	1,099	1,347	1,398	1,589	1,833	1,885	2.8%
Agilent	595	635	472	805	833	839	956	1,063	11.2%
Illumina	472	518	454	674	674	730	700	681	-2.7%
Danaher (Leica Biosystems)	650	659	471	477	507	557	570	583	2.3%
Hologic	480	472	411	480	471	509	485	490	1.0%
Abbott Diagnostics	241	251	227	276	263	277	282	289	2.5%
Becton Dickinson	180	180	112	121	164	130	138	120	-13.0%
Total	**3,765**	**3,876**	**3,246**	**4,180**	**4,310**	**4,631**	**4,964**	**5,111**	**3.0%**

Source: Kalorama Information, company reports

Roche Diagnostics Tissue Diagnostics remains one of the leading global suppliers of automated immunohistochemistry and in situ hybridization systems. Over the past two decades, Roche has built a dominant position through development of automated staining

platforms, a broad menu of diagnostic assays, and integration of workflow and digital pathology tools.

Roche markets instruments and reagents that automate and standardize tissue preparation and staining. Core platforms include the BenchMark ULTRA system, a widely adopted random-access IHC/ISH stainer that supports continuous loading and flexible workflows without strict batch processing. Earlier systems, such as BenchMark XT and LT, remain in the installed base but are being phased out in favor of newer platforms. Research-focused systems such as Discovery XT continue to support translational and life science applications, while older platforms such as NexES are largely legacy systems.

Roche also offers automation for special stains, built around its VENTANA workflow, with features including walk-away operation, integrated deparaffinization, and connectivity to laboratory workflow solutions. Software integration, remote support, and traceability tools are now standard across Roche's staining platforms, supporting quality control and regulatory compliance.

A major area of expansion for Roche has been digital pathology. The company has introduced high-throughput slide scanners, including the VENTANA DP 200 and DP 600 systems, designed for large-scale laboratory digitization and integration with image management and analysis software. These platforms are increasingly paired with AI-based image analysis tools and enterprise workflow systems, reflecting the broader shift toward fully digital pathology environments.

Roche's strategic focus has also shifted toward companion diagnostics and precision medicine. The company offers extensive collaborations with pharmaceutical partners to develop tissue-based assays that guide targeted therapies, particularly in oncology. These efforts include both IHC-based protein markers and molecular assays linked to specific drug therapies.

Agilent Technologies remains a major competitor in tissue diagnostics through its Dako portfolio, offering automated staining systems and a broad menu of antibodies and companion diagnostic assays. The company expanded its partnerships with pharmaceutical firms to support the development of biomarker-driven therapies.

Abbott Laboratories participates in tissue-based diagnostics primarily through its molecular and cytogenetics portfolio. The Vysis product line includes widely used fluorescence in situ hybridization (FISH) assays such as PathVysion HER2 and UroVysion for bladder cancer

detection and monitoring. Abbott continues to invest in molecular oncology and companion diagnostics, although it is not a major provider of automated histology instrumentation.

Becton Dickinson entered the cytology and adjacent histology workflow segment through its acquisition of TriPath Imaging. BD's portfolio includes liquid-based cytology systems such as SurePath and automation platforms like the BD Totalys system, which integrates cytology sample preparation with molecular testing workflows. The BD Onclarity HPV assay, run on BD molecular platforms, supports high-risk HPV detection and genotyping and is integrated into cervical cancer screening workflows. BD's 2025 performance decline was driven primarily by reduced research funding affecting its biosciences segment, post-pandemic normalization of diagnostics demand, pricing pressure in China, and margin compression, with additional impact from the strategic restructuring of its diagnostics and life sciences businesses heading into 2026.

Histology and cytology have historically been labor-intensive and manual, but this has changed significantly. Increasing test complexity, higher volumes, and demand for standardized results have driven widespread adoption of automation and digital pathology. Automated staining, slide preparation, and image analysis systems now support faster turnaround times and improved consistency. While most histology testing remains centralized in hospitals and reference laboratories, some workflow elements have expanded into larger physician practices and integrated health systems, particularly where digital pathology enables remote review and collaboration.

Traditional Stains

Traditional stains used on all types of formalin-fixed, paraffin-embedded tissues and fluids constitute the most mature segment of this market. The most widely used stain is hematoxylin & eosin (H&E), which provides a general overview of tissue structures and cells. Hematoxylin, a basic dye, stains nuclei blue due to an affinity to nucleic acids in the cell nucleus; eosin, an acidic dye, stains the cytoplasm pink. There are hundreds of various other techniques that have been used to selectively stain cells and cellular components. The most widely used special stains include: Congo red, elastin, Feulgen, giemsa, Gomori, iron, Masson, PAS (periodic acid schiff) and reticulin.

This segment of histology is estimated at $498 million in 2025 and is growing at 3.2% annually, reaching $582 million in 2030. Since all tissue sections are stained with one or

more of these stains, growth derives from increased cancer tumor samples. The major players are listed below.

Table 13-9: Selected Vendors of Traditional Histology Stains

Vendor
Agilent
BioMeda
Biosource
Immunon
QuidelOrtho
Roche Tissue Diagnostics
Siemens Healthcare
Spectrum

Source: Kalorama Information

Pap Testing

Cervical cancer screening has traditionally relied on the Papanicolaou (Pap) test, which remains an important component of cytology laboratories alongside routine staining techniques used for a wide range of tissue and cell samples. However, screening strategies have evolved, and high-risk HPV molecular testing is increasingly used either alongside cytology or as a primary screening method. Cervical cancer remains a major global health issue, with approximately 660,000 new cases and 350,000 deaths each year. While it is no longer among the most common cancers globally, it continues to be a leading cause of cancer-related death in women, particularly in low- and middle-income countries, where about 80% of cases and deaths occur.

Screening programs have significantly reduced cervical cancer incidence and mortality in developed countries. In the United States, screening rates are below national targets, reflecting ongoing gaps in access and follow-up care. Although mortality has declined over

time, the rate of improvement has slowed in recent years. Globally, access to screening remains uneven. In many developing regions, barriers such as cost, limited infrastructure, shortages of trained personnel, and lack of awareness continue to restrict participation. Cultural factors and reluctance to undergo pelvic examinations also play a role, leaving large portions of the at-risk population under-screened.

Advances are reshaping screening practices. Primary HPV testing is now widely adopted for women over 30, with cytology used more often for triage. Self-collected HPV sampling has emerged as an important development, showing comparable performance to clinician-collected samples when validated methods are used, and improving access for underserved populations. In addition, the introduction of at-home HPV testing options is expanding participation among individuals who might otherwise remain unscreened. These developments, along with global public health initiatives aimed at increasing screening coverage, are expected to further reduce the burden of cervical cancer by improving early detection and access to care.

Table 13-10: Primary and Secondary Prevention of Cervical Cancer, Screening Responses, by Country, 2021

Country	Existence of national screening program for cervical cancer	Type of national cervical cancer screening program	Most widely used screening method in national cervical cancer screening program	Coverage of national cervical cancer screening program (%)
Afghanistan	No	Not applicable	Not applicable	Not applicable
Argentina	Yes	Organized population-based screening	HPV test	Don't know
Australia	Yes	Organized population-based screening	PAP smear	more than 50 but less than 70
Bangladesh	Yes	Opportunistic screening	Visual inspection	Don't know
Belgium	Yes	Organized population-based screening	PAP smear	more than 50 but less than 70
Brazil	Yes	Opportunistic screening	PAP smear	70 or more
Canada	Yes	Opportunistic screening	PAP smear	70 or more
Chile	Yes	Organized population-based screening	PAP smear	Don’t know
China	Yes	Organized population-based screening	PAP smear	10-50
Colombia	Yes	Organized population-based screening	PAP smear	More than 50 less than 70
Denmark	Yes	Organized population-based screening	HPV test	more than 50 but less than 70
Dominican Republic	Yes	Organized population-based screening	PAP smear	70 or more
Ecuador	Yes	Organized population-based screening	PAP smear	Less than 10
Egypt	No	Not applicable	Not applicable	Not applicable
El Salvador	Yes	Organized population-based screening	PAP smear	10 to 50
France	Yes	Organized population-based screening	PAP smear	More than 50 but less than 70
Germany	Yes	Opportunistic screening	HPV test	70 or more
Hungary	Yes	Organized population-based screening	HPV test	10 to 50

Country	Existence of national screening program for cervical cancer	Type of national cervical cancer screening program	Most widely used screening method in national cervical cancer screening program	Coverage of national cervical cancer screening program (%)
India	Yes	Organized population-based screening	Visual inspection	70 or more
Indonesia	Yes	Organized population-based screening	Visual inspection	10 to 50
Iran (Islamic Republic of)	Yes	Organized population-based screening	HPV test	Less than 10
Iraq	Yes	Opportunistic screening	Visual inspection	N/A
Ireland	Yes	Organized population-based screening	PAP smear	70 or more
Israel	Yes	Opportunistic screening	PAP smear	10 to 50
Italy	Yes	Organized population-based screening	PAP smear	70 or more
Japan	Yes	Organized population-based screening	PAP smear	10 to 50
Malaysia	Yes	Opportunistic screening	PAP smear	10 to 50
Mexico	Yes	Opportunistic screening	PAP smear	Don't know
Netherlands	Yes	Organized population-based screening	HPV test	more than 50 but less than 70
New Zealand	Yes	Organized population-based screening	PAP smear	70 or more
Peru	Yes	Organized population-based screening	Visual inspection	10 to 50
Philippines	Yes	Opportunistic screening	Visual inspection	Don’t know
Poland	Yes	Opportunistic screening	PAP smear	10 to 50
Republic of Korea	Yes	Organized population-based screening	PAP smear	more than 50 but less than 70
Romania	Yes	Organized population-based screening	PAP smear	10 to 50
Russian Federation	Yes	Organized population-based screening	PAP smear	more than 50 but less than 70
Saudi Arabia	No	Not applicable	Not applicable	Not applicable

Country	Existence of national screening program for cervical cancer	Type of national cervical cancer screening program	Most widely used screening method in national cervical cancer screening program	Coverage of national cervical cancer screening program (%)
Singapore	Yes	Organized population-based screening	PAP smear	more than 50 but less than 70
Slovakia	Yes	Opportunistic screening	PAP smear	10 to 50
Slovenia	Yes	Organized population-based screening	PAP smear	10 to 50
South Africa	Yes	Opportunistic screening	PAP smear	more than 50 but less than 70
Spain	Yes	Opportunistic screening	PAP smear	more than 50 but less than 70
Sweden	Yes	Organized population-based screening	PAP smear	70 or more
Switzerland	Yes	Opportunistic screening	PAP smear	70 or more
Thailand	Yes	Organized population-based screening	PAP smear	more than 50 but less than 70
Turkey	Yes	Organized population-based screening	HPV test	70 or more
Ukraine	Yes	Organized population-based screening	PAP smear	Less than 10
United Arab Emirates	Yes	Organized population-based screening	PAP smear	Less than 10
United Kingdom of Great Britain and Northern Ireland	Yes	Organized population-based screening	Pap smear	70 or more
United States of America	Yes	Opportunistic screening	PAP smear	Less than 10
Venezuela (Bolivarian Republic of)	Yes	No data received	PAP smear	10 to 50
Viet Nam	Yes	Organized population-based screening	PAP smear	10 to 50

Note: Most recent data available

Source: WHO, Global Health Observatory data repository

Table 13-11: Three approaches to cervical cancer screening and future tests

Molecular	Cytologic	Visual inspection
Nucleic acid amplification tests (NAAT)[a] » high-risk HPV DNA/ NAAT » mRNA DNA methylation[b] Protein biomarkers[b] » HPV antibodies » oncoproteins	Conventional Pap smear[a] Liquid-based cytology (LBC)[a] Dual staining to identify p16 and Ki-67[a]	Visual inspection with acetic acid or with Lugol's iodine (VIA/VILI)[a] » naked eye » magnified by colposcope or camera Automated visual evaluation of digital images[b]

Note: a Current tests; b Tests under evaluation

Source: WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021. License: CC BY-NC-SA 3.0 IGO

The market for Pap testing accounts for $1,110 million in 2025 and with 3.5% annual growth will reach $1,320 million in 2030. The market for Pap tests is primarily North America and Europe with at least 70% of the market.

U.S. guidelines align on making primary high-risk HPV testing every 5 years the preferred strategy for women aged 30 to 65, with self-collected HPV samples accepted under clinical supervision. Younger individuals (21–29) continue with Pap testing every 3 years, while options like co-testing (HPV + Pap) every 5 years or Pap alone remain acceptable if HPV testing isn't available. Screening is no longer recommended for individuals over age 65 with a history of adequate prior testing, or those who've had a hysterectomy with no prior high-grade lesions.

In 2025, new European guidelines establish primary HPV testing every 5 years (ages 30–64) as the preferred cervical cancer screening strategy, replacing cytology or co-testing. Organized screening programs should avoid initiating screening before age 25 or beyond age 64 unless prior adequate screening is absent. Self-sampling and quality assurance

frameworks are key to improving access and effectiveness, with policy goals aiming to have at least 70% screening coverage by 2025 and 90% of eligible individuals are offered screening.

Japan, Australia, Singapore, Hong Kong, Taiwan and Korea have national screening programs. In Korea, the national screening program has coverage of about 55%, and so the country still has a high cervical cancer rate.

In Thailand, Indonesia, Philippines, Vietnam, and Malaysia local non-government organizations and healthcare groups run screening programs, but there is no national screening policy.

There are no official screening programs in Africa and Bangladesh. However, government and non-government organizations have collaborated to establish demonstration centers that are expected to provide real data about the prevalence of cervical cancer in these countries. The heart of cervical cancer control is regular Pap testing as performed in developed countries. In developing countries, the test is available to women who can afford it in urban areas but is largely unavailable to those living in the rural areas of even higher income developing countries. There is a huge need for company-supported initiatives in this area.

India has more incidence of cervical cancer cases than any other country in the world, followed by China. The World Health Organization (WHO) estimated in 2021, the incidence of cervical cancer was 18.7 per 100,000 women. China has an estimated incidence of cervical cancer of 15.6 per 100,00 women. The WHO estimates that only about 5% of women in the developing world have been screened for cervical disease in the previous five years, compared to 40%-50% in the developed world.

In China, more than 12 million Pap tests are performed every year, mostly through private labs. The available Pap test market comprises 300 million women aged 30 to 50 who have at least basic health coverage under government insurance programs. Recent screening rates were boosted by the central government-led free screening program for 10 million rural Chinese women as part of healthcare reform.

Continuous improvements have perfected the test in the past 10 years or so. Monolayer preparation has become an important development in cytology sample preparation. It is an important element in the automated reading of cytological samples such as Pap smear, urine cytology, bone marrow, cerebral, and spinal fluid. Hologic's ThinPrep is the major product in this area. Automated Pap smear systems are available from Hologic/Cytyc, BD/Tripath,

Roche/Ventana, Molecular Diagnostics, AccuMed International and Neuromedical Systems. Liquid-based Pap tests using liquid transport media such as ThinPrep currently account for approximately 75% of the Pap tests performed in the U.S., Europe and Japan.

The most successful liquid and automated Pap smear analysis systems are available from Hologic/Cytyc, Roche Tissue Diagnostics and BD/Tripath. These companies claim that their products are used in approximately 90% of the 65 million Pap tests performed in the U.S. After almost 20 years on the market, Hologic's ThinPrep system has become the state-of-the-art in cervical cell preparation for Pap and other cytology tests.

Hologic offers the CE marked ThinPrep Genesis Processor, an automated cytology slide and molecular sample system. The ThinPrep Genesis processor provides the same trusted reliability as the ThinPrep 2000 system for cytology slide processing, with added features such as automated division of the sample into smaller volumes for molecular testing. The processor also provides automated barcoding of samples, ensuring accurate sample tracking as well as reducing manual steps.

Widely available in developed countries, the Pap test has led to at least a 50% decrease in cervical cancer rates in the last 30 years. However, only 20 million Pap tests are performed each year in all of the developing countries. This means that only 1.2% of the at-risk population of 1.7 billion women receive a Pap test. So, the right technology at the right price can really make a significant difference in the developing nations.

Immunohistochemistry and In Situ Hybridization

Despite growing interest in downstream molecular analysis, traditional IHC and ISH performed on FFPE tissue sections are used in cancer diagnostics. Histologic evaluation still begins with routine morphology, followed by IHC and, when appropriate, ISH-based methods to further characterize tumor type, origin, and biomarker status. Advances in multiplex IHC and continued expansion of antibody panels have strengthened the role of these techniques in both diagnosis and treatment selection.

Traditional staining methods offers a range of targeted techniques, including IHC, ISH, chromogenic ISH (CISH), and fluorescence in situ hybridization (FISH). These methods enable the detection of protein expression and genetic alterations directly within tissue structure. FISH is an important tool for identifying chromosomal abnormalities and gene

amplifications and is widely used in both hematologic malignancies and solid tumors, including breast and lung cancer.

The markets for IHC and ISH continue to grow, driven by increasing demand for biomarker testing, companion diagnostics, and more precise tumor classification. IHC represents the larger, higher-volume segment, whereas ISH procedures typically demand higher test costs and are used for more targeted applications. Growth in both segments is realized by the expanding number of clinically relevant biomarkers and the integration of tissue-based testing with molecular diagnostics.

Interesting developments are expanding the capabilities of these technologies. RNA-based in situ hybridization is increasingly being integrated into automated staining platforms, allowing faster detection of gene expression while preserving tissue morphology. Platforms such as RNAscope from Bio-Techne enable sensitive detection of RNA transcripts, including viral markers like high-risk HPV, in head and neck cancers. These methods are moving beyond research use and into clinical and translational workflows. At the same time, spatial biology approaches are emerging that combine RNA and protein detection within the same tissue section, providing more detailed insight into tumor biology and the surrounding microenvironment.

While laboratory-developed tests remain important, particularly in specialized settings, there has been a shift toward standardized, automated platforms and validated assays, including companion diagnostics linked to targeted therapies. Multiplex staining and high-parameter analysis are becoming more common, especially in oncology, where multiple biomarkers are assessed on a single slide. In some applications, advanced RNA-based ISH methods are beginning to complement or replace traditional FISH approaches.

Table 13-12: Selected In Situ Hybridization-based Tests

Company	Location	Details
Abbott Diagnostics	U.S.	nonaggressive prostate cancer gene panel
Abbott Diagnostics	U.S.	Vysis ALK Break Apart FISH as companion test
Abbott Diagnostics	U.S.	Vysis ALK Break Apart FISH Probes
Advanced Cell Diagnostics	U.S.	BaseScope single-molecule detection RNA ISH
Advanced Cell Diagnostics	U.S.	multiplexed fluorescence RNA biomarkers in situ
Advanced Cell Diagnostics	U.S.	RNAscope 2.5 RNA biomarkers
Advanced Cell Diagnostics	U.S.	with Leica Biosystems, FISH tests
Agilent Technologies	U.S.	Applied Spectral's GenASIs & Dako Omnis, automated FISH
Applied Spectral Imaging	U.S.	GenASIs ALK gene analysis
Applied Spectral Imaging	U.S.	GenASIs imaging platform, ISH
BioGenex Laboratories	U.S.	Xmatrx Mini system, ISH, isPCR
BioGenex Laboratories	U.S.	eFISHiency system, ISH probes
Biocare (formerly Cymogen Dx)	U.S.	Next-Gen FISH probes enhanced imaging
Biocare (formerly Cymogen Dx)	U.S.	Deletion Detection Probe sets, next-gen multicolor FISH
BioView Ltd	Israel	lung cancer from sputum
BioView Ltd	Israel	DUET Automated FISH Scanning and Analysis systems
BioView Ltd	Israel	QSD certificate from the Taiwanese FDA
BioView Ltd.	Israel	Abbott Vysis ALK Break Apart FISH on DUET
BioView Ltd.	Israel	Lung cancer FISH, early lung cancer, sputum
Dako/Agilent	Denmark	automated HER2 IQFISH pharmDx
Dako/Agilent	Denmark	IQISH technology results in 3.5 hours
Dako/Agilent	Denmark	Ono Pharma PD-L1 companion test
Dako/Agilent	Denmark	HER2 IQFISH pharmDx automated on Dako Omnis

Company	Location	Details
Dako/Agilent	Denmark	collaborations with top pharma companies
Dako/Agilent	U.S.	Dako HER assays companion to Roche/Genentech's Kadcyla
DiaCarta Inc.	U.S.	QClamp KRAS, NRAS, EGFR, BRAF, PIK3CA
Empire Diagnostics	U.S.	fluorescent in situ hybridization probes
Flagship Biosciences	U.S.	ACD's RNAScope for B-cell non-Hodgkin lymphomas
GeneCentric Diagnostics	U.S.	Lung Subtype Platform, tumor genome
Labcorp	U.S.	Dako's PD-L1 IHC 22C3 pharmDx assay
Leica Biosystems	Germany	BMS automated companion Dx on BOND system
Leica Biosystems	Germany	Synthon Biopharmaceuticals companion Dx
Oxford Gene Technologies	UK	Cytocell Aquarius bladder cancer FISH probe kit
Oxford Gene Technologies	UK	Cytocell FISH probes
Quest Diagnostics	U.S.	Dako PD-L1 IHC 28-8 pharmDx, lung cancer/melanoma
Reveal Biosciences	U.S.	Reveal ImageDx IT with Affymetrix ViewRNA ISH
Skyline Urology	U.S.	bladder cancer in urine
Thermo Fisher (formerly Affymetrix)	U.S.	ViewRNA ISH portfolio
Thermo Fisher (formerly Affymetrix)	U.S.	Quantigene DNA/RNA in tissue
Thermo Fisher (formerly Affymetrix)	U.S.	Siemens' bDNA technology, multiplex CISH and FISH
Ventana Medical/Roche	U.S.	INFORM HER2 Dual ISH DNA Probe cocktail
Ventana Medical/Roche	U.S.	Ventana ALK (D5F3) CDx Assay, lung cancer
Ventana Medical/Roche	U.S.	numerous companion test deals

Source: Kalorama Information, company reports

Immunohistochemical stains refer to the process of detecting proteins in cells of a tissue section by using the principle of antibody/antigen binding specifically to antigens in biological tissues. The table below presents a selection of IHC tests.

Table 13-13: Selected IHC Test Innovations

Company	Location	Details
20/20 GeneSystems	U.S.	PD-L1 companion tests various lung cancer drugs
Applied Spectral Imaging	U.S.	PathFusion, a digital tissue-matching workflow solution
Becton Dickinson	U.S.	BD ProEx C reagent, IHC
Biocare Medical	U.S.	p63 protein in prostate, breast, bladder, and lung
BioGenex	U.S.	Quantitative IHC; in collaboration with University of Rochester and Konica-Minolta
Dako	Denmark	Cell Signaling Technology antibodies
Dako	Denmark	immunohistochemistry products
Dako/Agilent	Denmark	FLEX Human Estrogen Receptor alpha
Empire Diagnostics	U.S.	nCounter multiplex digital immunohistochemistry
IncellDx, Inc.	U.S.	OncoBreast 3Dx, mRNA, DNA cell ploidy, biopsy
Leica Biosystems	Germany	Novocastra HD, immunohistochemistry
Leica Biosystems	Germany	Novocastra HD IHC panel head and neck pathology
Leica Biosystems	Germany	Novocastra HD IHC breast pathology
NanoString Technologies	U.S.	nCounter Vantage products for 3D Biology analysis
NanoString Technologies	U.S.	Dako's PD-L1 IHC 22C3 PharmDx IHC
Quest Diagnostics	U.S.	Cell Marque Corp's IHC stains
Sigma-Aldrich	U.S.	ALK IHC companion diagnostic for Pfizer's Xalkori
Theracode GmbH	Germany	CLAUDETECT 18.2, IHC for CLDN18.2 protein

Source: Kalorama Information, company reports

Pharmacodiagnostic Histology

Growth in specialized histology diagnostics is being driven by the expanding number of clinically relevant biomarkers, including molecular assays used for diagnosis, prognosis, and therapy selection, as well as the continued expansion of targets evaluated by IHC and ISH in tissue samples. Advances in genomics and pharmacogenomics have enabled more precise characterization of tumors, supporting the shift toward individualized therapy based on the molecular profile of a patient's cancer.

The concept of personalized medicine is well established in oncology. Physicians increasingly rely on tissue-based biomarker testing to guide treatment decisions, aiming to match each patient to the most effective therapy for their specific tumor type and molecular profile. Rather than a single uniform disease, cancer is now understood as a collection of biologically distinct subtypes, and treatment strategies reflect this growing level of precision. Tumor-agnostic biomarkers are also gaining importance, allowing certain therapies to be applied across multiple cancer types based on shared molecular features rather than tissue of origin.

Advances in cancer management have facilitated significant changes in histopathology workflows. Histology now integrates protein expression, gene alterations, and, in some cases, RNA-based data, allowing pathologists to evaluate multiple biomarkers in the context of tissue architecture. Tissue biomarkers are important to personalized cancer care, and many therapies are developed alongside companion diagnostic tests that identify patients most likely to benefit from a specific drug. This approach has improved patient selection and treatment outcomes across a range of cancers.

A range of technologies reinforce this approach, including PCR-based assays, next-generation sequencing, and in situ hybridization techniques applied to formalin-fixed paraffin-embedded tissue. Improvements in extraction methods and assay design have enabled the reliable generation of molecular data from archived tissue samples, supporting both retrospective studies and routine clinical testing. At the same time, integration of tissue-based testing with liquid biopsy is becoming more common, allowing clinicians to combine detailed tumor characterization with real-time monitoring of disease progression and treatment response.

Tissue-based diagnostic testing is the gold standard for cancer diagnosis because it preserves the biological and spatial context of the disease. From a biopsy, pathologists determine tumor

type, grade, and extent of invasion, and support biomarker analysis that guides therapy. FFPE tissue remains the dominant sample type in oncology diagnostics and underpins the majority of histology-based testing.

Advances in spatial biology and multiplex analysis are providing deeper insight into the tumor microenvironment, particularly in the context of immunotherapy. In addition, artificial intelligence is increasingly being incorporated into pathology workflows to improve biomarker quantification, reduce variability in interpretation, and offer more consistent diagnostic outcomes. These innovations reinforce the central role of histology while extending its capabilities in precision oncology.

The foundation of targeted cancer therapy was established with early biomarker–drug relationships such as HER2 testing for trastuzumab therapy. This model has expanded significantly, with numerous clinically relevant biomarkers now used to guide treatment decisions, including EGFR mutations in lung cancer, HER2 alterations across multiple tumor types, and BCR-ABL in hematologic malignancies. As cancer incidence continues to rise and treatment options become more complex, demand for integrated tissue-based diagnostics is expected to remain strong, driven by ongoing biomarker discovery, expansion of companion diagnostics, and increasing use of multiplex and molecularly informed testing within routine pathology workflows.

Table 13-14: Major Pharmacodiagnostic Markers

Marker
ALK
BCR/ABL
BRAF
BRCA1/BRCA2
Claudin 18.2
Epidermal growth factor (EGF) and its receptor (EGFR)
Estrogen receptor (ER)
Her-2/neu oncogene/c-erb-B2 protein
KRAS
Markers of angiogenesis
Progesterone Receptors (PR)

Source: Kalorama Information

The application of pharmacodiagnostic histology continues to become more sophisticated. In addition to standard IHC and ISH staining procedures, DNA and RNA extracted from tissue samples are now routinely analyzed using PCR, next-generation sequencing, and other molecular techniques. More advanced approaches, including multiplex analysis and spatial profiling, are expanding the amount of information that can be derived from a single tissue section. While liquid biopsy testing has grown rapidly and provides a less invasive method for molecular analysis, it is generally complementary to tissue-based testing rather than a replacement, as tissue remains essential for diagnosis and full tumor characterization.

As understanding of cancer biology and treatment response improves, additional tests have been developed to evaluate factors such as tumor biology and, in some cases, radiosensitivity, although clinical adoption of radiosensitivity assays remains limited and varies by application. The pharmacodiagnostic market remains highly dynamic, with a mix of FDA-approved companion diagnostics and laboratory-based testing services.

Immune checkpoint biomarkers have become a major area of growth. PD-L1 assays are widely used to guide immunotherapy decisions across multiple tumor types. For example, the VENTANA PD-L1 (SP263) assay from Roche Diagnostics is performed on the BenchMark ULTRA platform and evaluates PD-L1 expression in both tumor and immune cells within the tumor microenvironment. PD-L1 testing is now established across multiple indications and therapies, with ongoing expansion into additional tumor types and treatment settings.

Companion diagnostics linked to targeted therapies continue to expand. HER2 testing is increasing in breast cancer and has recently been extended to include HER2-low classification, supporting treatment selection for newer therapies. Molecular assays detecting mutations such as IDH1, KRAS G12C, and PDGFRA are now routinely used to guide therapy selection in cancers such as acute myeloid leukemia, lung cancer, and gastrointestinal tumors. These assays are performed using PCR or sequencing-based platforms and are increasingly integrated into broader genomic testing workflows.

Several important regulatory developments have occurred in recent years. Companion diagnostics for immunotherapy and targeted therapy continue to receive expanded approvals across multiple tumor types. Liquid biopsy–based companion diagnostics, including next-generation sequencing assays, have also gained regulatory acceptance and are being used to identify actionable mutations when tissue is limited or unavailable. At the same time, multi-gene panel tests, such as comprehensive genomic profiling assays, are increasingly used to support treatment decisions across a range of cancers.

The trend to personalized medicine (PGx) is expected to create a huge market for histology diagnostics. The market leaders are Agilent, Illumina, and Roche/Ventana Medical that have collaborations with pharmaceutical companies to develop companion tests along with therapeutics.

A listing of companion tests cleared by the FDA can be found at https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools#CDx_Table.

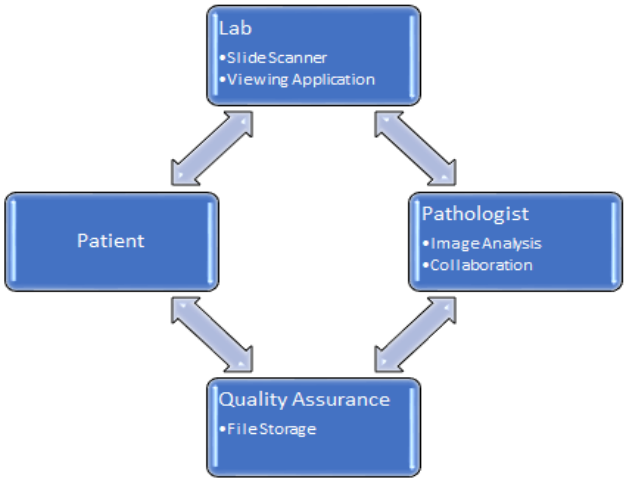
Table 13-15: Selected Pharmacodiagnostic Histology Tests

Company	Location	Details
Abbott Diagnostics	U.S.	Vysis ALK Break Apart FISH Probes
Abbott Diagnostics	U.S.	PathVysion HER-2 DNA FISH Probe Kit
Abbott Diagnostics	U.S.	Abbott RealTime IDH-1
Advanced Cell Diagnostics	U.S.	Partnership with Leica Biosciences; Bayer companion Dx on RNAscope-based BOND systems
ARUP Laboratories, Inc.	U.S.	PDGFRB FISH Assay for Gleevec eligibility in myelodysplastic syndrome/myeloproliferative disease
BioGenex	U.S.	InSite Her-2/neu
BioView Ltd.	Israel	Abbott Vysis ALK Break Apart FISH on DUET
Dako/Agilent	Denmark	automated HER2 IQFISH pharmDx
Dako/Agilent	Denmark	Ono Pharma PD-L1 companion test
Dako/Agilent	Denmark	HER2 IQFISH pharmDx automated on Dako Omnis
Dako/Agilent	Denmark	collaborations with top pharma companies
Dako/Agilent	Denmark	PD-L1 companion tests various lung cancer and melanoma drugs
Dako/Agilent	Denmark	Dako HER assays companion to Roche/Genentech's Kadcyla
DiaCarta Inc.	U.S.	QClamp KRAS, NRAS, EGFR, BRAF, PIK3CA
GeneCentric Diagnostics	U.S.	Lung Subtype Platform, tumor genome
GeneCentric Diagnostics	U.S.	Bladder, Colorectal, Prostate, and Renal Subtype Platforms, tumor genome
Inspirata	U.S.	Image-based breast cancer companion diagnostic; collaboration with Case Western Reserve University
Labcorp	U.S.	Dako's PD-L1 IHC 22C3 pharmDx assay
Leica Biosystems	Germany	BMS automated companion Dx on BOND system
Leica Biosystems	Germany	Synthon Biopharmaceuticals companion Dx
QIAGEN	U.S.	Therascreen FGFR RGQ RT-PCR Kit

Company	Location	Details
QIAGEN	U.S.	Therascreen PIK3CA RGQ PCR
Quest Diagnostics	U.S.	Dako PD-L1 IHC 28-8 pharmDx, lung cancer/melanoma
Quest Diagnostics	U.S.	Dako's PD-L1 IHC 22C3 PharmDx IHC
Ventana Medical/Roche	U.S.	Ventana ALK (D5F3) CDx Assay, lung cancer
Ventana Medical/Roche	U.S.	PD-L1 (SP142) IHC companion diagnostic for Roche's Tecentriq, for lung and bladder cancer
Ventana Medical/Roche	U.S.	PD-L1 (SP263) IHC companion diagnostic for AstraZeneca's Imfinzi, for urothelial carcinoma
Ventana Medical/Roche	U.S.	ALK IHC companion diagnostic for Pfizer's Xalkori

Source: Kalorama Information

Digital Imaging and Computational Pathology



Microscopy has been the mainstay of digital pathology, as well. Advances in digital photography and the decreasing cost of digital cameras are revolutionizing traditional ways of documenting pathology findings, collaborating on slide review, and analyzing images. More and more histology laboratories are going digital. The primary reason is to simplify the microscopy task and allow more widespread dissemination of histological analyses, even in smaller hospitals and in countries that lack skilled oncology pathologists. There is considerable skill involved in the processing and staining of tissues and fluids for investigation. But the real art is in reading the slides. Digital histology allows pathologists to collaborate in reviewing slides or send images to experts for a first reading.

Advancements in digital imaging combined with bioinformatics tools are reshaping the practice of pathology. Although digital workflows are expanding, glass slides remain

essential in current laboratory processes, as tissue must still be collected, processed, and mounted before it can be digitized. Whole-slide imaging systems allow slides to be scanned at high resolution and integrated into digital platforms for storage, analysis, and remote review.

Automation in histology has been evolving for decades, but recent progress has focused on linking sample preparation, staining, imaging, and reporting into more unified workflows. Advances in digital optics, high-capacity computing, and artificial intelligence have enabled more effective deployment of these systems in routine laboratory settings. As a result, digital pathology is moving from early adoption into broader clinical use.

Staining procedures provide critical information about protein expression and, increasingly, molecular characteristics that help distinguish tissue and cell attributes associated with disease progression and therapeutic response. The goal is to identify clinically relevant biomarkers in tissue samples to guide diagnosis and treatment. While oncology remains the primary focus, these techniques are also used in applications such as chromosome analysis, infectious disease detection, and molecular characterization of tissue samples.

Histology slide analysis has traditionally been labor-intensive, relying on microscopic examination by trained technologists and pathologists. Digital image capture and analysis have begun to change this model. Laboratories are increasingly adopting integrated solutions that span slide preparation, image analysis, and reporting. These systems support faster turnaround times, improved workflow efficiency, and greater consistency in results.

Artificial intelligence is becoming an important component of digital pathology, assisting with tasks such as tumor detection, biomarker quantification, and case prioritization. While these tools do not replace the pathologist, they are increasingly used to support decision-making and improve reproducibility.

Table 13-16: Selected Digital Pathology Image Capture and Viewing Solutions

Company	Location	Details	Status
Applied Spectral Imaging	USA	GenASIs Scan & Analysis automated microscopy	FDA
Applied Spectral Imaging	USA	Version 7.2 of GenASIs, cytogenetic/pathology imaging	RUO
Applied Spectral Imaging	USA	GenASIs HiPath IHC image capture/analysis on microscopes	FDA
Bioevopeak Co., Ltd.	China	Digital Pathology Slide Scanner	FDA
Fluxion Biosciences	USA	CytoFlux System for imaging cytometry and analysis	RUO
Inspirata, Inc. (Omnyx, LLC)	USA	Omnyx Precision Integrated Digital Pathology Solution, scanner and IT	CE
Inspirata, Inc. (Omnyx, LLC)	USA	Dynamax Digital Pathology Software	FDA
Leica Biosystems	Germany	Aperio AT2 high throughput digital slide scanner	CE
Leica Biosystems	Germany	Aperio VERSA, automated digital slide scanner FISH	RUO
Leica Biosystems	Germany	Aperio LV1 digital pathology system	RUO
Leica Biosystems	Germany	mobile APiQ (Anatomic Pathology with Extra Intelligence)	RUO
Paige	USA	FullFocus Viewer	FDA
PerkinElmer	USA	Lamina multilabel slide scanner	RUO
PerkinElmer	USA	Panoramic P250 Flash II digital slide scanner	RUO
Philips	Netherlands	IntelliSite digital pathology solution	CE, FDA
Roche Diagnostics	USA	VENTANA iScan HT & DP 200 scanner	CE
Sectra AB	Sweden	Sectra Digital Pathology Module	CE, FDA

Source: Kalorama Information, company reports

Philips expanded its digital pathology portfolio with its IntelliSite platform, which offers high-resolution slide scanning, image management, and workflow integration. The system is designed to improve efficiency and diagnostic consistency while supporting remote review and integration with artificial intelligence tools as pathology workloads continue to grow.

Clarapath acquired Crosscope, combining automated tissue sectioning and transfer with digital imaging and computational pathology capabilities. The integration aims to create a more complete, automated workflow from tissue preparation through digital analysis, although full end-to-end automation is still evolving.

Leica Biosystems offers the Aperio GT 450 DX digital pathology system, a high-throughput whole-slide imaging platform designed for primary diagnosis. This clearance reflects the continued transition of digital pathology from research and archival use into routine clinical practice.

Partnerships with companies such as PathAI, Proscia, and Lumea are accelerating the integration of artificial intelligence, advanced image analysis, and emerging techniques such as virtual staining into core pathology workflows. These collaborations are helping laboratories improve efficiency, standardization, and diagnostic support.

Recent developments are also being driven by regulatory progress and broader healthcare trends. Increasing numbers of digital pathology systems are now cleared for primary diagnosis, enabling broader clinical adoption. At the same time, laboratories are implementing cloud-based and enterprise-level platforms that allow remote case review and collaboration across multiple sites. Workforce shortages in pathology are further accelerating adoption, as digital workflows enable more efficient case distribution and access to subspecialty expertise. Artificial intelligence is moving beyond pilot use into routine workflow, particularly for biomarker quantification and case prioritization. Vendors are developing open-platform systems that enable the integration of third-party analytical tools, supporting more flexible and scalable digital pathology environments.

Market growth in digital pathology remains steady. The global market for digital imaging systems in histology and cytology is estimated at just over $1,275 million in 2025, with 10.1% CAGR through 2030. North America remains the largest market, accounting for a significant share of adoption, while Europe and Asia are experiencing faster growth as regulatory approvals expand and infrastructure improves.

The competitive landscape is led by major diagnostics and imaging companies, including Danaher Corporation (through Leica Biosystems), Philips, and Roche Diagnostics. Other important participants include Sectra, Menarini Group, Indica Labs, and Visiopharm, as well as a growing number of software- and AI-focused developers.

Table 13-17: Selected Digital Imaging Innovations

Company	Location	Details
Applied Spectral Imaging	U.S.	GenASIs Scan & Analysis automated microscopy
Applied Spectral Imaging	U.S.	Version 7.2 of GenASIs, cytogenetic/pathology imaging
Applied Spectral Imaging	U.S.	GenASIs HiPath IHC image capture/analysis on microscopes
Cernostics (Castle Biosciences)	U.S.	TissueCypher Barrett's Esophagus Assay, digital slide image analysis
Clarient Diagnostic Services (GE Healthcare)	U.S.	Definiens automated image analysis software
ClearLight Diagnostics	U.S.	tissue processing and imaging platform for 3D analysis
Corista	U.S.	Digital Pathology Network Platform
Dako/Agilent	Denmark	Omnyx image analysis with Dako HercepTest
Fluxion Biosciences	U.S.	CytoFlux System for imaging cytometry and analysis
Inspirata	U.S.	with Philips automated image analytics, Solution-as-a-Service
Leica Biosystems	Germany	Aperio AT2 high throughput digital slide scanner
Leica Biosystems	Germany	Aperio VERSA, automated digital slide scanner FISH
Leica Biosystems	Germany	Aperio LV1 digital pathology system
Leica Biosystems	Germany	mobile APiQ (Anatomic Pathology with Extra Intelligence)
Leica Biosystems	Germany	with Mayo Clinic, fast cytogenetics imaging software
Revvity	U.S.	Lamina multilabel slide scanner
Revvity	U.S.	Panoramic P250 Flash II digital slide scanner
Royal Philips	Netherlands	IntelliSite digital pathology solution
TissueGnostics	Austria	TissueFaxs 200 scanner slides and TMAs
Sectra Group	Sweden	Sectra Digital Pathology Module (for use with Leica scanner AT2 Dx)

Source: Kalorama Information, company reports

Circulating Tumor Cells

Circulating tumor cells (CTCs) are cells that detach from a primary or metastatic tumor and enter the bloodstream. They are thought to play a role in metastasis and are of interest as potential biomarkers of disease progression. Detection of CTCs offers a noninvasive approach to monitoring cancer, and these cells may provide insight into baseline disease status, treatment response, and the biology of metastasis.

Evaluation of cancer biomarkers in blood and other accessible tissues has enabled the development of liquid biopsy approaches that complement traditional tissue biopsy. CTCs represent one component of liquid biopsy testing, alongside circulating tumor DNA (ctDNA) and other analytes. While blood-based sampling is less invasive and allows for repeat testing, tissue biopsy remains essential for initial diagnosis and comprehensive tumor characterization.

Interest in CTCs has been ongoing for more than two decades. Early commercial systems, such as the CellSearch platform, originally developed by Veridex (now part of Johnson & Johnson), were the first to receive FDA clearance for monitoring patients with metastatic breast, colorectal, and prostate cancer. These systems primarily focused on measuring CTCs as a prognostic indicator, and their clinical use has remained limited to specific settings.

Subsequent generations of CTC technologies have expanded beyond simple cell counting to include molecular and phenotypic characterization of captured cells. Advances in enrichment methods, imaging, and single-cell analysis have improved the ability to study tumor heterogeneity and identify clinically relevant mutations. Newer approaches enable genomic and transcriptomic profiling at the single-cell level, providing deeper insight into tumor biology and mechanisms of treatment resistance. Improved capture technologies, including microfluidic systems, label-free enrichment methods, and AI-based imaging, are making inroads, increasing detection sensitivity for these rare cells, which may occur at extremely low concentrations in blood.

Recent research has also highlighted the importance of circulating tumor cell clusters, which may have greater metastatic potential than individual cells. In addition, CTC analysis is increasingly being combined with other liquid biopsy markers, such as ctDNA, to provide a more comprehensive assessment of disease. This multi-analyte approach reflects a broader shift in liquid biopsy toward integrated testing strategies.

Compared with ctDNA-based liquid biopsy approaches, CTC testing has seen slower clinical adoption. ctDNA assays are more widely used for mutation detection and treatment selection, whereas CTCs are more commonly used in research and select clinical applications. The clinical value of CTCs is mixed.

Several companies continue to invest in liquid biopsy technologies, including CTC-based approaches, although many commercial offerings now focus more heavily on ctDNA and multi-analyte testing. For example, blood-based cancer detection tests such as the Avantect assay from ClearNote Health rely on analysis of cell-free DNA rather than CTCs, reflecting a broader market shift.

Nevertheless, the market for commercial CTC tests is estimated to have grown from $100 million in 2016 to $152 million in 2025. CTC test services are expected to grow at a 4.0% compound rate.

Table 13-18: Innovations in CTC Technology

Company	Location	Area	Details
Abnova	Taiwan	capture	Clear Cell CTChip
Affymetrix	U.S.	cell enrich	ScreenCells CTC isolation
Agena Bioscience	U.S.	analysis	UltraSEEK for rare cell analysis, mass spec
Angle plc	UK	analysis	cancer detection: ovarian, pr, br
Angle plc	UK	capture	Parsortix cell separation
ApoCell (Precision for Medicine)	U.S.	capture	ApoStream technology
Bioaffinity Technologies	U.S.	analysis	CyPath cell stain
Biocartis	Switzerland	analysis	Idylla liquid biopsy RAS biomarker, PCR
Celsee Diagnostics (BioRad)	U.S.	analysis	Celsee ANALYZER CTC downstream analysis
Celsee Diagnostics (BioRad)	U.S.	smpl prep	Celsee PREP400 CTC downstream prep
Clearbridge BioMedics	Singapore	capture	ClearCell FX System, automated CTChip
Cynvenio Biosystems	U.S.	analysis	ClearID Breast Cancer recurrence monitoring, CTC
Cynvenio Biosystems (LungLife AI)	U.S.	analysis	Liquid Biopsy DNA in CTC & ctDNA
Cynvenio Biosystems (LungLife AI)	U.S.	capture	ClearID SCORE, CTC
DestiNA Genomics	Scotland	analysis	with Master Diagnostica, Spain colon cancer liq biopsy
EKF Molecular Diagnostics	UK	analysis	CTC and cfDNA assays
Epic Sciences	U.S.	analysis	metastatic bladder cancers, CTC
Epic Sciences	U.S.	analysis	high-definition CTC microscopy
Epic Sciences	U.S.	analysis	35th collaboration pharmaceutical companies
Exosome Diagnostics	U.S.	analysis	prostate cancer predictive score, exoRNA
Fluxion Biosciences	U.S.	cell enrich	IsoFlux EMT, epithelial

Company	Location	Area	Details
Fluxion Biosciences (Cell Microsytems)	U.S.	Analysis	CTC isolation IsoFlux System
Fluxion Biosciences (Cell Microsystems)	U.S.	cell enrich	IsoFlux System NGS sample prep
Fraunhofer Institute	Germany	capture	PoCyton cytometer miniature CTC counter
Genomic Health	U.S.	analysis	line of liquid biopsy tests
Genyo	Spain	analysis	MishCTC, miRNA in situ hybridization in CTC
Guardant Health	U.S.	analysis	Guardant360 biopsy-free cancer, CTC
Horizon Discovery	UK	QC	standards for circulating DNA tests
IncellDx	U.S.	smpl prep	IncellPrep Liquid Biopsy cell suspension: FFPE
NeoGenomics	UK	analysis	with Biodesix, Tam-Seq lung cancer, cfDNA
NeoGenomics	UK	analysis	TAm-Seq, cell free DNA: sequencing
Janssen Diagnostics	U.S.	analysis	PD-L1 immune marker
Janssen Diagnostics	U.S.	analysis	CellSearch technology for breast cancer analysis
Janssen Diagnostics	U.S.	capture	CTC-iChip CTC isolation, cytology
Janssen Diagnostics	U.S.	cell enrich	Cellsearch with Asuragen's SuraSeq panels
Kindstar Global	China	analysis	Advanced Cell CTCscope, ISH
Labcorp	U.S.	analysis	Sysmex Inostics' OncoBEAM CTC technology
Leica Biosystems	Germany	analysis	Leica's Bond RX IHC and RareCyte's AccuCyte CyteFinder
MDxHealth	Belgium	analysis	DNA methylation markers, liquid biopsy test for bladder cancer
Menarini Diagnostics	Italy	analysis	GluCyte, liquid biopsy processing & analysis
Menarini Silicon Biosystems	U.S.	capture	DEPArray NxT digital cell-sorting system
NeoGenomics	U.S.	analysis	RaDaR ST
OvaGene Oncology	U.S.	POC	rapid, POC molecular diagnostic tests microfluidic

Company	Location	Area	Details
ProKyma Technologies	UK	capture	KymaSep POC CTC isolation
QIAGEN	Netherlands	analysis	AdnaTest Breast Cancer/ Prostate Cancer relapse monitor
QIAGEN	Netherlands	analysis	therascreen EGFR RGQ Plasma PCR, cfDNA
QIAGEN	Netherlands	cell enrich	AdnaGen's enrichment and molecular analysis
QIAGEN Hanover	Germany	analysis	AdnaTest Cancer kits, RNA PCR
Rarecells Diagnostics	France	analysis	ISET test, cell sizing
RareCyte	U.S.	analysis	AccuCyteSystem, CTC microscopy
Revvity	U.S.	analysis	Advanced Cell RNAscope portfolio, CTC
Roche Diagnostics	U.S.	analysis	cell-free DNA (cfDNA) technology
Savran Technologies	U.S.	capture	tumor cell detection
ScreenCell	France	capture	ScreenCell MB, DNA or RNA extraction from CTCs
SeraCare Life Sciences	U.S.	QC	cell-free circulating tumor DNA (ctDNA), NGS
Silicon Biosystems (Menarini)	Italy	analysis	DEPArray, CTC molecular characterization
Streck	U.S.	QC	Cell-Free DNA BCT
Swift Biosciences	U.S.	analysis	Swift's Accel-Amplicon panel with Fluxion IsoFlux
Sysmex Inostics	Germany	analysis	BEAMing: digital PCR and flow cytometry for CTCs
Sysmex Inostics	Germany	analysis	OncoBEAM companion tests, CTC
Thermo Fisher Scientific	U.S.	smpl prep	Cynvenio's LiquidBiopsy with Ion Chef & AmpliSeq Cancer Hotspot

Source: Kalorama Information, company reports

Flow Cytometry

Flow cytometry has made significant advancements over the past decade, evolving from a tool primarily used for cell counting and basic immunophenotyping into a highly sophisticated platform capable of high-dimensional, multiparametric analysis and sensitive

detection of rare cell populations. Modern systems can analyze multiple physical and chemical characteristics of thousands of cells per second, with many platforms simultaneously detecting dozens of parameters. Flow cytometry is routinely used in the diagnosis and classification of hematologic malignancies, immune monitoring, such as CD4/CD8 testing in HIV, minimal residual disease (MRD) detection, stem cell analysis, and cell sorting for both clinical and research applications.

Technology is expanding into additional applications, including advanced immune profiling, cell therapy development, and selected areas of infectious disease and translational research. While flow cytometry has potential applications in areas such as urinalysis and prenatal testing, its primary clinical role remains in hematology and immunology rather than solid tumor diagnostics.

IHC and FISH are widely used to detect protein expression, gene alterations, and chromosomal abnormalities in tissue samples. However, these techniques are less suited for rapid, high-throughput detection of rare cells in suspension, where flow cytometry offers clear advantages. Flow cytometry enables analysis of large numbers of individual cells and can identify rare subpopulations using panels of labeled antibodies or probes.

For applications such as minimal residual disease detection in leukemia, highly sensitive assays are required. Modern flow cytometry methods can detect very low levels of disease, often at frequencies of one abnormal cell among tens of thousands or more normal cells, depending on the assay design and instrumentation.

Flow cytometry is extensively used in hematologic malignancies for diagnosis, classification, and disease monitoring. While there is ongoing research into its use for detecting circulating tumor cells in solid tumors, these applications are less established clinically compared with other technologies, such as molecular assays

The global market for flow cytometry (not used exclusively in histology) is estimated at $1,765 million in 2025, and with 4.8% annual growth will reach $2,230 by 2030. It is beyond the scope of this research to estimate the share of the flow cytometry market used for cancer analysis. Two companies dominate the flow cytometry industry. BD and Beckman Coulter together hold almost 86% of the flow market. BD is the clear leader with product sales estimated at roughly around $1,139 million in 2025. Both companies continue to update their systems and test kits to maintain complete dominance of this market.

Other major companies active in flow cytometry are Bio-Rad Laboratories, Sysmex, Diagnostics, Agilent, Diasorin and Miltenyi Biotec.

In flow cytometry, BD's success derives from continuous product developments that make flow cytometry more user-friendly and flexible. BD's future strength is found in the mix of bead array, image and flow cytometry technologies that are now part of its holdings.

Becton Dickinson (BD) is a leading player in the global flow cytometry market, focusing on simplifying workflows and expanding access to high-dimensional cell analysis. The company has long offered a broad portfolio of antibodies, reagents, and fluorochromes, including its Horizon Brilliant dye series, which supports increasingly complex multicolor and spectral assays.

BD’s installed base still includes systems such as FACSCalibur and FACSCanto II, although newer platforms have largely replaced these in current purchasing decisions. More recent instruments include the FACSLyric clinical system, often paired with the FACSDuet automated sample preparation module, which improves workflow efficiency and standardization in clinical laboratories. BD also continues to expand its high-parameter systems, such as the FACSymphony platform, which enables the simultaneous measurement of dozens of cellular parameters and is widely used in advanced research and immunology applications.

In recent years, BD has introduced next-generation platforms such as the FACSDiscover series, which combines spectral flow cytometry with real-time cell imaging capabilities. These systems allow cells to be analyzed not only by fluorescence but also by spatial and morphological characteristics, representing a significant advancement toward imaging-enabled cytometry.

Beckman Coulter is another major competitor, with platforms such as the CytoFLEX series supporting both research and clinical applications. Recent developments include spectral upgrade modules that expand detection capabilities and allow laboratories to enhance existing systems without full instrument replacement.

Agilent Technologies has expanded its NovoCyte portfolio, including high-parameter systems such as the NovoCyte Penteon and newer spectral-enabled platforms such as the NovoCyte Opteon, which provide increasingly complex multicolor assays with expanded detection channels.

Thermo Fisher Scientific continues to offer the Attune platform, which uses acoustic focusing technology for high-throughput sample analysis, along with advanced sorting systems designed for complex and large-cell applications.

Other key participants include Cytek Biosciences, a leader in full-spectrum cytometry with platforms such as the Aurora and newer Aurora Evo systems, which offer enhanced throughput, automation, and improved detection of small particles such as extracellular vesicles. Standard BioTools (formerly Fluidigm) offers mass cytometry systems such as CyTOF for high-dimensional single-cell analysis.

Product development in the market has focused on spectral cytometry, higher parameter counts, and integration with imaging and automation. Many modern systems provide the simultaneous measurement of dozens of parameters, and in some cases more than 50, enabling detailed single-cell analysis. In addition, newer platforms are being designed to detect smaller particles, including extracellular vesicles and viruses, expanding the application range of flow cytometry beyond traditional cell analysis.

Automation and standardization are also focal areas of innovation, with vendors introducing features that streamline instrument setup, quality control, and data acquisition. Integration with advanced computational tools and artificial intelligence is becoming increasingly important for managing and interpreting high-dimensional datasets.

The Commercial Outlook for Histology and Cytology Tests

Histology and cytology have been fundamental components of the pathology laboratory, providing critical insight into the structure and function of cells, tissues, and organs. Through histopathological examination, a wide range of diseases, including cancer, can be identified. Physicians rely heavily on pathologists' diagnostic findings to determine the presence of malignancy and other pathological conditions, thereby guiding treatment decisions and prognostic evaluation.

Recent technological advances have significantly expanded the understanding of tissue biology and its relationship to disease. Innovations in digital imaging, quantitative microscopy, artificial intelligence, and virtual histology are transforming the field. These tools are improving diagnostic consistency, enabling automation, and enhancing workflow efficiency across pathology laboratories.

Drivers of the histology and cytology testing market include the rising global burden of cancer and increasing demand for automation and standardization. In addition, changes introduced during the COVID-19 period accelerated the adoption of digital pathology and remote review, supporting broader use of advanced diagnostic workflows.

Automation of histology and cytology processes is now well established in developed markets and continues to expand into emerging regions, particularly in large urban centers. While elements of automation and digital imaging have been available for many years, recent advances in computing power, digital optics, and artificial intelligence have enabled more integrated and scalable solutions. These systems are increasingly capable of providing end-to-end workflows from sample preparation through image analysis and reporting.

As seen in other laboratory segments, consolidation and workflow integration are expected to drive adoption of platforms that can automate multiple traditional manual processes. However, a single platform capable of fully integrating all microscopic procedures remains a goal rather than a current reality, as different applications such as hematology, cytology, and histology often require specialized systems.

Advances in tissue analysis techniques have also expanded the ability to isolate and study specific cell populations. Technologies such as laser capture microdissection allow precise extraction of selected cells from tissue sections, enabling downstream molecular analysis

using PCR, sequencing, and mass spectrometry. These approaches support a more detailed investigation of tumor biology and early disease changes.

Recent developments are further expanding the capabilities of histology and cytology through the integration of spatial biology and multiplex analysis. New techniques allow simultaneous evaluation of protein and RNA expression within the same tissue section, providing deeper insight into tumor biology and the surrounding microenvironment. This is particularly important in immuno-oncology, where spatial relationships between tumor and immune cells can influence treatment response. In addition, histology is increasingly being integrated with genomic and molecular data, creating a more comprehensive diagnostic framework that combines morphology with molecular profiling.

Despite the maturity of the histology and cytology segment, ongoing advances in cancer diagnostics continue to reshape traditional workflows. New approaches are enabling the detection of multiple biomarkers within a single tissue section and improving the integration of molecular and morphological data. Workforce constraints and the need for greater efficiency are also accelerating the adoption of digital and automated solutions, although cost and reimbursement considerations continue to influence the pace of implementation.

Chapter 14: Company Profiles: The Top Tier

Scope

These top competitors are presented in alphabetical order. The profiles include events that have occurred in the past few years; they are not a comprehensive review or history of the companies selected to appear in the section. For this update, all companies and product segments were reviewed for any innovative products. New and innovative information was gleaned for 2025 and the first half of 2026 to help industry participants to see what is trending in product and company releases. However, some company segments revealed no significant new product developments.

Abbott Diagnostics

Abbott Park, IL 60064

www.abbott.com

Table 14-1: Abbott Diagnostics Revenue History, 2023-2025 ($ million)

	2023	2024	2025
Total Dx	15,749	15,426	16,935

Source: company reports, Kalorama Information

The United States garnered about 40% of sales and the other 60% was garnered by non-United States areas.

The following is Kalorama's estimated breakdown of Abbott's revenue in selected test segments:

Table 14-2: Abbott Diagnostic Revenues, by Segment, 2023-2025 ($ million, estimated)

Segment	2023	2024	2025	YoY Growth 2024-2025
Diabetes	5,761	6,085	7,998	31.4%
Core Laboratory	5,159	5,235	5,360	2.4%
Rapid & Alere	3,692	2,997	2,454	-18.1%
Molecular	995	521	517	-0.8%
Point of Care	525	588	606	3.1%
Total	**16,132**	**15,426**	**16,935**	**9.8%**

Source: Kalorama Information

Abbott Diagnostics focuses on infectious disease testing, with a significant portion of its sales generated in the European Union, emerging markets, and the U.S. The company is preparing for the future with the development of next-generation systems, informatics to help labs manage and retrieve test data, new infectious disease diagnostics, and gene-based oncology tests for targeted therapeutics. Abbott's diabetes care attained worldwide sales of $7,998 million in 2025.

The core lab revenues increased 2.4%. Rapid diagnostics decreased 18.1% due to lower COVID-19 sales and challenging market conditions in China, while molecular increased 0.7%.

Abbott entered into a partnership with Medtronic to develop an integrated CGM system based on FreeStyle Libre technology that will connect with Medtronic’s automated insulin-delivery and smart insulin-pen systems.

In November 2025, Abbott Laboratories announced a definitive agreement to acquire Exact Sciences, expanding Abbott’s diagnostic portfolio in oncology and cancer screening. The acquisition is expected to strengthen Abbott’s precision diagnostics segment by integrating Exact Sciences' cancer screening and precision oncology diagnostic portfolio. Exact Sciences announced in mid-2025 that it exceeded 20 million cumulative Cologuard tests. This acquisition, completed in March 2026, will add a robust oncology franchise to Abbott's diagnostic segment, creating new growth opportunities. Exact Sciences will benefit from Abbott’s deep global commercial infrastructure and broad international presence in the IVD market.

Core Lab

Abbott Laboratories maintains a comprehensive core laboratory diagnostics portfolio spanning clinical chemistry, immunoassay, hematology, molecular diagnostics, and blood screening systems. The company’s ARCHITECT family of instruments continues to be widely used globally for clinical chemistry and immunoassay testing across multiple disease areas, including cardiovascular, infectious disease, oncology, endocrine, fertility, and metabolic disorders. A substantial installed base of ARCHITECT systems remains in operation, often alongside Abbott’s newer platforms.

Abbott’s core laboratory focus is the Alinity family of harmonized diagnostic systems, designed to improve laboratory efficiency through higher throughput, faster turnaround

times, and streamlined workflows. The Alinity platform features standardized system architecture and a common user interface across disciplines, enabling laboratories to simplify operations, training, and instrument management.

The Alinity ci-series integrates clinical chemistry and immunoassay testing through the Alinity c clinical chemistry analyzer and the Alinity i immunoassay analyzer. These systems can operate independently or as a modular, integrated solution, allowing laboratories to scale testing capacity while optimizing space and workflow.

Abbott's hematology portfolio includes the Alinity h-series, which combines automated hematology analysis with slide preparation and staining capabilities. These systems support complete blood count testing with advanced multi-parameter analysis and rapid turnaround times, thereby improving laboratory productivity and diagnostic consistency.

In molecular diagnostics, the Alinity m system provides a fully automated, real-time PCR–based platform for high-throughput, random-access testing. The system supports continuous sample loading, STAT prioritization, and an expanding menu of molecular assays, including infectious disease testing for viruses and sexually transmitted infections.

Abbott's core laboratory portfolio also includes blood and plasma screening systems under the Alinity s platform, supporting high-volume donor screening, as well as integrated informatics and workflow solutions. AlinIQ and Alinity PRO software provide centralized system monitoring, data analytics, and workflow optimization, enabling laboratories to improve operational efficiency and instrument utilization across networks.

Abbott continues to expand assay menus across its core platforms, particularly in immunoassay and clinical chemistry, including advanced cardiac biomarkers such as high-sensitivity troponin I assays used for early detection and risk assessment of myocardial infarction. These assays are broadly available across both ARCHITECT and Alinity systems.

Hematology

Abbott's Alinity h-series is a next-generation hematology solution that integrates high-throughput complete blood count (CBC) testing with automated slide preparation and staining. The system combines the Alinity hq hematology analyzer with the Alinity hs slide maker and stainer, creating a harmonized workflow that improves laboratory efficiency while reducing manual intervention.

The Alinity hq analyzer delivers a complete blood count with a 6-part white blood cell differential, reticulocyte testing capability, and multiple advanced hematologic parameters. The analyzer uses Abbott's proprietary Advanced Multi-Angle Polarized Scatter Separation technology, which applies multiple light-scatter measurements at additional angular intervals to improve differentiation and classification of white blood cells, red blood cells, and platelets as cells pass through the optical detection chamber.

Abbott's hematology technology also incorporates advanced computational analysis, including machine-learning-based cell classification algorithms, Gaussian Mixture Modeling, and Graph Adaptive Clustering to improve abnormal cell recognition, flagging performance, and analytical precision. These digital classification tools enhance cell population separation and support improved detection of clinically significant abnormalities.

The integrated Alinity hs module automates blood smear preparation and staining, enabling a fully connected hematology workflow from sample loading through slide production. Combined, the Alinity h-series system can process approximately 119 CBC tests per hour, supporting medium- to high-volume laboratories.

For selected international markets, Abbott also offers the CELL-DYN Emerald 22 AL, a compact automated hematology analyzer designed for small- to mid-sized laboratories. This analyzer provides a 5-part differential and remains available in certain regions, although commercial availability varies by country, and the system is not broadly positioned in the U.S. market.

Blood Banking

Abbott markets its Alinity s blood and plasma screening system, which has become a major component of the company's transfusion diagnostics portfolio. The Alinity s System is designed to improve blood and plasma screening efficiency through a compact footprint, high assay throughput, and increased automation compared with earlier-generation blood screening platforms. The system supports continuous loading of samples and reagents, automated maintenance functions, and reduced operator intervention, helping blood centers and plasma collection laboratories improve workflow productivity while maintaining high analytical accuracy and traceability.

The Alinity platform uses chemiluminescent immunoassay technology for screening donated blood and plasma for infectious disease markers, including HIV, hepatitis B, hepatitis C,

HTLV, syphilis, and other transfusion-transmissible infections, depending on regional regulatory approvals. Abbott positions the system as part of an integrated blood screening solution, alongside its molecular screening platforms, enabling blood centers to standardize operations across serology and nucleic acid testing workflows.

Abbott has also explored digital donor engagement technologies, including immersive mixed-reality and virtual reality experiences designed to improve donor comfort and engagement during blood donation sessions, particularly to encourage participation among younger donor populations. These programs have been introduced in selected blood donation initiatives and pilot collaborations as part of broader efforts to improve donor recruitment and retention, although they are not a primary commercial product within Abbott's diagnostics portfolio.

Infectious Diseases – Molecular

Abbott is a global leader in immunoassay diagnostics and has extended this expertise into molecular diagnostics through a broad portfolio of nucleic acid amplification technologies. The company has expanded its molecular testing menu, with strategic emphasis on infectious disease, sexual health, oncology, transplant monitoring, and blood screening. Abbott Molecular develops assays that analyze DNA and RNA targets at the molecular level, supporting clinical decision-making in infectious disease management, women's health, transplantation, and selected genetic applications.

Abbott's molecular portfolio includes the widely installed m2000 RealTime system, which supports real-time PCR assays for HIV-1, HBV, HCV, Chlamydia trachomatis/Neisseria gonorrhea, CMV, and other infectious disease targets. Abbott also markets sequencing-based products, including the ViroSeq HIV-1 Genotyping System, which historically played an important role in antiretroviral resistance testing, although sequencing strategies in many laboratories have increasingly shifted toward next-generation sequencing technologies.

The company also offers the m2000 platform with its Alinity m molecular diagnostics system. Alinity m uses fully automated real-time PCR technology with ReadiFlex random-access sample handling, continuous loading, and STAT prioritization, allowing laboratories to run multiple assay types simultaneously with high workflow flexibility.

Abbott continues to offer molecular viral load assays for HIV-1, HBV, HCV, and CMV, including the Abbott RealTime CMV assay, which remains important in transplant medicine.

The CMV assay amplifies two conserved genomic regions of cytomegalovirus to reduce the risk of under-quantification due to viral mutations and is standardized to the World Health Organization International Standard for CMV nucleic acid testing, thereby supporting the management of transplant patients undergoing antiviral therapy.

A major area of Abbott's molecular expansion is sexual health testing. The Alinity m STI assay simultaneously detects Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, and Mycoplasma genitalium in a single multiplex molecular assay, enabling comprehensive sexually transmitted infection screening from a single sample and improving laboratory efficiency.

Abbott also markets the Alinity m high-risk HPV assay; a molecular test used for cervical cancer screening and detection of high-risk human papillomavirus genotypes associated with cervical cancer. The assay identifies HPV 16 and HPV 18 individually while simultaneously detecting 12 additional high-risk HPV genotypes in pooled groups, supporting primary HPV screening, co-testing with cytology, and triage of atypical cervical cytology results. The assay is approved in multiple global markets, including the U.S. and Europe.

Abbott continues to expand the Alinity m menu with assays across infectious disease, virology, blood screening, and women's health, positioning molecular diagnostics as a major long-term growth driver within its core laboratory business.

Diabetes

Abbott's advanced continuous glucose monitoring portfolio is led by the FreeStyle Libre family of biosensor systems, which has become one of the world's largest continuous glucose monitoring franchises. The system uses a small wearable sensor applied to the back of the upper arm to continuously measure interstitial glucose levels without routine fingerstick calibration. Abbott's factory-calibrated sensor technology remains a major differentiator, eliminating the need for routine finger-prick calibration while providing continuous glucose data for diabetes management.

Abbott's current CGM portfolio includes FreeStyle Libre 2, FreeStyle Libre 2 Plus, FreeStyle Libre 3, and next-generation expanded Libre platforms, with sensors designed to provide up to 14 days of continuous wear. The FreeStyle Libre 3 system delivers glucose readings automatically to a smartphone every minute and remains one of the smallest and thinnest

commercially available CGM sensors. Abbott continues to position Libre 3 as a high-accuracy, low-profile sensor priced comparably to earlier Libre generations.

The FreeStyle LibreLink mobile application remains central to Abbott's digital diabetes ecosystem, allowing users to view current glucose readings, trend arrows, historical glucose patterns, and alarms directly on smartphones. Smartphone connectivity is now standard across Abbott's current Libre systems, and users can share glucose data with caregivers and healthcare professionals through Abbott's connected digital platforms.

Abbott's FreeStyle Libre 2 and Libre 3 systems include optional real-time low- and high-glucose alarms and are widely reimbursed across major markets, including Medicare in the United States for eligible patients with insulin-treated diabetes. The Libre systems are broadly distributed through retail pharmacy channels and diabetes care providers worldwide.

Abbott has expanded Libre integration into automated insulin delivery systems through partnerships with insulin pump manufacturers. In the United States, FreeStyle Libre 2 Plus is integrated with the Tandem Diabetes Care t:slim X2 insulin pump, marking Abbott's first U.S. automated insulin-delivery integration. Abbott also maintains an integration partnership with Insulet Corporation for future automated insulin-delivery applications. In Europe, FreeStyle Libre 3 sensors are compatible with Ypsomed mylife Loop and CamDiab systems, supporting closed-loop insulin delivery.

The company offers Lingo, an over-the-counter consumer glucose biosensor designed for adults seeking metabolic insights, personalized coaching, and wellness monitoring. Abbott also introduced Libre Rio, an over-the-counter CGM designed for adults with Type 2 diabetes who are not using insulin and manage their glucose through diet, exercise, and oral therapies. Abbott also markets the Libre Sense Glucose Sport Biosensor, developed for athletes seeking real-time glucose monitoring during exercise and performance training.

Abbott continues to develop next-generation biosensors, including dual-analyte sensors capable of monitoring glucose together with ketones, reflecting the company's long-term strategy to expand beyond glucose monitoring into broader metabolic and chronic disease management.

HIV Point of Care

Abbott introduced one of the world's first licensed HIV blood screening tests in 1985, establishing an early leadership position in HIV diagnostics that continues today across laboratory, blood screening, molecular, and point-of-care testing. Abbott's current HIV portfolio includes assays for screening, diagnosis, viral load monitoring, treatment management, and digital connectivity, with products designed for both centralized laboratories and decentralized care settings. The company continues to invest in HIV testing as part of its broader infectious disease diagnostics strategy, particularly in support of global HIV treatment programs and underserved healthcare regions.

Abbott's laboratory HIV portfolio includes high-throughput immunoassays on its ARCHITECT, Alinity i, and Alinity s platforms, as well as molecular viral load assays on the Alinity m system for monitoring treatment response and disease progression. Abbott's molecular HIV assays are widely used for viral load quantification and support antiretroviral therapy monitoring in both developed and emerging healthcare markets.

A major component of Abbott's POC HIV strategy is the m-PIMA HIV-1/2 VL, a portable molecular point-of-care viral load test designed for use in remote and underserved communities. The m-PIMA HIV-1/2 VL is a quantitative nucleic acid amplification test that measures viral load for HIV-1 groups M, N, and O, as well as HIV-2, directly from plasma samples.

The system is designed for POC testing and can deliver quantitative viral load results in less than 70 minutes, allowing healthcare providers to make treatment decisions during the same patient visit. Abbott positions the platform as an important tool for reducing patient loss to follow-up, improving treatment adherence, and expanding viral load monitoring access in decentralized healthcare environments.

The m-PIMA platform is particularly important in global HIV programs supported by international public health organizations, where rapid viral load monitoring is essential for treatment management in resource-limited settings.

i-STAT Business

Abbott's point-of-care diagnostics portfolio is designed to provide healthcare professionals with immediate access to rapid, clinically actionable test results directly at the site of patient

care. The company's flagship point-of-care platform is the i-STAT Alinity System, a handheld blood analysis system that delivers laboratory-quality results within minutes using small whole blood samples obtained at the bedside.

The i-STAT Alinity System uses single-use, test-specific cartridges that require only two to three drops of whole blood. After sample application, the cartridge is inserted into the handheld analyzer, where fully self-contained microfluidic and biosensor technology performs the test without additional preparation. Results are typically available in two to ten minutes, depending on the assay.

Abbott's cartridge menu includes tests for blood gases, electrolytes, chemistries, cardiac markers, coagulation, hematology, lactate, glucose, and renal function, supporting use in emergency medicine, critical care, operating rooms, ambulances, urgent care settings, and hospital bedside testing. The system remains widely used where rapid decision-making is critical.

The i-STAT Alinity platform also incorporates wireless connectivity and data integration capabilities, allowing results to be transmitted directly into hospital information systems and electronic medical records, improving workflow efficiency and reducing transcription errors.

Abbott has expanded beyond traditional bedside chemistry testing with specialized rapid assays such as the i-STAT TBI Plasma, a plasma-based test used to assist in evaluating mild traumatic brain injury. The assay measures brain injury biomarkers and provides results in approximately 15–18 minutes, helping clinicians assess whether CT imaging may be necessary.

Unlike i-STAT cartridge-based bedside assays, the i-STAT TBI Plasma test is performed on Abbott's central laboratory immunoassay platforms, including the ARCHITECT and Alinity i systems, linking Abbott's point-of-care and core laboratory strategies in acute care diagnostics.

Abbott continues to expand its point-of-care testing portfolio by integrating rapid diagnostics, connectivity, and handheld testing across acute care, outpatient, and decentralized healthcare environments.

Abbott markets the STAT TBI test to be used with whole blood. This will enable testing to be performed in a variety of healthcare settings including on the sidelines of sporting events.

The test is run on the i-Stat Alinity analyzer and measures two biomarkers – UCH-L1 and GFAP.

Agilent Technologies

Santa Clara, CA

www.agilent.com

Table 14-3: Agilent Revenue History, 2023-2025 ($ million)

	2023	2024	2025
Total Life Sciences and Diagnostics	2,780	2,466	2,726

Source: company reports, Kalorama Information

Agilent operates three principal business segments: Life Sciences and Diagnostics Markets, Agilent CrossLab, and Applied Markets. This reporting structure replaced the earlier segmentation that included a separate Diagnostics and Genomics business, with the reorganization beginning in fiscal 2025 to align diagnostics, genomics, and life science activities more closely within a single operating segment. In fiscal 2025, Life Sciences and Diagnostics Markets became one of Agilent's strongest growth areas, supported by pathology, companion diagnostics, genomics, and biopharma-related demand.

The Life Sciences and Diagnostics Markets segment includes a broad portfolio of clinical, genomic, and analytical technologies supporting pharmaceutical development, clinical diagnostics, and biomedical research. Major product areas include pathology products, specific proteins and flow reagents, companion diagnostics, target enrichment technologies, cytogenetic research solutions and microarrays, PCR and qPCR instrumentation and molecular biology reagents, nucleic acid analysis solutions, and automated electrophoresis and microfluidics platforms.

Agilent's pathology business, largely derived from Dako, includes routine and advanced clinical solutions for tissue-based cancer diagnostics. These solutions comprise antibodies, reagents, staining instruments, image analysis software, and workflow systems used in both primary and advanced oncology diagnostics. The CoverStainer and Artisan product families support primary cancer diagnostics through hematoxylin and eosin (H&E) staining and special stains used for tissue characterization and identification of abnormal or malignant

tissue. Agilent's pathology portfolio also includes immunohistochemistry (IHC), in situ hybridization (ISH), and companion diagnostic assays used in precision oncology.

Agilent remains a leader in commercial lab-on-a-chip microfluidics technology, an area established through its early development of integrated microfluidic platforms. Lab-on-a-chip systems enable sample handling, mixing, dilution, electrophoresis, chromatographic separation, staining, and detection on miniaturized integrated systems. Agilent's chips are processed using the Agilent 2100 Bioanalyzer platform and continue to be widely used for DNA, RNA, protein, and cell analysis in research, translational medicine, and selected clinical laboratory workflows.

Agilent's microfluidic and array technologies continue to support molecular diagnostics. For example, Agendia uses Agilent microarray technology in its MammaPrint breast cancer recurrence assay, which remains an FDA-cleared genomic profiling test used in oncology decision support.

Through a series of mergers and acquisitions, Agilent expanded into a diversified life sciences and diagnostics company serving analytical laboratories and clinical markets through technology platforms that include automation, bioreagents, fluorescence in situ hybridization probes, chromatography, immunohistochemistry, informatics, mass spectrometry, microarrays, sequencing support technologies, and spectroscopy.

Agilent's CrossLab business provides laboratory services and consumables including enterprise asset management, laboratory informatics, equipment service, software maintenance, regulatory compliance support, sample preparation products, genomics reagents, chromatography columns, spectroscopy supplies, and general laboratory consumables. CrossLab is important because it provides recurring revenue and broad customer penetration across pharmaceutical, academic, and clinical laboratory markets.

Mergers and acquisitions continue to support Agilent's long-term strategy. Recent important acquisitions include Advanced Analytical Technologies, Lasergen, Genohm, ACEA Biosciences, and Avida Biomed, which strengthened Agilent's genomics and target enrichment capabilities.

In diagnostics and clinical markets, Agilent offers pathology laboratories globally, with strongest penetration in North America, Western Europe, and Japan. Emerging markets continue to increase investment in pathology, oncology testing, and molecular diagnostics.

Agilent's genomics business includes arrays for DNA mutation detection, genotyping, copy number analysis, gene rearrangement analysis, methylation profiling, gene expression profiling, and next-generation sequencing target enrichment. These technologies support translational research, biomarker development, and clinical laboratory testing for inherited disease and oncology.

Its nucleic acid solutions business provides equipment and expertise for synthesis of oligonucleotides under pharmaceutical GMP conditions for use as active pharmaceutical ingredients in nucleic acid therapeutics, including siRNA, antisense, and gene editing applications.

Agilent collaborates with pharmaceutical companies to develop companion diagnostics. The company continues partnerships in precision oncology and digital pathology, including work with PathAI to integrate AI algorithms into companion diagnostic assay development and with Theragen Bio to support comprehensive genomic profiling using Agilent's SureSelect Cancer CGP Assay platform.

Agilent also markets an on-deck thermal cycler integrated with the Agilent Bravo automated liquid handling system to support next-generation sequencing workflows, improving automation in molecular biology and genomic sample preparation.

The company has a collaboration with Incyte to develop advanced companion diagnostics in hematology and oncology. This allows Agilent to expand its companion diagnostic portfolio with novel biomarkers.

In March 2026, Agilent entered into an agreement to acquire Biocare Medical. Biocare is a pathology antibody provider. The acquisition will strengthen Agilent's pathology portfolio and expand its footprint in the United States. The transaction is expected to be final by Q4 2026.

Genomics

Agilent's genomics business includes arrays for DNA mutation detection, genotyping, gene copy number determination, identification of gene rearrangements, DNA methylation profiling, gene expression profiling, and next-generation sequencing (NGS) target enrichment. Agilent remains a major supplier of target-enrichment technologies for research,

translational genomics, and clinical oncology workflows, with its SureSelect portfolio continuing to be one of the company's strongest genomics franchises.

SureSelect target-enrichment solutions enable highly focused sequencing of genomic regions of interest through custom-designed oligonucleotide capture chemistry. The platform supports somatic oncology testing, inherited disease analysis, whole-exome sequencing, and comprehensive genomic profiling. Agilent has increasingly positioned SureSelect for both translational research and clinical laboratory use, with workflows optimized for high-throughput sequencing and automation.

The older HaloPlex chemistry is part of Agilent's historical targeted sequencing portfolio, but SureSelect has become the dominant platform in current commercial genomics strategy, particularly for higher-complexity oncology and precision medicine applications. SureSelect workflows generate sequencing-ready libraries with streamlined sample preparation and compatibility across major sequencing platforms.

Agilent's microarray portfolio continues to include SurePrint technology for genome-wide gene expression analysis, copy number variation studies, and cytogenetic research applications. Array-based offerings support copy number assessment, SNP analysis, methylation studies, and cytogenomic interpretation in both research and selected clinical laboratory settings.

Agilent also maintains a strong fluorescence in situ hybridization portfolio through SureFISH, which uses synthetic oligonucleotide probe technology for highly specific chromosomal analysis. SureFISH probes are widely used in cytogenetics, oncology research, and pathology workflows requiring targeted gene rearrangement detection.

Agilent SureFISH probes are marketed as Class I analyte specific reagents (ASRs) in the United States and are supported by complementary arrays, scanners, and Agilent CytoGenomics software for chromosomal analysis and interpretation. The probe menu includes break-apart assays targeting clinically important oncology markers such as ALK, ROS1, and RET, which remain relevant in lung cancer biomarker assessment and translational oncology research.

For nucleic acid quality assessment and workflow control, Agilent markets the Agilent 2100 Bioanalyzer and TapeStation systems, both of which are widely used for DNA and RNA quantitation, integrity assessment, and sequencing library quality control in genomics laboratories.

Cytogenetic Analysis

Agilent is a leading provider of microarray-based cytogenetic solutions, particularly for comparative genomic hybridization (CGH) and single nucleotide polymorphism (SNP)-based chromosomal analysis used in cytogenetics laboratories, reproductive genetics, and research settings. Agilent arrays enable genome-wide detection of copy number alterations at high resolution, ranging from whole chromosome abnormalities to microdeletions and microduplications associated with constitutional and oncologic disorders.

The company's array portfolio supports multiple array formats, allowing laboratories to select different probe densities, resolutions, and sample throughput configurations depending on clinical or research requirements. Arrays can also be customized using SureDesign, which allows laboratories and researchers to design targeted probe content for specialized genomic applications.

In addition to microarrays, Agilent provides a full cytogenetics workflow that includes sample preparation reagents, labeling kits, hybridization systems, scanning hardware, and interpretation software. This integrated workflow includes Agilent CytoGenomics for visualization, copy number analysis, and chromosomal interpretation.

Agilent's cytogenetics portfolio also includes SureFISH, a line of synthetic oligonucleotide fluorescence in situ hybridization probes used in cytogenetics, cancer research, and pathology laboratories. SureFISH probes remain important for targeted gene rearrangement analysis and chromosomal localization studies, with probe menus including clinically important oncology targets such as ALK, ROS1, and RET.

SureScan Dx Microarray Scanner remains an important regulated platform in Agilent's cytogenetics offering. The CE-marked system is intended for use in clinical laboratory environments for measuring fluorescence signals of labeled DNA or RNA hybridized to microarrays used within validated diagnostic workflows. The scanner continues to support both cytogenetics and translational genomic applications.

Agilent also continues to market GenetiSure Dx Postnatal Assay for detection of genomic aberrations associated with developmental delay, intellectual disability, congenital anomalies, and unexplained dysmorphic features. The assay is performed on the SureScan Dx platform and remains one of Agilent's primary regulated chromosomal microarray offerings for postnatal constitutional testing.

In reproductive genomics, Agilent continues to offer OnePGT, a genome-wide next-generation sequencing solution for preimplantation genetic testing (PGT). OnePGT supports simultaneous detection of monogenic disorders (PGT-M), structural rearrangements (PGT-SR), and aneuploidies (PGT-A) from a single embryo biopsy, enabling embryo prioritization and reproductive decision support in assisted reproduction laboratories.

While microarrays remain important in cytogenetics, Agilent's strategic growth emphasis in 2026 increasingly centers on NGS target enrichment, reproductive genomics, oncology profiling, and integrated cytogenomic interpretation workflows, where array and sequencing technologies increasingly complement one another.

Sequencing

Agilent entered into several licensing and strategic technology agreements over the last several years to strengthen its portfolio of clinical next-generation sequencing products, particularly in target enrichment, molecular barcoding, and ultra-sensitive variant detection. These agreements expanded Agilent's ability to support high-sensitivity somatic mutation analysis, liquid biopsy workflows, and comprehensive genomic profiling applications.

SureSelect XT HS remains one of Agilent's core advanced target-enrichment platforms. The SureSelect XT HS workflow incorporates molecular barcode technology (unique molecular identifiers, UMIs) that improve detection of low-frequency variants by reducing sequencing artifacts and increasing confidence in rare mutation calling. This molecular barcode capability was strengthened through licensing agreements involving patented barcode technologies used in population genetics and precision oncology workflows.

Agilent continues to market the SureSelect Cancer CGP Assay as a major oncology sequencing solution for somatic variant profiling of solid tumors. The assay is designed for comprehensive genomic profiling and includes a broad hybrid-capture NGS panel covering hundreds of cancer-related genes for detection of SNVs, indels, CNVs, and gene rearrangements. Agilent has continued refining this platform for translational oncology, biomarker discovery, and companion diagnostic development, including collaborations with pharmaceutical and software partners.

Agilent no longer owns Resolution Bioscience. Agilent divested Resolution Bioscience to Exact Sciences, allowing Exact Sciences to expand its precision oncology and liquid biopsy portfolio. Resolution Bioscience had developed next-generation sequencing oncology

solutions focused on liquid biopsy, fusion detection, and targeted cancer profiling, and these technologies now contribute to Exact Sciences' oncology testing strategy.

The divestiture reflects Agilent's broader strategy to focus internal genomics growth on SureSelect target enrichment, companion diagnostics partnerships, cytogenomics, and clinical laboratory workflow technologies, rather than directly operating a standalone oncology testing business.

CRISPR

Agilent provides a sophisticated suite of CRISPR research tools through its SureGuide CRISPR portfolio, designed to support genome editing, functional genomics, and high-throughput screening applications. The SureGuide offering includes custom and pre-designed CRISPR libraries for gene knockout, gene activation, and gene repression studies used in oncology research, drug discovery, and broader life sciences applications.

Every SureGuide CRISPR library is synthesized using Agilent's SurePrint DNA synthesis platform, which enables highly parallel production of complex oligonucleotide pools with very high sequence fidelity and uniform library representation. SurePrint technology allows simultaneous synthesis of billions of DNA bases, supporting accurate guide RNA library construction with strong reproducibility across large-scale screening experiments.

Agilent continues to position SureGuide within its broader genomics workflow by integrating CRISPR library synthesis with target enrichment, oligonucleotide manufacturing, and nucleic acid quality-control platforms, allowing researchers to move efficiently from guide design through downstream sequencing validation

Flow Cytometry

Agilent's flow cytometry business has limited direct participation in routine clinical diagnostics compared with major clinical flow cytometry suppliers, but its platforms increasingly support clinical diagnostic development, translational pathology, and laboratory-developed testing environments, particularly in oncology and hematology.

The flow cytometry portfolio, developed through the acquisition of ACEA Biosciences, is marketed under the NovoCyte brand and includes systems used in hospital-based specialty

laboratories, cancer centers, and reference laboratories where advanced cellular analysis supports diagnostic decision-making and biomarker evaluation.

NovoCyte Opteon Spectral Flow Cytometer provides spectral flow cytometry with configurations ranging from three to five lasers and support for up to 73 detection channels, allowing detailed cellular characterization in complex hematology and immunology applications. In clinical diagnostic environments, spectral flow cytometry is increasingly valuable for high-complexity immunophenotyping, rare-cell analysis, and expanded marker panels used in hematologic malignancy assessment.

Agilent's flow systems are most relevant clinically in:

- leukemia and lymphoma immunophenotyping
- minimal residual disease assessment
- immune status monitoring
- transplant-related immune analysis
- oncology biomarker validation
- cellular characterization for advanced laboratory-developed tests

NovoCyte Penteon and NovoCyte Quanteon also support multiparameter cellular assays in specialty clinical laboratories where laboratories require flexible panel design and high analytical sensitivity.

Although Agilent does not currently dominate the regulated clinical flow cytometry segment led by Becton Dickinson and Beckman Coulter, its instruments increasingly support clinical research and diagnostic assay development linked to precision medicine, particularly where high-dimensional cell analysis is needed alongside molecular and pathology workflows.

Agilent's broader clinical diagnostics strategy positions flow cytometry as a complementary technology to its pathology, genomics, and companion diagnostic businesses, especially in oncology where cellular phenotyping and genomic profiling increasingly converge.

Companion Diagnostics - Dako

Agilent acquired Dako for $2.2 billion in 2012, and the acquisition remains one of the most important strategic moves in Agilent's expansion into clinical pathology and companion diagnostics. Dako is now fully integrated into Agilent's pathology and diagnostics business rather than operating as a separate subsidiary, and it continues to serve as the foundation of Agilent's tissue-based cancer diagnostics franchise.

Dako established a leadership position in tissue-based cancer diagnostics and companion diagnostics through early innovation in immunohistochemistry, including introduction of some of the first conjugated antibodies used in pathology workflows. Over time, the portfolio expanded into immunohistochemistry (IHC), in situ hybridization (ISH), fluorescence in situ hybridization (FISH), chromogenic in situ hybridization (CISH), special stains, image analysis, and automated pathology workflow systems.

The pharmDx brand remains Agilent's core companion diagnostic platform for tissue-based oncology assays. pharmDx assays are designed to identify patients eligible for targeted therapies or immunotherapies and remain central to Agilent's precision oncology strategy.

Agilent's pathology portfolio includes antibodies, ISH probes, staining systems, and automation platforms. Older systems such as TechMate and ChemMate are largely legacy technologies, while the current core automation platform is Dako Omnis, which serves as Agilent's flagship high-throughput pathology staining and companion diagnostics instrument. Dako Omnis supports integrated immunohistochemistry, ISH, and advanced tissue staining workflows in clinical pathology laboratories.

Agilent continues to market major PD-L1 companion diagnostic assays under the pharmDx portfolio. PD-L1 IHC 22C3 pharmDx remains one of the most widely used companion diagnostics globally and supports multiple indications linked to Merck & Co.'s Keytruda across non-small cell lung cancer, urothelial carcinoma, gastroesophageal cancers, and additional solid tumor indications.

PD-L1 IHC 28-8 pharmDx is an important complementary diagnostic linked to Bristol Myers Squibb's Opdivo and supports expanded use in multiple oncology indications including urothelial carcinoma, esophageal squamous cell carcinoma, and head and neck cancers.

Agilent also expanded its in situ hybridization portfolio. SureFISH probes offer oncology and cytogenetic applications with break-apart and dual-fusion assays targeting clinically

important markers including MALT1, BCL2, BCL6, CCND1, MYC, and IGH rearrangements. Agilent also maintains chromogenic ISH offerings, including EBER RNA CISH and kappa/lambda mRNA probes for tissue-based hematopathology applications.

The company markets accessory systems that extend Dako Omnis workflow flexibility, allowing combined IHC and ISH workflows on a single platform. These technologies support increasingly complex pathology workflows that require multiplex biomarker assessment.

Agilent strengthened digital pathology collaboration through its agreement with Visiopharm, under which both companies co-market AI-driven pathology image analysis solutions. This partnership supports the adoption of digital pathology, biomarker quantification, and companion diagnostic interpretation in oncology laboratories.

Agilent's companion diagnostic strategy also includes pharmaceutical collaborations beyond checkpoint inhibitors. The company maintains development agreements with oncology drug developers, including Incyte, to expand biomarker-driven companion diagnostics in hematology and oncology.

Agilent no longer owns Resolution Bioscience following divestiture to Exact Sciences, so liquid biopsy products such as Resolution ctDx FIRST are no longer core Agilent products. Agilent's present precision oncology focus remains centered on tissue-based companion diagnostics, SureSelect genomic profiling, and digital pathology integration.

Agilent markets the MME HIC pharmaDx companion diagnostic test for colorectal cancer. The test identifies mismatch repair-deficient colorectal cancer patients who are eligible for treatment with BMS's Opdivo.

In February 2026, Agilent released its PD-L1 IHC 22C3 pharmDx as a companion diagnostic to help identify patients with epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 and may benefit from treatment with Keytruda.

Digital Pathology

Agilent has expanded its role in digital pathology by combining tissue diagnostics, automated staining, slide scanning, image analysis, and artificial intelligence into a more integrated pathology workflow. Its digital pathology strategy centers on helping pathology laboratories

transition from conventional microscopy to digital slide review, remote collaboration, and AI-assisted interpretation.

The company's digital pathology portfolio is anchored by the Dako Omnis platform, which supports automated immunohistochemistry (IHC) and in situ hybridization (ISH) staining for tissue-based cancer diagnostics. Agilent has also strengthened its digital workflow through slide scanning systems and software partnerships that support whole-slide imaging, digital case management, and quantitative biomarker assessment.

Agilent collaborates with digital pathology companies to expand AI-based image analysis and improve the interpretation of companion diagnostic assays. These efforts are particularly important in oncology, where digital pathology supports more consistent biomarker scoring, improved workflow efficiency, and broader adoption of precision medicine in clinical pathology laboratories.

Beckman Coulter / Danaher

Brea, CA

www.beckmancoulter.com

Beckman Coulter, Inc., a subsidiary of Danaher Corporation (DHR), develops, manufactures and markets IVD tests for more than 80 years. The company reports that more than 275,000 Beckman Coulter systems operate in both diagnostics and life sciences laboratories on six continents.

With an 80-year history, Beckman Coulter's scalable instruments, comprehensive diagnostic test portfolio and business management services are used by hospitals, laboratories and other critical care settings around the world.

Beckman Coulter partnered with Biogen and Fujirebio to advance the development of blood-based biomarkers for Alzheimer's disease, particularly assays targeting phosphorylated tau proteins associated with neurodegeneration. These efforts have progressed from early development into the commercialization of automated immunoassays designed for use on high-throughput laboratory platforms. The collaboration supports the growing adoption of blood-based testing as a less invasive alternative to cerebrospinal fluid analysis and imaging, enabling broader access to Alzheimer's disease assessment in routine clinical practice.

Hematology

Beckman Coulter was the long-time global leader in hematology, but in recent years Sysmex has strengthened its global position through aggressive instrument placement, workflow expansion, and strong penetration in high-volume laboratories, leaving the two companies closely matched, with Sysmex leading in several major markets.

Beckman Coulter maintains a strong hematology position through a broad analyzer portfolio spanning low-, mid-, and high-volume laboratories, supported by workflow automation, digital morphology integration, and advanced clinical parameters. Its hematology line continues to emphasize first-pass accuracy, workflow efficiency, and expanded clinical decision support in a mature but highly competitive market.

The company's hematology portfolio includes systems ranging from the DxH 500 for lower-volume laboratories to the DxH 900 for high-throughput clinical laboratories. The DxH 500 remains designed for smaller laboratories and near-patient environments, offering CBC plus 5-part differential testing with low sample volume requirements, including capillary blood collection suitable for pediatric and geriatric patients.

Beckman Coulter markets the DxH 520, which provides 5-part differential testing in low-volume laboratories using small blood sample volumes and rapid turnaround times. The system remains important in physician office laboratories, outpatient clinics, and smaller hospital laboratories.

For mid- and high-volume laboratories, the DxH 900 and DxH 690T incorporate Beckman Coulter's core hematology technologies, including the enhanced Coulter Principle, VCS 360 cellular analysis, and DataFusion analytics. These systems are designed to reduce repeat testing, improve flagging accuracy, and provide detailed cellular analysis in near-native cell states.

A key differentiator for Beckman Coulter is its Early Sepsis Indicator, which is available on select DxH hematology systems. This parameter uses monocyte morphological analysis to detect early cellular changes associated with sepsis risk as part of a routine complete blood count with differential. It provides clinicians with earlier insight into potential sepsis without the need for separate, dedicated testing.

Beckman Coulter has expanded hematology workflow automation through integrated workcell solutions that combine analyzers, slide preparation, staining, and digital morphology. Its hematology automation platforms connect analyzers with slidemaker-stainers and digital cell morphology through collaboration with Scopio Labs, allowing laboratories to integrate automated blood smear preparation with AI-assisted digital review.

This digital workflow strategy strengthens Beckman Coulter's position in high-throughput hematology laboratories where labor shortages, standardization, and remote review are increasingly important.

Hematology IT

Beckman Coulter Diagnostics continues to offer both new and installed DxH 500 systems through upgraded software designed to improve analytical performance and workflow

efficiency in small-volume clinical laboratories. The software enhancements strengthen flagging performance, quality control functions, and user workflow management for laboratories performing routine complete blood count and 5-part differential testing.

The updated software incorporates Beckman Coulter's proprietary dynamic-gating methodology, which improves cell population discrimination by adjusting thresholds between cellular clusters. This approach enhances differential accuracy, particularly for challenging cell populations, and helps reduce unnecessary slide reviews that can slow laboratory workflow.

Quality control functions have also been expanded, allowing laboratories greater flexibility in QC management and documentation. Enhanced QC file capacity and improved reporting tools help laboratories support accreditation requirements and maintain more efficient daily instrument monitoring.

Additional software refinements include simplified system setup, expanded user access controls, backup and restore capabilities, and access to research-use-only parameters in selected markets that support broader laboratory evaluation.

The DxH 500 remains designed for low-volume laboratory settings where simplicity, small sample volume requirements, and rapid turnaround are important. Its compact footprint, simplified reagent system, and low maintenance requirements continue to make it suitable for physician office laboratories, outpatient settings, and smaller hospital laboratories.

Clinical Chemistry

In clinical chemistry, Beckman Coulter continues to offer a broad test menu of more than 150 chemistry, immunochemistry, and specific protein assays, supporting routine chemistry, therapeutic drug monitoring, drugs of abuse testing, and specialty protein analysis across low-, mid-, and high-volume laboratories.

The company has strengthened its integrated chemistry and immunoassay workflow through scalable analyzer families and workcell automation. Earlier UniCel branding has largely transitioned to the current DxC and DxI platform families, with automation focused on improving throughput, sample handling, and operational efficiency in core laboratories.

DxC 700 AU remains a major mid- to high-volume chemistry platform, combining Beckman Coulter DxC workflow design with the proven analytical performance of the Olympus AU chemistry architecture. The analyzer continues to serve laboratories requiring high throughput, menu breadth, and strong reliability in routine chemistry testing.

Beckman Coulter also continues to market the DxC 500 AU, designed for mid-volume laboratories seeking a compact clinical chemistry system with broad assay capability and workflow flexibility.

Integrated chemistry and immunoassay automation remains a major focus through DxC 500i and higher-volume workcell solutions. The DxC 500i combines chemistry and immunoassay testing on a single platform and uses FlexMode operation, allowing laboratories to prioritize either chemistry or immunoassay workload depending on demand.

At the high-volume end, Beckman Coulter has positioned the DxC 880i as a flagship integrated clinical chemistry and immunoassay platform for large core laboratories, designed for high throughput, reduced manual intervention, and advanced workflow connectivity.

In urinalysis, DxU Iris Workcell is an important automated solution. The workcell integrates particle imaging and urine chemistry analysis by combining the DxU 850m Iris with urine chemistry instrumentation to support high-throughput automated urinalysis.

Immunoassays

Beckman Coulter remains a major supplier of immunoassay and protein testing systems, with an immunoassay menu that now exceeds 60 assays covering cardiac disease, cancer markers, thyroid function, reproductive endocrinology, anemia, autoimmune conditions, diabetes, infectious disease, inflammatory markers, therapeutic drug monitoring, toxicology, and specialty proteins.

The company's immunoassay portfolio is focused on the Access family and the high-throughput DxI 9000 Access Immunoassay Analyzer, which has become Beckman Coulter's flagship immunoassay platform for high-volume laboratories. The DxI 9000 delivers high throughput, simplified maintenance, and expanded menu capability for large core laboratories, while older systems such as Access 2 and UniCel DxI 800 remain widely installed in routine laboratory settings.

Beckman Coulter offers its cardiac marker portfolio through Access hsTnI assay, which supports early myocardial infarction assessment and cardiovascular risk stratification across the Access immunoassay family. The assay remains important because it offers flexibility for testing in both serum and plasma.

The company also maintains strong positioning in heart failure testing through its Access NT-proBNP assay, which provides a rapid assessment of acute and chronic heart failure and is increasingly used on high-throughput immunoassay platforms.

In sepsis and inflammatory testing, Beckman Coulter markets both Access PCT and IL-6 assays. Access PCT provides sepsis risk assessment and septic shock evaluation, while procalcitonin integration through middleware allows laboratories to incorporate sepsis testing directly into routine core laboratory workflows.

The company has strengthened its reproductive endocrinology with Access AMH and sensitive estradiol assays, maintaining one of the strongest reproductive hormone menus in automated immunoassay testing. Beckman Coulter remains a leader in AMH testing, where its antibody technology continues to support broad clinical adoption in fertility assessment and ovarian reserve evaluation.

In toxicology and therapeutic monitoring, Beckman Coulter supports drugs-of-abuse testing through Syva EMIT assays on AU chemistry platforms, including buprenorphine and 6-acetylmorphine testing.

Beckman Coulter also continues to strengthen quality control and data management through collaboration with Technopath, expanding use of external QC materials and automated QC data management in chemistry and immunoassay laboratories.

A major emerging area is neurodegenerative disease biomarkers. In 2025, Beckman Coulter received FDA Breakthrough Device Designation for its plasma-based Access p-Tau217/β-Amyloid 1-42 Plasma Ratio, designed to support identification of amyloid pathology associated with Alzheimer's disease. This positions Beckman Coulter among the first major core laboratory companies advancing automated blood-based Alzheimer biomarker testing.

Microbiology

DxM 6100 Autoplak Advanced System markets automated microbiology specimen processing steps, including plate inoculation, streaking, Gram stain slide preparation, and enrichment broth inoculation. The system is designed to improve laboratory standardization, reduce manual handling, and support higher specimen throughput in clinical microbiology laboratories.

The open-platform design is an important differentiator, allowing laboratories to use liquid transport tubes and consumables from multiple suppliers while customizing protocols to fit existing laboratory workflows. This flexibility helps laboratories integrate automation without major workflow redesign.

The DxM 6100 competes in microbiology automation with systems from Copan Diagnostics and other automated specimen-processing providers, particularly in laboratories seeking to improve efficiency amid staffing shortages and rising specimen volumes.

Beckman Coulter markets the DxM MicroScan WalkAway for bacterial identification and antimicrobial susceptibility testing. The system supports organism identification and susceptibility determination using direct minimum inhibitory concentration (MIC) methodology, which remains important for detecting antimicrobial resistance patterns and emerging resistant organisms.

MicroScan WalkAway is especially helpful in routine hospital microbiology laboratories, where standardized antimicrobial susceptibility testing and resistance surveillance remain essential components of the clinical microbiology workflow.

IT Clinical

Beckman Coulter provides its laboratory informatics and remote service strategy through the DxONE digital platform, which supports instrument connectivity, workflow optimization, predictive service, and operational analytics across chemistry, immunoassay, hematology, and automation systems.

DxONE PROService is the company's remote monitoring and predictive service application, enabling continuous monitoring of instrument performance and early identification of potential system issues that could affect turnaround time or laboratory workflow. The

platform securely transmits instrument performance data through Beckman Coulter's cloud infrastructure, enabling service teams to provide remote diagnostics and faster intervention when needed.

Beckman Coulter also offers middleware capabilities through REMISOL Advance, which remains a core middleware platform for mid- and high-volume laboratories. REMISOL Advance supports real-time sample tracking, autoverification, quality control monitoring, and consolidated analyzer connectivity, helping laboratories improve result delivery and operational visibility.

Within the DxONE portfolio, DxONE Workflow Manager enables laboratories to standardize workflow rules, automate sample routing, and manage exceptions across multiple analytical systems. Cloud-based deployment reduces local IT burden while supporting broader laboratory integration across Beckman Coulter chemistry, immunoassay, and hematology platforms.

A major part of Beckman Coulter's automation strategy is the DxA 5000, which automates preanalytical sample handling and quality assessment. The system rapidly evaluates tube identification, sample type, pending orders, and specimen integrity while helping laboratories reduce preanalytical errors and improve sample workflow before analysis begins. The DxA 5000 remains especially important in high-volume laboratories where automation, specimen integrity control, and labor efficiency are increasingly critical.

Flow Cytometry

Beckman Coulter has been active in flow cytometry since the 1970s and is one of the major suppliers in the global flow cytometry market alongside Becton Dickinson. Flow cytometry remains an important part of Beckman Coulter's Life Sciences and clinical diagnostics strategy, with the company maintaining both research and clinical platforms for cellular analysis, immunophenotyping, and hematologic disease assessment.

For clinical applications, AQUIOS CL Flow Cytometer is a key automated clinical flow cytometry platform. The system combines sample preparation and flow cytometric analysis within a single instrument using load-and-go automation, supporting routine immunophenotyping with minimal operator intervention and first results in approximately 20 minutes.

The AQUIOS platform supports laboratory-developed and standardized assays through AQUIOS Designer Software, which allows laboratories to create customized applications beyond predefined CD4 and basic immunophenotyping workflows. This flexibility has increased its usefulness in hospital laboratories performing specialized immune monitoring and hematology testing.

Beckman Coulter offers the ClearLLab 10C System, a standardized clinical flow cytometry solution designed for hematologic malignancy analysis. ClearLLab panels provide multiparameter immunophenotyping for lymphoid and myeloid disorders, including chronic leukemia, acute leukemia, non-Hodgkin lymphoma, myelodysplastic syndromes, myeloproliferative neoplasms, and plasma cell disorders.

The ClearLLab system includes standardized reagent panels, control materials, and integrated software designed to reduce manual validation requirements and improve consistency in clinical hematology laboratories.

Beckman Coulter's ClearLLab analysis through Kaluza C, provides clinical data analysis, compensation, and reporting designed to support standardized interpretation and quality control.

For higher-complexity laboratories, Navios EX remains an important clinical platform supporting advanced multicolor immunophenotyping and standardized hematologic malignancy workflows.

Beckman Coulter's clinical flow cytometry is focused on leukemia and lymphoma testing, automation, and workflow simplification, while research systems continue to support higher-dimensional cell analysis in translational medicine.

Blood Banking

Beckman Coulter continues to provide the PK7400 Automated Microplate System for blood donor centers, plasma collection facilities, and reference immunohematology laboratories. The system remains a high-throughput, automated microplate platform designed for blood grouping, antibody screening, and donor testing workflows in which large sample volumes require reliable automation and standardized processing.

The PK7400 continues to support high-volume testing, processing up to 300 samples per hour and performing multiple assays per specimen within a single automated workflow. The platform integrates reagent handling, incubation, centrifugation, and result interpretation, helping blood centers improve throughput and consistency in donor screening operations.

Beckman Coulter markets reagents and consumables for the PK7400 to donor testing laboratories where high-capacity microplate automation remains important.

Beckman Coulter Life Sciences

Beckman Coulter Life Sciences strengthened its sample preparation and automation portfolio through the acquisition of Labcyte, whose Echo technology introduced acoustic droplet ejection for highly precise, contactless transfer of samples and reagents. Echo uses sound energy to transfer nanoliter-scale liquid volumes without physical contact, reducing contamination risk and improving precision in genomics, drug discovery, and high-throughput laboratory workflows.

Beckman Coulter Life Sciences expanded liquid biopsy sample preparation through collaboration with Apostle Inc. The partnership provides for the use of the Apostle MiniMax High Efficiency Cell-Free DNA Isolation Kit, a magnetic nanoparticle-based system for extracting circulating cell-free DNA from plasma in both manual and automated workflows. The technology is used for liquid biopsy applications, including oncology, prenatal testing, and infectious disease analysis.

In 2025, Beckman Coulter expanded its spectral flow cytometry portfolio with the launch of the CytoFLEX mosaic Spectral Detection Module, which allows laboratories to upgrade selected CytoFLEX systems for spectral detection and higher-dimensional cellular analysis. This launch strengthened Beckman Coulter's position in advanced cell analysis by enabling broader fluorochrome discrimination and more flexible panel design.

The company also markets cell-preparation tools, including the OptiMATE Gradient Maker, designed to improve reproducibility in density-gradient workflows for cell isolation and sample preparation.

Beckman Coulter additionally offers the NGS Basophil Activation Test for allergy research applications, supporting advanced immune response analysis and expanding the company's role in specialized translational research workflows.

Becton, Dickinson and Company (BD)

Franklin Lakes, NJ

www.bd.com

Table 14-4: BD Revenue History, 2023-2025 ($ million, estimated) FYE Sept 30

	2023	2024	2025
Total Revenues	19,372	20,178	21,840

Source: company reports, Kalorama Information

Geographically, BD's clinical diagnostic IVD product sales were generated 53% internationally and 47% in United States.

Becton, Dickinson and Company (BD) is a global medical technology company that develops, manufactures, and markets medical devices, diagnostic systems, laboratory instruments, and reagents for healthcare providers, life science researchers, pharmaceutical companies, and clinical laboratories worldwide. Founded in 1897 and headquartered in Franklin Lakes, BD employs approximately 72,000 people and serves customers in more than 61 countries. The company has maintained a long-standing international presence, including operations in China since the mid-1990s and India since 1996.

BD operates through three major business segments: BD Medical, BD Life Sciences, and BD Interventional. The Interventional segment includes most of the product portfolio acquired through the 2017 purchase of C. R. Bard. BD Medical now also includes the former critical care assets acquired from Edwards Lifesciences, which were integrated into BD Advanced Patient Monitoring following the acquisition in 2024.

In 2025, BD announced plans to separate its Biosciences and Diagnostic Solutions business to create two independent companies: a streamlined BD focused on core medical technology and a second company centered on diagnostics and life sciences. That strategy evolved in July 2025 when BD entered into a definitive agreement to combine its Biosciences and

Diagnostic Solutions business with Waters Corporation. BD announced the completion of the spin-off with Waters, which was finalized on February 6, 2026.

BD's diagnostics portfolio includes specimen collection and transport systems, microbiology media, automated blood culture systems, molecular diagnostics, rapid immunoassays, cervical cancer screening systems, HPV testing platforms, microorganism identification and antimicrobial susceptibility testing, and laboratory automation solutions. Its diagnostic technologies support infectious disease testing, healthcare-associated infection monitoring, women's health, and oncology applications.

Within life sciences, BD Biosciences, based in San Jose, continues to market the FACSCanto, FACSLyric, FACSymphony, and related flow cytometry systems, maintaining BD's strong position in clinical and research flow cytometry.

BD previously separated its diabetes care business, completing the spin-off of Embecta in 2022. BD retained no ownership stake after the transaction, allowing Embecta to operate independently in insulin delivery and diabetes management products.

Cytology

Becton, Dickinson and Company markets a comprehensive cervical cancer screening portfolio built around the BD Onclarity HPV Assay, BD SurePath Liquid-Based Pap Test, and automated laboratory workflow systems, including the BD COR System and legacy BD Totalys platform. The company's cervical screening solutions support primary HPV testing, co-testing, cytology preparation, and high-volume laboratory automation.

BD Onclarity HPV Assay detects 14 high-risk human papillomavirus genotypes in a single assay, with extended genotyping that individually identifies several clinically important HPV types while grouping others by risk category. The assay remains widely used for primary cervical cancer screening and reflex testing and is performed primarily on the BD COR molecular automation platform, which has increasingly replaced the earlier BD Viper LT System in many laboratories. The assay also remains compatible with selected installed Viper systems in existing workflows.

BD SurePath Liquid-Based Pap Test remains a major cytology collection method in the U.S. market and is integrated with BD's automated sample-preparation and slide-processing systems. BD originally developed the BD Totalys System to automate specimen preparation,

imaging, and slide review, including aliquoting for molecular follow-up testing. While legacy Totalys and Viper LT systems remain in some laboratories, newer is focused on BD's consolidated molecular workflow platforms.

The Onclarity assay is approved for use with both BD SurePath specimens and certain samples collected in Hologic ThinPrep PreservCyt media, allowing laboratories greater flexibility in specimen processing and improving compatibility across existing cervical screening programs.

BD has also expanded Onclarity's role in self-collected screening. In 2025–2026, self-collection received increased clinical attention as healthcare systems sought to improve access to screening for underserved populations, rural patients, and individuals less likely to attend traditional pelvic examination visits. This expansion supports broader cervical cancer prevention efforts by increasing access while maintaining the sensitivity of molecular tests.

Molecular Microbiology

The company offers the BD MAX System platform as part of its molecular microbiology portfolio. BD MAX System is a fully integrated molecular instrument that performs nucleic acid extraction, amplification, and real-time PCR detection in a single workflow, delivering results for up to 24 samples in under 3 hours, depending on the assay type. The platform remains widely used in hospitals and clinical laboratories for medium-throughput molecular testing across multiple infectious disease categories.

The BD MAX assay menu includes tests for healthcare-associated infections, antimicrobial resistance markers, gastrointestinal pathogens, respiratory infections, reproductive health, and sexually transmitted infections. Available assays include panels for MRSA, CPO detection, enteric bacterial pathogens, vaginitis, group B streptococcus, and CT/GC testing, as well as respiratory panels that include SARS-CoV-2, influenza A/B, and RSV. The combined COVID-19, influenza A/B, and RSV molecular assay continues to support respiratory testing demand, with results typically available in approximately two hours.

A key advantage of BD MAX remains its open-system capability, which allows laboratories to develop and automate laboratory-developed tests and integrate additional assays through BD collaboration partners. This flexibility has helped maintain the platform's relevance in laboratories requiring both commercial and customized molecular workflows.

BD expanded its respiratory and STI diagnostics offerings in Europe with the certification of two VIASURE assays developed by Certest Biotec for use on the BD MAX System. This allows clinical laboratories to detect a broad range of pathogens quickly and accurately. The assays include VIASURE Respiratory Virus Extended Mix Real Time PCR Detection Kit for BD MAX and the VIASURE HSV-1, HSV-2 & Treponema pallidum Assay for BD MAX System.

For higher-volume molecular testing, BD increasingly emphasizes the BD COR System, which supports expanded automation and assay consolidation. The BD Vaginal Panel, performed on the BD COR System, directly detects the three most common infectious causes of vaginitis—bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis, and is part of BD's broader women's health molecular strategy. In Europe. The company offers its Enteric Bacterial Panel and Enteric Bacterial Panel plus for the BD COR System.

In microbiology automation, BD Kiestra remains BD's flagship laboratory automation solution. The Kiestra platform includes robotic specimen processing, smart incubation, digital imaging, and track-based automation, enabling laboratories to configure customized workflows for culture setup, plate transport, incubation, and reading. BD continues to expand Kiestra adoption as laboratories seek greater efficiency, standardization, and integration with digital microbiology.

Traditional Microbiology - ID/AST

Becton Dickinson markets a broad microbiology portfolio designed as an integrated laboratory workflow spanning specimen collection, culture, organism identification, antimicrobial susceptibility testing, and informatics. Its microbiology strategy emphasizes connected laboratory solutions that improve turnaround time, standardization, and antimicrobial identification.

BD BACTEC is BD's flagship blood culture platform, providing automated blood culture incubation, detection, and continuous monitoring to diagnose bacteremia and fungemia. The BD BACTEC portfolio supports all major stages of blood culture testing, from specimen collection and transport through culture analysis, and remains widely used in hospital microbiology laboratories worldwide.

BD markets a large culture media portfolio through its longstanding BD Difco and BD BBL brands, supplying prepared plated media, dehydrated media, selective media, and specialized microbiology reagents used in clinical, industrial, and research laboratories.

For organism identification and antimicrobial susceptibility testing, BD Phoenix M50 remains a core platform. The system delivers automated microbial identification and AST for a broad range of gram-positive, gram-negative, and yeast organisms. BD also continues its commercial collaboration with Bruker Corporation to offer MALDI-TOF identification workflows integrated with microbiology laboratory operations. BD BBL Sensi-Disc products remain in use for manual antimicrobial susceptibility testing.

BD has expanded microbiology informatics through the BD Synapsys Informatics Solution, which connects instruments, including Phoenix M50, and supports laboratory workflow management, result interpretation, and antimicrobial stewardship decision support. The system incorporates advanced rules-based analysis to help laboratories interpret complex susceptibility patterns and improve reporting efficiency.

In near-patient microbiology testing, BD Veritor Plus System provides rapid antigen-based testing for respiratory syncytial virus (RSV), influenza A and B, group A streptococcus, and SARS-CoV-2. The platform is widely used in physician offices, urgent care, and decentralized healthcare settings, delivering digital point-of-care results within minutes.

BD also maintains selected rapid immunoassay and serology offerings, including legacy BD Directigen rapid antigen tests and traditional microbiology reagents used for syphilis testing, such as RPR and VDRL reagents, fluorescent treponemal reagents, antisera, and specialty microbiology diagnostics.

Specimen collection is also an important part of BD's microbiology business, with swab-based transport systems, collection devices, and preservation media designed to optimize organism recovery and maintain specimen integrity across laboratory workflows.

Blood Culture

Despite continued expansion of molecular syndromic testing for bloodstream infections and hospital-acquired pathogens, blood culture remains the foundation of sepsis diagnosis and antimicrobial management. BD is one of the key vendors in the blood culture market.

BD BACTEC FX remains BD's core blood culture platform for detecting bloodstream infections. The system is designed for continuous monitoring of blood culture bottles and supports broad microorganism recovery, including aerobic bacteria, anaerobes, and yeast. BD offers a full blood culture workflow that spans specimen collection, incubation, detection, reporting, and informatics integration.

BD's blood culture portfolio includes:

- Preanalytical collection products for standardized blood culture collection and contamination reduction
- BD BACTEC FX instrumentation, with modular configurations that support small laboratories through high-volume hospital networks
- BD BACTEC blood culture media, including aerobic, anaerobic, pediatric, mycosis, and specialty formulations designed to improve microorganism recovery
- BD Synapsys Informatics Solution, which provides browser-based workflow management, result reporting, analytics, and blood culture tracking across microbiology operations
- Integrated data support tools that help laboratories monitor positivity trends, contamination rates, and turnaround performance

BD Synapsys Informatics Solution has become increasingly important as laboratories seek integrated microbiology decision support, antimicrobial stewardship connectivity, and multi-instrument workflow coordination. Synapsys connects blood culture, susceptibility testing, and microbiology automation platforms into a unified digital environment.

BD also expanded its specialty blood safety applications. Its FDA-cleared and CE-marked BD BACTEC platelet quality control media is important for detecting bacterial contamination in platelet products used by microbiology laboratories, blood banks, and transfusion services. These culture-based media support testing of leukocyte-reduced apheresis platelet units and pooled whole-blood platelet concentrates, thereby reducing the risk of transfusion-associated sepsis.

An addition to BD is broader laboratory integration between BD blood culture systems and downstream organism identification workflows, including BD Phoenix M50 AST/ID, MALDI-TOF partnerships, and microbiology automation under BD Kiestra, allowing faster movement from positive blood culture to organism identification and antimicrobial

susceptibility reporting. BD also continues promoting culture-based platelet testing as laboratories face tighter transfusion safety requirements and expanded pathogen surveillance protocols.

Hospital Acquired Infections

BD continues to market its antimicrobial resistance portfolio by combining molecular diagnostics, chromogenic media, automated susceptibility testing, and digital microbiology tools to support hospital infection prevention and antimicrobial stewardship programs.

BD MAX System is the main offering in BD's resistance testing strategy. The platform provides rapid molecular screening for major antimicrobial resistance markers, including carbapenemase-producing organisms (CPO), MRSA, and other healthcare-associated pathogens. The BD MAX Check-Points CPO Assay, developed with Check-Points Health, detects the five most clinically important carbapenemase genes—KPC, NDM, VIM, IMP, and OXA-48-like—in approximately 2.5 hours. The assay is CE-marked and widely used for rapid screening of colonized patients and for infection control surveillance.

BD also markets BD BBL CHROMagar CPE chromogenic plated media for phenotypic screening of carbapenemase-producing Enterobacterales. These media support direct culture-based detection and are commonly used alongside molecular testing to streamline laboratory workflows and confirm the growth of resistant organisms.

BD Phoenix M50 provides resistance characterization through the BD Phoenix CPO Detect panel, a phenotypic test that identifies carbapenemase-producing organisms while simultaneously performing organism identification and antimicrobial susceptibility testing. The system typically delivers CPO detection within 24–36 hours, helping laboratories rapidly distinguish resistance mechanisms while preserving phenotypic susceptibility data critical for treatment decisions.

BD has strengthened this workflow by integrating Phoenix data with BD Synapsys Informatics Solution, allowing faster interpretation of complex resistance patterns and improved reporting for antimicrobial stewardship teams.

In laboratory automation, BD Kiestra has expanded AI-assisted microbiology reading. BD's Kiestra MRSA Imaging Application uses artificial intelligence algorithms to analyze colony growth patterns on BD BBL CHROMagar MRSA II plates, helping laboratories automate

the detection of methicillin-resistant Staphylococcus aureus. The AI application improves standardization, reduces manual plate review time, and supports digital microbiology workflows.

Newer additions to BD's resistance-focused microbiology strategy also include expanded use of Kiestra digital imaging, automated plate transport, and integration of resistance screening into broader microbiology automation systems, allowing laboratories to connect molecular, phenotypic, and AI-supported workflows in a single environment.

Blood Collection

PreAnalytiX, the joint venture between BD and QIAGEN, continues in 2026 to develop and market integrated systems for the collection, stabilization, and purification of high-quality RNA, microRNA, cell-free DNA, and genomic DNA from human blood, bone marrow, and tissue specimens. Its core portfolio includes the PAXgene Blood RNA Tube, PAXgene Blood DNA Tube, PAXgene Blood cfDNA Tube, and PAXgene Tissue System, which are widely used in molecular diagnostics, liquid biopsy, translational research, and pharmaceutical development because they preserve specimen integrity during transport and storage and support both manual and automated downstream extraction workflows.

BD also continues expanding decentralized blood collection through its collaboration with Babson Diagnostics, with the goal of making laboratory-quality blood testing more accessible in retail and outpatient settings. The partnership integrates BD MiniDraw Capillary Blood Collection System with Babson's BetterWay automated sample-handling and analytical technology, enabling small fingertip blood samples to be processed for routine laboratory testing. This strategy enables the expansion of convenient, low-volume blood collection outside traditional phlebotomy settings and complements BD's broader specimen collection portfolio, which also includes Vacutainer blood tubes, Microtainer capillary collection systems, Vacutainer Barricor plasma tubes, and CPT cell preparation tubes for clinical laboratory and molecular applications.

Mass Spectrometry

BD continues its long-standing collaboration with Bruker Corporation, combining MALDI-TOF mass spectrometry–based organism identification with automated antimicrobial susceptibility testing and laboratory informatics. The co-marketing relationship remains

centered on integration of the MALDI Biotyper platform with BD's BD Phoenix M50, enabling laboratories to move efficiently from rapid organism identification to susceptibility testing within a streamlined microbiology workflow. BD supports the global distribution of co-branded MALDI systems and continues to expand access to newer Bruker technologies, including the MALDI Biotyper Sirius and MALDI Biotyper Smart platforms, as well as supporting solutions such as the Sepsityper workflow and MBT Compass software, which enhance speed, throughput, and data interpretation. The Sepsityper workflow remains particularly important in sepsis management, enabling direct identification of pathogens from positive blood culture samples and reducing the time to actionable results compared with conventional subculture methods. BD also provides consumables, calibration materials, and workflow components supporting routine MALDI operations. Integration across the MALDI Biotyper platform, BD Phoenix systems, and BD Synapsys Informatics Solution has continued to advance, increasingly replacing legacy middleware approaches and enabling more unified identification, susceptibility reporting, resistance interpretation, and antimicrobial stewardship support across modern microbiology laboratories.

Flow Cytometry

Becton Dickinson holds a leading global position in clinical and research flow cytometry, building on more than four decades of innovation in single-cell analysis. Its flow cytometry portfolio spans clinical diagnostics, cell sorting, immune monitoring, and high-parameter research applications, with continued expansion into automation, multi-omics, and software-driven workflow integration. In clinical diagnostics, the BD FACSVia System is an established platform for blood banking applications using the BD Leucocount Kit to identify and quantify residual white blood cells in leuko-reduced blood products. BD FACSLyric id BD's flagship IVD flow cytometer for immune monitoring and supports BD Multitest 4-Color and BD Multitest 6-Color TBNK assays for determining T-cell, B-cell, natural killer cell, CD4, and CD8 populations in patients with immune deficiency or immune dysfunction. BD has expanded the FACSLyric menu with additional standardized IVD assays and reagent panels, while the BD FACSDuet and BD FACSDuet Premium Sample Preparation System automate sample preparation, staining, washing, and acquisition workflows through integrated liquid-handling robotics and bidirectional connectivity via BD FACSLink middleware and laboratory information systems.

Immunoassay

BD offers its rapid near-patient infectious disease testing portfolio through the BD Veritor Plus System platform, a CLIA-waived digital immunoassay system for decentralized testing in physician offices, urgent care centers, pharmacies, and outpatient clinics. The BD Veritor System for SARS-CoV-2 is a rapid, digital, chromatographic lateral flow antigen test designed to detect COVID-19 antigens in symptomatic and selected asymptomatic individuals, delivering results in approximately 15 minutes. BD has broadened the Veritor respiratory menu to include combination assays such as BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B, which simultaneously detects COVID-19 and influenza A/B from a single specimen, and continued respiratory testing options for RSV, influenza A+B, and group A streptococcus. The platform uses digital optical reading to improve result interpretation and reduce subjective visual reading errors. BD also integrates the Veritor platform with simplified workflow features and connectivity options for result reporting, while maintaining its role as an important near-patient testing solution for respiratory infection screening during seasonal respiratory surges and routine outpatient infectious disease management.

bioMérieux Inc.

Marcy-l'Étoile, France

www.bioMérieux.com

Table 14-5: bioMérieux Revenue History, 2023-2025 (€ million)

	2023	2024	2025
Total	3,675	3,980	4,070

Source: company reports, Kalorama Information

bioMérieux is one of the world's leading microbiology and infectious disease diagnostics companies, with operations in more than 160 countries supported by over 45 subsidiaries and an extensive distributor network. Headquartered in Marcy-l'Étoile, the company is focused on clinical microbiology, molecular diagnostics, syndromic infectious disease testing, antimicrobial resistance management, and industrial microbiological control. In clinical diagnostics, bioMérieux provides integrated reagent, instrument, and software solutions used for infectious disease diagnosis, blood culture, sepsis management, antimicrobial susceptibility testing, syndromic molecular testing, selected cancer-related applications, and emergency biomarker testing.

In 2025/2026, bioMérieux reported annual sales above €4.1 billion, with continued growth driven primarily by microbiology and molecular infectious disease testing. Clinical applications continue to account for approximately 85% of total revenue, while industrial applications contribute about 15%, reflecting the company's strong concentration in clinical laboratory diagnostics. Microbiology remains the largest growth engine, supported by blood culture systems, identification and susceptibility testing, and syndromic molecular diagnostics.

BIOFIRE FilmArray is one of bioMérieux's strongest growth drivers, accounting for a major share of molecular diagnostics revenue. The BIOFIRE menu includes respiratory, gastrointestinal, meningitis/encephalitis, bloodstream infection, pneumonia, and antimicrobial resistance panels, with continued menu expansion and strong adoption in hospital laboratories. BIOFIRE SPOTFIRE has expanded rapidly and is now installed

broadly across hospitals, urgent care settings, and decentralized laboratories. SPOTFIRE availability has expanded beyond its initial 24-country rollout, with thousands of systems installed globally as bioMérieux continues to target faster near-patient molecular respiratory testing.

Traditional Microbiology

bioMérieux is a global leader in routine bacterial identification and antimicrobial susceptibility testing, with VITEK 2 continuing as one of the most widely installed ID/AST platforms in clinical microbiology laboratories. The VITEK 2 system identifies more than 300 clinically relevant microorganisms and delivers routine identification and susceptibility results in as little as 3 to 8 hours, depending on organism type and workflow. Its miniaturized reagent card technology offers broad antibiotic panels covering Gram-positive bacteria, Gram-negative bacteria, yeast, and selected resistant organisms. bioMérieux has strengthened this platform through software upgrades, expanded susceptibility algorithms, and integration with advanced laboratory informatics for antimicrobial stewardship.

For laboratories requiring faster and decentralized ID/AST workflows, VITEK Compact Pro is an important addition, designed for small- and medium-volume laboratories with simplified operation, faster turnaround, and connectivity to centralized microbiology data systems. bioMérieux also offers the VITEK REVEAL, which uses sensor-based detection of bacterial growth metabolites to deliver rapid phenotypic susceptibility results directly from positive blood cultures, supporting earlier antimicrobial decisions in sepsis management.

Sepsis is a major strategic area for bioMérieux, where the company combines blood culture, rapid identification, susceptibility testing, biomarkers, and syndromic molecular diagnostics. Its sepsis workflow centers on BacT/ALERT VIRTUO for blood culture detection, BIOFIRE molecular panels for bloodstream infection syndromic testing, VITEK MS MALDI-TOF for organism identification, and VITEK REVEAL for rapid AST. This integrated approach competes with offerings from Roche Diagnostics, T2 Biosystems, OpGen, Accelerate Diagnostics, and other emerging sepsis technology developers.

bioMérieux markets antimicrobial resistance testing through ETEST products, including strips for newer antibiotics such as ceftolozane/tazobactam and ceftazidime/avibactam, used for multidrug-resistant gram-negative organisms including Enterobacterales and Pseudomonas aeruginosa. The ETEST portfolio includes additional strips for newer beta-lactam/beta-lactamase inhibitor combinations and difficult-to-treat resistant pathogens.

For carbapenemase detection, RAPIDEC CARBA NP is an important manual confirmatory test, providing results in under two hours directly from agar culture isolates. bioMérieux also continues to market chromID CARBA, chromID ESBL, and expanded chromogenic media products for resistance surveillance and screening of carbapenemase-producing organisms, ESBL producers, MRSA, and VRE.

In addition, bioMérieux offers the VITEK MS PRIME, its newer MALDI-TOF microbial identification platform, which offers improved throughput, simplified maintenance, and enhanced workflow integration with VITEK ID/AST systems and microbiology informatics, further strengthening the company's position in fully connected microbiology laboratories.

Blood Culture

bioMérieux and BD are the major venders of blood culture systems. bioMérieux has been a major player in microbiology and has put together a comprehensive menu to tackle sepsis and hospital acquired infections, one of the most pressing problems in healthcare. The toolbox includes the BacT/ALERT VIRTUO blood culture platform, the procalcitonin immunoassay, and a toolbox of molecular testing tools including the BIOFIRE FILMARRAY Blood Culture Identification (BCID) assay test menu and the VITEK MS MALDI-TOF mass spec system, which performs automated identification testing within minutes. The goal is to aid in the rapid pathogen identification and appropriate antibiotic therapy.

bioMérieux offers the BacT/ALERT VIRTUO for blood culture detection. The company indicated that the system could fit into any-sized lab, even beyond the routine microbiology lab. Linked to the Myla software BacT/ALERT VIRTUO integrates the blood culture workflow to the lab information system. bioMérieux reports that the BACT/ALERT technology is in routine use by blood collection and transfusion facilities in over 25 countries worldwide and has a long-proven track record for testing platelets.

BACT/ALERT VIRTUO is a fully automated microbial detection system with motion-activated bottle loading and unloading. It offers proprietary algorithms, high thermal stability and sensitive optics, which enhance performance for more rapid time to detection if microbial contaminants are present.

bioMérieux provides the BacT/ALERT VIRTUO, a fully automated blood culture microbial system. According to bioMérieux it is a continuously monitoring blood culture microbial

detection system to offer "Load & Go" technology. Personnel of all skill levels can easily load bottles on the instrument at any time throughout the day or night, enabling prompt incubation and reducing hands-on time. Bottle unloading is fully automated with visual and audible alarms and alerts, helping laboratories to streamline their workflow.

bioMérieux also provides culture bottles BACT/ALERT BPA and BPN for quality control testing of leukocyte-reduced apheresis platelet units with the BACT/ALERT VIRTUO fully automated blood culture system. These bioMérieux quality control solutions can be used to extend platelet shelf life up to a total of seven days.

Immunoassays

bioMérieux markets the VIDAS family as one of the world's most established automated immunoassay platforms, including VIDAS 3, mini VIDAS, and legacy VIDAS systems. The installed base remains very large globally—estimated at well over 30,000 instruments—with strong use in hospitals, emergency laboratories, microbiology laboratories, and decentralized clinical settings. The VIDAS range uses ELFA (enzyme-linked fluorescent assay) technology and supports both random-access and batch testing through single-test ready-to-use reagent strips. The menu now includes well over 100 assays covering infectious disease serology, emergency biomarkers, endocrine testing, inflammatory markers, oncology markers, coagulation, and selected specialty assays.

The VIDAS portfolio is especially strong in acute care and infectious disease applications. VIDAS B.R.A.H.M.S PCT continues to be bioMérieux's flagship sepsis biomarker and is FDA-cleared for assisting antibiotic initiation and discontinuation decisions in lower respiratory tract infections and sepsis. It remains one of the few procalcitonin assays in the U.S. specifically cleared to support antibiotic stewardship and continues to be widely used in emergency departments, ICUs, and hospital antimicrobial stewardship programs. bioMérieux has also expanded emergency biomarker testing through VIDAS D-Dimer Exclusion II, which is widely used to help exclude deep vein thrombosis and pulmonary embolism when combined with clinical pre-test probability models, and through the continued growth of cardiac and inflammatory markers.

Following its acquisition of Banyan Biomarkers, bioMérieux expanded its traumatic brain injury diagnostics with VIDAS TBI, which measures GFAP and UCH-L1 in serum to aid assessment of mild traumatic brain injury and concussion. The assay is one of the few

commercially available blood-based TBI tests and continues to gain clinical attention in emergency medicine.

Kidney injury testing is another important specialty area offered by NEPHROCHECK, which measures the TIMP-2 and IGFBP7 biomarkers to identify kidney stress before overt acute kidney injury develops. The assay remains FDA-cleared and continues to appear in perioperative and critical care guidelines for cardiac surgery and ICU risk management.

The infectious disease VIDAS menu has expanded to include hepatitis serology assays for hepatitis A, B, C, and E, HIV testing, TORCH testing, and selected parasitology markers. Hepatitis E assays is important in regions where HEV testing demand is increasing. Additional newer VIDAS assays include expanded gastrointestinal markers, inflammatory markers such as VIDAS Calprotectin, and specialty assays supporting hospital acute care testing.

The company's routine chemistry-related immunoassays include VIDAS Vitamin B12 Total, which supports quantitative vitamin B12 assessment, along with ferritin, folate, thyroid, fertility, and hormone assays. bioMérieux continues to position VIDAS as a flexible mid-volume immunoassay platform where rapid single-test access remains valuable compared with large high-throughput analyzers.

Mass Spectrometry

bioMérieux expanded its MALDI-TOF microbial identification portfolio through VITEK MS PRIME, which has become the company's current flagship MALDI-TOF system for rapid organism identification in clinical microbiology laboratories. The platform provides rapid identification of bacteria, yeast, filamentous fungi, mycobacteria, and selected difficult-to-identify organisms within minutes, significantly accelerating organism identification compared with conventional biochemical methods. bioMérieux has continued to strengthen its mycobacteria and mold identification capabilities, including clinically important Mycobacterium tuberculosis complex, major non-tuberculous mycobacteria (NTM), Nocardia, and medically significant molds that are increasingly important in immunocompromised patient populations.

The current VITEK MS database includes tens of thousands of validated spectra derived from one of the world's largest private clinical strain collections and supports broad identification coverage for clinically relevant bacterial and fungal pathogens. The database continues to expand to improve differentiation of closely related organisms and emerging resistant pathogens. Database updates include identification of high-priority organisms such as Candida auris, Elizabethkingia anophelis, improved discrimination within the Acinetobacter baumannii complex, and continued support for highly pathogenic species, including Brucella, under controlled laboratory conditions.

bioMérieux has also expanded direct workflow integration between VITEK MS PRIME and its ID/AST platforms, allowing MALDI-TOF identification to connect directly with VITEK 2, VITEK Compact Pro, and VITEK REVEAL to accelerate antimicrobial decisions. Newer software enhancements improve database management, confidence scoring, and workflow standardization while supporting high-throughput microbiology laboratories.

In addition to organism identification, VITEK MS PRIME is an important component of bioMérieux's broader sepsis and antimicrobial resistance strategy, where rapid MALDI-TOF identification is increasingly combined with positive blood culture workflows, syndromic molecular testing, and rapid AST to shorten time to optimized therapy.

BIOFIRE Diagnostics Business

bioMérieux has significantly expanded the BIOFIRE FilmArray portfolio since acquiring BIOFIRE Diagnostics, transforming it into one of the broadest syndromic PCR menus in clinical diagnostics. The original FILMARRAY menu included respiratory, blood culture identification, gastrointestinal, and meningitis/encephalitis panels, but the current 2026 portfolio is substantially larger, featuring multiple updated generations and newer decentralized platforms. The current respiratory menu concentrates on BIOFIRE Respiratory Panel 2.1 and Respiratory Panel 2.1plus, which detect a broad set of respiratory viruses and bacteria, including SARS-CoV-2, influenza A/B, RSV, adenovirus, coronaviruses, and atypical bacteria, with results in about 45 minutes. These panels expanded earlier RP2 and RP2plus versions by incorporating COVID-19 testing and maintaining broad respiratory pathogen coverage. The earlier RP2plus addition of MERS-CoV remains relevant primarily in international markets.

For bloodstream infections, BIOFIRE FilmArray Blood Culture Identification 2 Panel has replaced the original BCID panel and detects a broader range of gram-positive bacteria, gram-negative bacteria, yeast, and key antimicrobial resistance genes directly from positive blood cultures, improving early sepsis management and antimicrobial stewardship. In lower respiratory infection testing, the BIOFIRE Pneumonia Panel and Pneumonia Panel plus are major products, detecting bacterial pathogens, respiratory viruses, and resistance markers directly from sputum, bronchoalveolar lavage, and endotracheal aspirates, while continuing to provide semi-quantitative bacterial results that help distinguish colonization from likely infection.

The gastrointestinal menu includes both the full BIOFIRE Gastrointestinal Panel and BIOFIRE Gastrointestinal Panel Mid, with the Mid version targeting a smaller set of common bacterial, viral, and parasitic pathogens for laboratories seeking narrower syndromic coverage. The meningitis/encephalitis panel is a major cerebrospinal fluid testing product that detects the principal bacterial, viral, and fungal pathogens associated with CNS infections.

Additions to the platform have expanded beyond traditional hospital syndromic testing. BIOFIRE SPOTFIRE is bioMérieux's faster decentralized multiplex PCR platform designed for urgent care, emergency departments, and near-patient settings. Current SPOTFIRE menus include respiratory panels, sore throat testing, and mini respiratory/sore throat panels that detect major viral and bacterial pathogens in approximately 15 minutes. Newer specialized assays also include the BIOFIRE Tropical Fever Panel, which detects pathogens associated with tropical febrile illnesses, including dengue, chikungunya, malaria species, leptospirosis, and related targets important in travel medicine and tropical disease diagnosis.

Additionally, FILMARRAY products include the Joint Infection Panel for prosthetic joint infections and expanded menu development in antimicrobial resistance and hospital-acquired infection testing. The FILMARRAY 2.0 and Torch systems remain the core installed platforms in hospital laboratories, while SPOTFIRE is driving newer decentralized growth.

Expansion

bioMérieux expanded its diagnostic portfolio through targeted acquisitions, strategic partnerships, and technology investments to strengthen acute care testing, molecular microbiology, and next-generation diagnostics. An earlier acquisition was Astute Medical, which brought the NEPHROCHECK platform into bioMérieux's acute care biomarker

portfolio. NEPHROCHECK measures TIMP-2 and IGFBP7 to assess kidney stress and predict acute kidney injury before overt renal damage develops. The acquisition expanded bioMérieux's critical care diagnostics business and complemented earlier commercialization of NEPHROCHECK on both the Astute140 Meter and adapted VIDAS workflows.

A major new move came in 2025 with the acquisition of SpinChip Diagnostics, adding a rapid immunoassay platform designed for POC testing. SpinChip's compact benchtop analyzer uses centrifugal microfluidics and high-sensitivity immunoassay technology to deliver laboratory-quality results in approximately 10 minutes. Initial menu priorities include high-sensitivity cardiac troponin I, NT-proBNP, and D-dimer, positioning bioMérieux to expand into rapid decentralized emergency diagnostics and acute cardiovascular testing.

bioMérieux also strengthened its sequencing and rapid pathogen characterization strategy through the 2025 acquisition of Day Zero Diagnostics. Day Zero developed technologies that combine direct-from-whole-blood sample preparation, genomic sequencing, and advanced bioinformatics to enable rapid pathogen identification and antimicrobial susceptibility prediction. This acquisition supports bioMérieux's longer-term strategy to integrate sequencing-based infectious-disease diagnostics into sepsis and antimicrobial-resistance workflows.

Additional strategic expansion includes continued integration of Banyan Biomarkers for traumatic brain injury diagnostics through VIDAS TBI, expansion of the BIOFIRE SPOTFIRE decentralized PCR platform, and continued investment in rapid microbiology solutions such as VITEK REVEAL and VITEK MS PRIME.

bioMérieux offers its BIOFIE SPOT FIRE for bioMérieux launched its BIOFIRE SPOTFIRE for pharmaceutical mycoplasma QC. Mycoplasma contamination in pharmaceutical production can compromise the quality of an entire batch, resulting in significant loss of product and time. The BIOFIRE SPOTFIRE Mycoplasma panel ensures continuity and helps manufacturers to improve operations.

Bio-Rad Laboratories, Inc.

Hercules, CA

www.bio-rad.com

Table 14-6: Bio-Rad Revenue History, 2023-2025 ($ million, estimated)

	2023	2024	2025
All Diagnostics	1,489	1,538	1,562

Source: company reports, Kalorama Information

Bio-Rad Laboratories reported 0.8% growth in full-year 2025 Clinical Diagnostics revenues, which reached $1,562 million, compared with $1,538 million in 2024. Growth was primarily driven by increased demand for quality control products, blood typing reagents, and diabetes testing products, partially offset by weaker sales of certain infectious disease assays.

Founded in 1952, Bio-Rad Laboratories, Inc. markets a broad range of products for the life science research and clinical diagnostics markets. The company offers more than 3,000 products covering over 300 clinical diagnostic tests that are used by hospital laboratories, reference laboratories, transfusion laboratories, and physician office laboratories worldwide.

Bio-Rad's clinical diagnostics business offers a number of specialized diagnostic niches, including infectious disease immunoassays, diabetes HbA1c testing, autoimmune immunoassays, neonatal screening, allergy testing, blood typing, microbiology media, pathogen identification assays, quality control products for clinical laboratories.

Bio-Rad acquired Curiosity Diagnostics, a developer of rapid PCR molecular testing systems. Curiosity's PCR|ONE platform is designed to perform rapid multiplex PCR detection of infectious diseases directly at the point of care.

Bio-Rad expanded its presence in oncology research through a licensing and product development agreement with NuProbe, a genomics and molecular diagnostics company focused on high-sensitivity mutation-detection technologies for liquid biopsy and precision oncology applications.

In February 2025, Bio-Rad announced a binding offer to acquire Stilla Technologies, a developer of digital PCR instruments and assays. The acquisition was completed in June 2025. Stilla's Nio digital PCR system is integrated into Bio-Rad's portfolio and rebranded as part of the QX700 series, expanding the company's droplet digital PCR platform capabilities. The addition strengthens Bio-Rad's position in high-sensitivity molecular analysis for oncology, infectious disease testing, genetic research, and cell- and gene-therapy applications.

Bio-Rad continues to expand its digital PCR and molecular diagnostics portfolio, which has become an important growth area for the company. The integration of Stilla's technology complements Bio-Rad's established QX200 and QX600 droplet digital PCR systems, enabling higher multiplexing capability and improved sensitivity for research and clinical applications.

Quality Control

Bio-Rad is a global leader in quality control (QC) products for clinical laboratories, offering one of the broadest QC portfolios in the diagnostics industry. Its controls cover analytes used in immunoassay, therapeutic drug monitoring (TDM), clinical chemistry, cardiac assessment, immunology, diabetes, coagulation, hematology, blood gas analysis, drugs-of-abuse testing, molecular diagnostics, and infectious disease testing. The company's External Quality Assurance Services (EQAS) programs enable laboratories to independently assess their performance by comparing their results with those of peer laboratories that use similar methodologies, instruments, and reagents. These programs include specimen packs, statistical reports, and peer comparison tools that support regulatory compliance and laboratory accreditation.

Bio-Rad's laboratory informatics and QC connectivity platform uses its Unity Quality Control and Unity Interlaboratory Programs, which connect laboratories globally and allow real-time comparison of QC data across large peer groups. The network includes more than 25,000 laboratories worldwide, helping laboratories identify shifts, trends, and instrument performance issues across multiple assay platforms.

In molecular diagnostics quality control, Bio-Rad has expanded its Amplichek product family to include Amplichek STI Control, a multi-analyte molecular quality control designed to monitor nucleic acid testing workflows for sexually transmitted infections. The control provides detection processes for Chlamydia trachomatis, Neisseria gonorrhoeae, and high-

risk HPV targets, covering both extraction and amplification steps in molecular workflows. Bio-Rad has expanded its molecular QC product line to include multiplex PCR systems for infectious disease testing, oncology, and transplant diagnostics.

Bio-Rad also has a strong oncology quality control portfolio, including products such as Liquichek Tumor Marker Control, which offers expanded analyte coverage for immunoassay-based tumor marker testing. Key analytes include HE4, HER-2/neu, low-concentration PSA, ferritin, and multiple cancer antigen markers, supporting performance verification across major automated immunoassay platforms. Expanded compatibility with high-throughput analyzers, including multiple Abbott Laboratories Alinity platforms, has strengthened Bio-Rad's role in third-party QC across large core laboratories.

Bio-Rad has continued to expand assay coverage across major instrument platforms, including additional QC assignments for Abbott Laboratories Alinity ci-series, Roche cobas systems, and Siemens Healthineers immunoassay and chemistry analyzers, reflecting ongoing demand for independent controls as laboratories consolidate onto larger automated systems.

For urinalysis testing, Bio-Rad offers qUAntify Advance Control, an independent QC product designed for routine monitoring. The control uses a human urine matrix and provides extended open-vial stability, supporting consistency in analytes such as glucose, protein, ketones, and other routine urine chemistry parameters used in clinical laboratories.

In molecular instrumentation, Bio-Rad markets the CFX Opus 96 Dx System and CFX Opus 384 Dx System, which are real-time PCR detection systems designed for high-performance amplification and quantification. These systems provide multiplex testing of up to five targets and are used for assay development, laboratory-developed tests, and regulated molecular workflows. Bio-Rad has increasingly positioned these systems alongside its digital PCR portfolio, including the expanding QX series and newly integrated QX700 platform, following the 2025 acquisition of Stilla Technologies, strengthening its position in high-sensitivity molecular quantification for oncology, infectious disease, and cell and gene therapy applications.

Blood Bank

Bio-Rad offers a broad transfusion diagnostics portfolio that includes automated and semi-automated platforms, gel reagents, software, and connectivity solutions for blood grouping,

phenotyping, crossmatching, antibody screening and identification, direct antiglobulin testing (DAT), and single-antigen typing. The company's blood banking portfolio remains centered on its IH-System gel card technology, which supports both automated and manual workflows used in hospital transfusion laboratories, blood centers, and reference laboratories.

Bio-Rad's automated blood bank systems include the IH-500 and IH-1000, along with connectivity solutions that enable laboratories to standardize blood typing workflows across varying testing volumes. The IH-500 is designed for small- to medium-volume laboratories and performs automated ABO/Rh grouping, reverse typing, phenotyping, antibody screening, antibody identification, DAT, crossmatching, and single-antigen testing using Bio-Rad's full range of gel cards. The system minimizes manual handling while supporting continuous loading and flexible test management.

The IH-1000 is Bio-Rad's higher-throughput automated blood typing platform for larger transfusion laboratories. It supports full automation of immunohematology workflows and integrates with the company's IH-Com patient data management software, which consolidates current and historical patient results, performs interpretation crosschecks, and supports secure transmission of results to laboratory information systems (LIS). IH-Com also enables instrument networking across multiple laboratory sites, improving traceability and standardization within hospital systems and blood networks.

Bio-Rad continues to enhance digital workflow integration through IH-Web remote results management, allowing authorized users to review and validate blood bank results remotely across connected instruments. These connectivity tools support increasing laboratory demand for centralized oversight, data traceability, and compliance with transfusion safety requirements.

For manual and semi-automated workflows, Bio-Rad markets the IH-Reader 24, a semi-automated centrifuge and reader designed for small- and medium-volume laboratories. The system automatically reads gel cards, standardizes interpretation of agglutination reactions, and transfers results directly into IH-Com software, reducing operator subjectivity and improving consistency in transfusion medicine testing.

Bio-Rad also offers the IH-Incubator L and IH-Centrifuge L, which support manual gel card testing using the full IH-System reagent menu. These instruments remain widely used in

laboratories that require flexible manual processing while maintaining compatibility with Bio-Rad's automated blood bank systems.

Blood typing is one of Bio-Rad's strongest growth areas in clinical diagnostics. In 2025, the company reported ongoing demand for transfusion diagnostics products, particularly in Europe, Latin America, and selected Asia Pacific markets, where gel-based immunohematology systems continue to maintain strong installed bases.

Bio-Rad has continued expanding reagent availability for extended phenotype testing and antibody investigation, while strengthening compatibility across its installed blood bank platform base. The company's transfusion diagnostics strategy remains focused on workflow standardization, data connectivity, and incremental automation to support laboratory efficiency and transfusion safety.

Diabetes

Bio-Rad has more than 40 years of experience in diabetes testing and is one of the longstanding leaders in high-performance liquid chromatography-based HbA1c testing for clinical laboratories. The company established an early market position through benchtop HPLC systems used for both glycated hemoglobin measurement and hemoglobin variant detection, and it continues to maintain a strong installed base in hospital and reference laboratories worldwide.

The company's principal HbA1c platform is the D-100 Hemoglobin Testing System, a high-throughput HPLC analyzer designed for laboratories requiring standardized HbA1c testing for diabetes diagnosis and long-term glucose monitoring. The D-100 incorporates Smart HPLC technology, automated calibration management, onboard quality monitoring, and Bio-Rad's integrated Advisor software, which automatically reviews chromatograms, flags abnormal patterns, and helps laboratories identify potential hemoglobin variants that may affect HbA1c interpretation. The system is widely used because it combines high analytical precision, reduced operator intervention, and strong alignment with international HbA1c standardization programs.

Bio-Rad also continues to market the D-10 Hemoglobin Testing System, which remains widely used in moderate-volume laboratories. The D-10 Hemoglobin A1c Program supports HbA1c measurement as an aid in both diagnosing diabetes and identifying individuals at increased risk of developing diabetes (prediabetes). The system provides laboratories with

automated HPLC-based analysis while maintaining compatibility with established diabetes diagnostic guidelines.

A major strength of Bio-Rad's diabetes portfolio is its ability to deliver high analytical specificity in patient populations with hemoglobin variants, an important advantage over some immunoassay-based HbA1c methods. This has helped sustain Bio-Rad's position in laboratories serving diverse patient populations where variant hemoglobins may affect test accuracy.

Bio-Rad supports diabetes laboratories through its strong quality-control portfolio, including HbA1c controls, calibrators, and external quality-assurance programs that are widely used across both HPLC and immunoassay testing platforms.

Although the global HbA1c market increasingly includes large, chemistry-based systems from Abbott Laboratories, Roche, and Siemens Healthineers, Bio-Rad maintains a differentiated position through specialized HPLC performance, variant-detection capability, and laboratory-standardization expertise.

Immunoassays

Bio-Rad's Bio-Plex assay portfolio is built around multiplex immunoassay technology derived from Luminex Corporation xMAP bead-based multiplex detection, allowing simultaneous measurement of multiple analytes in a single sample. In research applications, Bio-Rad continues to offer a broad menu of Bio-Plex multiplex assays for cytokines, chemokines, growth factors, cancer biomarkers, diabetes markers, and inflammatory mediators across multiple species. These assays remain widely used in translational research, immunology, oncology, and biomarker discovery.

For clinical diagnostics, Bio-Rad's principal multiplex immunoassay platform remains the BioPlex 2200 System, which is designed for automated high-throughput serology and autoimmune testing. The platform enables laboratories to perform multiplex or multiple individual immunoassays that would traditionally require separate analyzers, improving workflow efficiency while maintaining broad assay menus for infectious disease and autoimmune testing.

Bio-Rad markets the BioPlex 2200 Syphilis Total & RPR assay, which is one of the few fully automated dual syphilis testing solutions that combine treponemal and non-treponemal

testing in a single assay. The test simultaneously detects antibodies to Treponema pallidum, measures reagin antibodies, and determines the RPR titer, supporting both diagnosis and treatment monitoring in a single automated workflow. This dual approach remains attractive to laboratories seeking to reduce the number of manual reflex testing steps.

The company also offers the BioPlex 2200 ToRC IgM and IgG assays, multiplex prenatal screening panels for Toxoplasma gondii, rubella, and cytomegalovirus (CMV). These assays provide comprehensive serologic profiling for first-trimester prenatal screening and remain important in laboratories that perform maternal infectious disease testing.

Bio-Rad's BioPlex 2200 Lyme Total Assay is designed to detect multiple antibody targets associated with Lyme disease in a multiplex format. The assay supports automated first-line serologic screening and is positioned to improve consistency compared with traditional multi-step Lyme testing workflows.

In autoimmune diagnostics, the BioPlex 2200 platform supports multiplex autoimmune testing through assays for ANA screening, anti-dsDNA, and multiple extractable nuclear antigens (ENA). Multiplex autoimmune testing remains one of Bio-Rad's most differentiated immunoassay strengths, particularly in medium- and high-volume specialty laboratories.

Although Bio-Rad maintains the BioPlex 2200 installed base, growth in immunoassays has become more selective as many high-volume infectious disease laboratories increasingly migrate toward larger chemiluminescent systems from Abbott Laboratories, Roche, and Siemens Healthineers. Bio-Rad's competitive advantage remains strongest in specialized multiplex serology, autoimmune diagnostics, and niche infectious disease assays where multiplex efficiency and broad analyte coverage continue to offer workflow advantages.

Liquid Biopsy

Bio-Rad strengthens its position in digital PCR through its droplet digital PCR (ddPCR) portfolio, which is widely used for highly sensitive nucleic acid quantification in oncology, infectious disease, transplant monitoring, and genetic analysis. The company offers a ddPCR assay for the detection of BCR::ABL1 gene fusion transcripts, used to monitor treatment response in patients with chronic myeloid leukemia. This assay was Bio-Rad's first clinical ddPCR assay to receive CE marking and remains an important application for measuring very low levels of residual disease with greater sensitivity than many conventional molecular methods.

Bio-Rad's digital PCR business has expanded significantly with its QX200, QX600, and newer QX700 series platforms. The addition of higher multiplexing capability broadens Bio-Rad's ability to support oncology mutation detection, rare variant analysis, liquid biopsy research, measurable residual disease monitoring, and advanced molecular testing applications. The company increasingly positions ddPCR as a complementary technology to next-generation sequencing by providing precise absolute quantification and high sensitivity for targeted assays.

Bio-Rad also developed the Genesis Cell Isolation System and Celselect Slides for circulating tumor cell (CTC) enrichment and analysis in liquid biopsy workflows. Celselect Slides were designed to improve the enumeration and downstream characterization of circulating tumor cells for genomic analysis, digital PCR, and immunofluorescence staining. While these products remain part of Bio-Rad's broader oncology technology portfolio, the company's recent commercial emphasis has shifted more strongly toward digital PCR and molecular quantification, where demand continues to expand across both research and emerging clinical applications.

Droplet Digital PCR

Bio-Rad introduced droplet digital PCR in 2012, establishing one of the first commercially successful platforms for absolute nucleic acid quantification by partitioning samples into thousands of nanoliter-sized droplets. This partitioning approach allows each droplet to function as an individual PCR reaction, significantly improving sensitivity, precision, and reproducibility compared with conventional quantitative PCR, particularly when detecting very low-abundance targets.

Since its introduction, ddPCR has become widely adopted in oncology research, especially for liquid biopsy, rare mutation detection, measurable residual disease monitoring, copy number variation analysis, and low-frequency allele detection, where conventional PCR methods may lack sufficient analytical sensitivity. Bio-Rad's ddPCR technology is widely used in translational cancer research, infectious disease studies, cell and gene therapy development, and advanced molecular assay validation.

Bio-Rad strengthened its digital PCR capabilities through the acquisition of RainDance Technologies. RainDance Technologies droplet-based systems expanded Bio-Rad's intellectual property and technical reach in ultra-sensitive molecular analysis. RainDance contributed technologies such as RainDrop Digital PCR and targeted enrichment systems

designed for rare mutation analysis, inherited disease studies, and oncology applications. Although the RainDance brand has largely been integrated into Bio-Rad's broader digital PCR strategy, the acquisition helped accelerate Bio-Rad's expansion in highly sensitive liquid biopsy workflows and rare variant detection.

Bio-Rad advanced digital PCR into regulated clinical diagnostics through the QXDx AutoDG ddPCR System and the QXDx BCR-ABL %IS Kit, which became the first digital PCR system and assay combination to receive FDA clearance for clinical diagnostic use. The system is used to monitor molecular response in patients with Chronic Myeloid Leukemia chronic myeloid leukemia by quantifying BCR:ABL1 transcript levels with very high precision. The assay monitors residual disease during tyrosine kinase inhibitor therapy and helps guide long-term treatment management.

The QXDx AutoDG system also provides laboratories seeking flexibility between FDA-cleared assays and laboratory-developed molecular applications. Automated droplet generation improves workflow standardization and reduces hands-on variability, which has increased adoption in clinical molecular laboratories.

Bio-Rad has expanded its multiplex capabilities through the QX600 Droplet Digital PCR System, which enables the detection of multiple targets within a single reaction and is widely used for oncology biomarker research, gene expression analysis, orthogonal validation of next-generation sequencing results, and mutation profiling. The company has further advanced its digital PCR portfolio with the introduction of the QX700 series, which incorporates enhanced multiplexing and workflow improvements. This newer platform strengthens Bio-Rad's position in high-precision molecular quantification across oncology, infectious disease, and emerging applications such as cell and gene therapy

Bio-Rad entered into a partnership with Gencurix as the exclusive distributor of Gencurix' Droplex digital PCR oncology testing kits throughout Europe. The partnership builds on the companies' existing relationship and will provide physicians with enhanced biomarker testing.

Sequencing

Bio-Rad and Illumina previously collaborated to introduce the Illumina Bio-Rad Single-Cell Sequencing Solution, one of the early integrated next-generation sequencing workflows designed for single-cell transcriptomic analysis. The workflow combined Bio-Rad's droplet-

partitioning technology with Illumina sequencing platforms, enabling researchers to study gene expression at the single-cell level and supporting investigations into tissue heterogeneity, disease progression, immune response, and therapeutic mechanisms.

The original solution used Bio-Rad's ddSEQ Single-Cell Isolator together with the SureCell WTA 3' Library Prep Kit, allowing individual cells to be isolated, barcoded, and prepared for downstream sequencing. Bio-Rad's droplet technology generated microdroplet partitions containing single cells and molecular barcodes, enabling transcript capture before sequencing on Illumina instruments. Data analysis was performed in Illumina's BaseSpace environment, with downstream visualization supported by SeqGeq software developed by FlowJo.

Although this collaboration helped establish early commercial single-cell sequencing workflows, the market has since evolved rapidly, with broader adoption of higher-throughput single-cell platforms led by specialized providers such as 10x Genomics. Bio-Rad's more recent strategic emphasis has shifted toward digital PCR, molecular quantification, and advanced genomics tools rather than expanding the ddSEQ platform aggressively.

The collaboration is significant because it demonstrated Bio-Rad's ability to extend droplet-partitioning expertise beyond digital PCR into genomics workflows. Many of the underlying droplet handling principles developed through these single-cell efforts continue to complement Bio-Rad's broader molecular technologies

Bruker Corporation

Billerica, MA

www.bruker.com

Table 14-7: Bruker Revenue History Product Revenue, 2023-2025 ($ million)

	2023	2024	2025
BSI CALID Group	960	1,094	1,210
Total Revenues	**2,964**	**3,364**	**3,437**

Source: company reports, Kalorama Information

In 2025, Bruker Corporation reported total revenues of approximately $3.4 billion, representing modest growth over 2024. Within the company's diagnostics-related business, the CALID Group (Cell Biology, Automation, Life Science and In Vitro Diagnostics) remained one of the stronger growth contributors, supported by continued expansion in microbiology and infectious disease diagnostics. Growth was driven primarily by strong global demand for MALDI Biotyper systems, increased molecular diagnostics sales from ELITechGroup, and expanding installed-base utilization in clinical microbiology laboratories.

Bruker's microbiology and diagnostics portfolio is concentrated within the CALID segment and includes activities from ELITechGroup ELITechGroup, Bruker Daltonics Bruker Daltonics, and selected optical and molecular technologies from Bruker Optics Bruker Optics. These businesses collectively support mass spectrometry-based microbiology, molecular infectious disease testing, sample-preparation systems, and specialty diagnostic instrumentation.

The strongest growth in clinical diagnostics continues to come from the MALDI Biotyper platform, which remains one of the leading mass spectrometry systems for rapid microbial identification in clinical microbiology laboratories. Bruker has continued to expand its assay menu and workflow capabilities in MALDI-based diagnostics, including applications for blood culture identification, antimicrobial resistance detection, and direct specimen analysis.

A major growth area for Bruker is the Sepsityper workflow, which enables rapid identification of pathogens directly from positive blood cultures. The product has achieved strong adoption in Europe and other international markets because it shortens time to organism identification in bloodstream infections and supports earlier antimicrobial decision-making. Bruker continues to pursue broader regulatory expansion of Sepsityper-based workflows and additional blood culture applications.

Bruker is also advancing the integration of susceptibility testing through new MALDI-based antimicrobial resistance solutions, aiming to expand beyond organism identification to more comprehensive microbiology workflows. This strategy supports the company's long-term goal of increasing recurring consumables revenue, since instrument sales still account for the majority of total microbiology revenues while assay and reagent pull-through remain growth priorities.

In molecular diagnostics, ELITechGroup offers syndromic infectious disease testing, sample-preparation systems, and transplant-related molecular assays. Bruker has continued to integrate ELITech molecular technologies into its broader microbiology strategy to strengthen infectious disease diagnostics across hospital and specialty laboratories.

Geographically, Bruker generates balanced revenue across major regions, with Europe remaining particularly strong in microbiology adoption, while the United States and Asia Pacific continue to expand through growing MALDI installed bases and rising demand for molecular testing.

Bruker Daltonics is the company's central mass spectrometry division and continues to supply a broad range of analytical systems including MALDI-TOF, MALDI-TOF/TOF, LC-MS, FTMS, and QTOF systems used across pharmaceutical research, clinical microbiology, proteomics, and applied markets. In clinical diagnostics, Bruker's strongest competitive advantage remains its early and sustained leadership in MALDI mass spectrometry for microbial identification, where it continues to compete primarily with bioMérieux.

More recently, Bruker has also expanded development in tuberculosis testing, fungal identification, and resistance marker detection, reflecting growing demand for faster microbiology workflows and improved antimicrobial stewardship support in hospital laboratories.

Acquisitions and Collaborations

Bruker uses acquisitions as a key strategy to expand its capabilities in clinical diagnostics, microbiology, molecular testing, and laboratory informatics. Over the past several years, the company has increasingly targeted businesses that strengthen assay development, consumables manufacturing, molecular diagnostics, antimicrobial resistance testing, and software integration, supporting its broader goal of building a more complete clinical diagnostics platform beyond core instrument sales.

Bruker acquired InVivo Biotech Services in Germany to add expertise in consumables development and manufacturing, particularly in monoclonal antibodies, recombinant proteins, and immunoassay component production. This acquisition strengthened Bruker's internal capacity for assay development and supports continued expansion of consumables for the MALDI Biotyper platform as well as future infectious disease assay development, including molecular and syndromic testing products.

The acquisition of MERLIN Diagnostika added specialized expertise in antimicrobial susceptibility testing (AST) and antibiotic resistance testing (ART). MERLIN's MICRONAUT platform remains important in Bruker's effort to expand beyond microbial identification into susceptibility testing. MICRONAUT supports phenotypic detection of microbial growth inhibition across major resistance phenotypes, including MRSA, VRE, ESBL, carbapenemases, and antifungal susceptibility testing, while software integration with MALDI Biotyper supports broader microbiology workflow development.

A major diagnostics expansion came through the acquisition of Hain Lifescience Hain Lifescience, which formed the basis for Bruker-Hain Diagnostics. This acquisition added a well-established molecular assay menu, including GenoType assays for tuberculosis, antimicrobial resistance, sexually transmitted infections, and HIV. Hain's tuberculosis molecular assays remain strategically important because they complement Bruker's microbiology portfolio and strengthen its presence in high-burden infectious disease testing markets.

Bruker acquired Arxspan Arxspan, a provider of cloud-based scientific software for chemistry, pharmaceutical, and analytical laboratory workflows. This reflects Bruker's broader effort to strengthen informatics and digital laboratory integration across its analytical and diagnostic businesses.

The company acquired PreOmics, IonSense, and other specialty businesses supporting proteomics and mass spectrometry workflows. These additions strengthen Bruker's CALID segment by improving automation and sample preparation for high-performance analytical workflows.

Bruker completed the acquisition of ELITechGroup, which significantly expanded its molecular diagnostics portfolio. ELITech adds sample-preparation systems, specialty PCR assays, transplant testing, and infectious-disease molecular solutions that complement Bruker's MALDI-based microbial-identification systems.

Bruker acquired NanoString Technologies, adding the nCounter, GeoMx, CosMx, and AtoMx product lines. This acquisition expands Bruker's position in spatial biology, transcriptomics, and advanced biomarker analysis, areas increasingly relevant to translational medicine and oncology research.

In June 2025, Bruker acquired Biocrates Life Sciences, a mass spectrometry-based metabolomics company that provides standardized kits covering more than 1,000 metabolites across over 40 metabolite classes. This acquisition strengthens Bruker's metabolomics capabilities and supports growing interest in biomarker discovery, precision medicine, and clinical translational research.

Bruker has increasingly aligned these acquisitions around a long-term strategy that combines microbiology, molecular diagnostics, metabolomics, spatial biology, and laboratory informatics, positioning the company to expand recurring revenue from assays, software, and consumables alongside its established instrument business.

Mass Spectrometry

Bruker offers the DART-EVOQ triple quadrupole mass spectrometer for high-throughput quantitative analyses at the POC. Bruker sells the timsTOF Ultra Mass Spectrometer with transformative Sensitivity. It incorporates a new Captive Spray Ionization Ultra ion source.

Additionally, Bruker offers the EVOQ DART-TQ+ system for chromatography-free triple quadrupole mass spectrometry for POC analysis.

The company markets the MALDI-TOF/TOF system-neoflex Imaging Profiler for mass spectrometry-based tissue imaging. It comes with a proprietary smartbeam 3D laser and fits on a bench top.

Additionally, Bruker markets its Omni Mass Spectrometer system – timsTOF-based mass spectrometer.

Microbiology

Antimicrobial identification and susceptibility testing (ID/AST) in clinical microbiology continues to rely heavily on established automated phenotypic systems such as the Becton Dickinson BD Phoenix platform and bioMérieux VITEK systems, but mass spectrometry has now become a firmly established component of routine microbial identification in major laboratories worldwide. Over the past decade, matrix-assisted laser desorption ionization time-of-flight (MALDI-TOF) mass spectrometry has moved from early adoption into broad routine use because of its speed, lower cost per test, and high species-level identification performance. MALDI-TOF works by generating characteristic protein spectral fingerprints that act as unique signatures for microorganisms. These spectral patterns are matched against curated reference libraries to identify bacteria, yeasts, fungi, and selected mycobacteria within minutes, allowing organism identification often in less than an hour once microbial growth is available.

Bruker Corporation pioneered MALDI-TOF adoption in clinical microbiology through the MALDI Biotyper MALDI Biotyper, which remains one of the leading microbial identification systems globally. The platform identifies bacteria, yeasts, fungi, and mycobacteria by matching protein fingerprints from cultured colonies against Bruker's continuously expanding microbial reference database, which now includes thousands of clinically relevant bacterial and fungal species, including expanded coverage for rare organisms, filamentous fungi, and non-tuberculous mycobacteria. Bruker has continued expanding the MALDI Biotyper family through newer systems including the MALDI Biotyper sirius MALDI Biotyper sirius and the compact MALDI Biotyper sirius one MALDI Biotyper sirius one, which broaden access to MALDI identification across both large and smaller microbiology laboratories.

Rapid bloodstream infection testing is a major Bruker growth area through the Sepsityper Sepsityper workflow, which enables direct identification of pathogens from positive blood cultures without overnight subculture, significantly shortening time to organism identification in sepsis management. Bruker has further expanded this workflow with functional resistance assays, such as MBT STAR-Carba for carbapenem resistance detection and MBT STAR-Cepha for third-generation cephalosporin resistance testing, enabling laboratories to obtain early antimicrobial resistance information alongside organism identification.

Molecular PCR

In addition to its mass spectrometry portfolio, Bruker Corporation has continued expanding its clinical molecular diagnostics business through PCR-based assay systems largely built on technologies obtained through the acquisition of Hain Lifescience. That acquisition established Bruker-Hain Diagnostics within the company's microbiology and diagnostics operations and added a strong menu of molecular infectious disease assays focused on tuberculosis, antimicrobial resistance, mycobacteria, and selected viral infections.

The company offers the FluoroCycler XT, a high-performance PCR thermal cycler and reader designed for Bruker's LiquidArray molecular assay family. The system is designed for mid-plex molecular testing with high analytical sensitivity and relatively rapid turnaround times, allowing laboratories to perform direct molecular detection from patient samples without prolonged culture steps in selected applications.

Bruker's FluoroType MTBDR assay family is one of its most important molecular offerings for tuberculosis testing. The FluoroType MTBDR 2.0 assay is designed for rapid detection of Mycobacterium tuberculosis and major drug-resistance mutations directly from patient samples, reducing time to resistance profiling compared with conventional culture-based workflows. The assay detects multiple mutations associated with resistance to rifampicin and isoniazid and remains particularly important in regions with high tuberculosis burden and multidrug-resistant TB prevalence.

The company has also expanded its mycobacteria testing menu through the FluoroType Mycobacteria assay, which differentiates a broad range of clinically relevant non-tuberculous mycobacteria species. This addresses growing clinical demand for faster identification of non-tuberculous mycobacterial infections, especially in immunocompromised patients and chronic pulmonary disease cases.

Bruker offers multiplex infectious disease assays based on its LiquidArray technology, including the LiquidArray Gastrointestinal panel, which enables simultaneous detection of multiple bacterial, viral, and parasitic pathogens associated with gastrointestinal infections. The syndromic panel is designed to improve laboratory efficiency by consolidating multiple targets into a single workflow.

Additional molecular development has focused on invasive fungal disease testing and selected transplant-related infectious disease assays, where Bruker aims to build differentiated specialty menus rather than compete directly in broad high-volume syndromic PCR markets dominated by larger molecular diagnostics companies.

Bruker's molecular diagnostics complement its MALDI microbiology franchise by combining rapid organism identification, resistance characterization, and targeted molecular confirmation within specialized microbiology workflows.

Cepheid / Danaher

Sunnyvale, CA

www.cepheid.com

Cepheid is one of the leading molecular diagnostics companies, focused on highly automated cartridge-based PCR systems designed for use across decentralized point-of-care settings, hospital laboratories, and high-volume reference centers. As part of Danaher Corporation, Cepheid continues to expand the global installed base of its GeneXpert systems, with tens of thousands of instruments deployed across more than 180 countries. The platform is widely used in both low-resource healthcare settings and advanced clinical laboratories because it combines automated sample preparation, nucleic acid extraction, amplification, and detection in a fully enclosed cartridge, minimizing contamination risk and simplifying molecular testing workflows.

The GeneXpert System is Cepheid's core platform and features one of the broadest decentralized molecular menus in diagnostics, spanning tuberculosis, respiratory infections, sexually transmitted infections, antimicrobial resistance, blood virology, hospital-acquired infections, and oncology. The menu offers more assays available globally than in the U.S., including products for HIV viral load, hepatitis B and C monitoring, tuberculosis resistance testing, women's health, and leukemia monitoring. The platform's ability to deliver results directly from minimally processed specimens differentiates it from conventional PCR systems that require more manual laboratory steps.

Cepheid's Xpert HCV Viral Load Fingerstick is one of its most important decentralized hepatitis products. The assay quantifies hepatitis C virus RNA directly from capillary whole blood obtained by finger stick and produces results in about one hour, allowing diagnosis and treatment decisions during a single clinic visit. The test reduces dependence on centralized laboratory infrastructure and improves access in outreach clinics, addiction treatment programs, and underserved settings. Its broad genotype coverage supports use across multiple geographic regions where genotype diversity remains clinically important.

In 2025 and continuing into 2026, Cepheid also advanced strategic collaboration with Oxford Nanopore Technologies to develop integrated sequencing-based workflows that combine Cepheid's cartridge-based automated sample preparation with nanopore sequencing

technology. This collaboration is designed to extend Cepheid's reach beyond rapid PCR into future sequencing-enabled clinical applications, including infectious disease characterization and genomic analysis.

New product offerings include expanded use of Xpert HBV Viral Load, broader deployment of Xpert HIV-1 Viral Load XC, continued adoption of Xpert MTB/XDR for extended tuberculosis drug resistance detection, and growth in rapid syndromic respiratory panels that combine COVID-19, influenza, and RSV detection. Cepheid's strategy remains centered on delivering laboratory-quality molecular results closer to the patient while expanding into higher-complexity molecular applications beyond traditional PCR.

GeneXpert/ Xpress Line

Cepheid markets its rapid near-patient molecular testing menu through the GeneXpert Xpress family, available in single-, two-, and four-module configurations for decentralized laboratories, urgent care centers, physician offices, and hospital near-patient settings. The GeneXpert Xpress II and GeneXpert Xpress IV platforms are FDA-cleared and CLIA-waived multi-module systems, allowing multiple rapid PCR tests to be run simultaneously while maintaining the same cartridge-based workflow used across the broader GeneXpert portfolio. The Xpress systems provide faster turnaround by using optimized cartridge chemistry that shortens amplification time compared with standard GeneXpert assays.

Within respiratory diagnostics, Xpert Xpress Flu, Xpert Xpress Flu/RSV, and Xpert Xpress SARS-CoV-2/Flu/RSV combinations remain core products in Cepheid's near-patient menu. Xpert Xpress Flu/RSV detects influenza A, influenza B, and RSV using multiple molecular targets to improve strain coverage and maintain sensitivity as circulating viruses evolve, with results typically available in about 20 to 30 minutes. Cepheid has also continued to emphasize broader use of multiplex respiratory assays that combine COVID-19, influenza, and RSV detection in a single cartridge to support emergency department and outpatient respiratory triage during seasonal surges.

For streptococcal testing, Xpert Xpress Strep A is a CLIA-waived molecular assay that detects Streptococcus pyogenes directly from throat swabs in as little as 18 minutes. The test is valuable because negative molecular results generally eliminate the need for reflex culture in many clinical settings, allowing faster treatment decisions for suspected Group A streptococcal infections.

Cepheid offers additions to its women's health portfolio. Its multiplex vaginal PCR panel provides simultaneous molecular detection of organisms associated with bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis, supporting syndromic diagnosis from a single specimen. This panel improves diagnostic accuracy compared with microscopy and conventional microbiology while reducing time to treatment.

In virology, Xpert Xpress CoV-2 plus offers an additional conserved genetic target to improve SARS-CoV-2 detection as variants continue to emerge. Cepheid has also maintained broader global placement of its COVID assays alongside multiplex respiratory panels that provide continued hospital and outpatient respiratory testing.

For hematologic oncology, Xpert NPM1 Mutation enables measurable residual disease monitoring in acute myeloid leukemia by rapidly quantifying mutant NPM1 mRNA transcripts directly from peripheral blood or bone marrow specimens. In infectious disease monitoring, Xpert HIV-1 Viral Load XC is an important next-generation assay for viral load measurement, designed to provide broader subtype coverage and improved performance across diverse HIV strains while supporting decentralized viral load testing in both developed and resource-limited settings.

Newer menu expansion in 2026 also includes broader global adoption of Cepheid's rapid antimicrobial resistance assays, expanded hepatitis testing, and continued rollout of syndromic molecular panels, strengthening the company's position in decentralized PCR testing across respiratory disease, sexual health, oncology, and chronic infectious disease monitoring.

Tuberculosis

Cepheid plays a major role in rapid molecular diagnosis of tuberculosis through its Xpert MTB/RIF and Xpert MTB/RIF Ultra assays on the GeneXpert platform. Xpert MTB/RIF is one of the most widely adopted rapid molecular tuberculosis tests globally because it simultaneously detects Mycobacterium tuberculosis complex DNA and rpoB mutations associated with rifampin resistance, directly from clinical specimens. The assay produces results in approximately two hours and has become a standard frontline molecular tool in many national tuberculosis control programs because it significantly shortens the time to diagnosis compared with smear microscopy and conventional culture.

Cepheid's Xpert MTB/RIF Ultra is the company's most sensitive second-generation tuberculosis assay and is increasingly preferred in many clinical settings, particularly for patients with low bacterial burden, such as children, HIV-positive individuals, and those with extrapulmonary tuberculosis. The assay was redesigned to improve analytical sensitivity by more than tenfold compared with the original MTB/RIF test through enhanced molecular targets and automated melt curve analysis that improves detection of rifampin resistance mutations. This expanded sensitivity has improved identification of smear-negative tuberculosis while maintaining rapid turnaround on the GeneXpert system.

The Ultra assay was developed through collaboration involving Cepheid, academic partners, and global tuberculosis organizations, and it offers international tuberculosis elimination efforts through widespread deployment in both centralized and decentralized testing environments. In 2026, GeneXpert tuberculosis testing remains central to global TB programs, with Cepheid continuing to support high-burden countries through broad instrument deployment, cartridge supply agreements, and expanded access initiatives to improve early diagnosis of drug-resistant tuberculosis.

Microbiology

The Xpert Carba-R assay is an important rapid molecular test for infection control because it detects five major carbapenemase resistance genes commonly associated with carbapenem-resistant organisms, including KPC, NDM, VIM, OXA-48, and IMP. Rather than identifying the organism itself, the assay detects the resistance genes directly from rectal swabs or cultured isolates, enabling hospitals to rapidly identify patients carrying highly drug-resistant organisms and strengthen infection prevention measures within hours rather than days.

In sexually transmitted infection testing, Cepheid markets the Xpert TV assay, a rapid molecular urine-based and swab-based test for detection of Trichomonas vaginalis. The assay remains widely used because it provides highly sensitive molecular results in approximately 35 minutes, allowing same-visit diagnosis and treatment in women's health clinics, urgent care settings, and decentralized laboratories. Cepheid's sexually transmitted infection menu continues to benefit from increasing demand for rapid syndromic molecular testing.

For healthcare-associated infection control, Cepheid's Xpert MRSA NxG is a key product for rapid methicillin-resistant Staphylococcus aureus screening. This next-generation assay detects MRSA colonization directly from nasal swabs with improved target design for

broader strain coverage and delivers actionable molecular results in about one hour, supporting faster patient isolation decisions and hospital infection control workflows.

Cepheid offers a strong maternal and neonatal testing portfolio through its Group B Streptococcus assays. Xpert GBS LB XC is used for qualitative molecular detection of Group B Streptococcus from enriched Lim broth cultures and supports prenatal screening programs with fast PCR-based confirmation on GeneXpert systems. Additionally, Xpert Xpress GBS is an important rapid intrapartum test because it uses dual molecular targets to improve sensitivity and strain detection directly during labor, producing results in approximately 30 minutes. These assays are valued because rapid identification of maternal GBS colonization helps guide antibiotic prophylaxis and reduce the risk of early-onset neonatal sepsis.

POC Testing

Cepheid expanded its molecular diagnostics portfolio with a strong emphasis on rapid infectious disease testing on the GeneXpert platform. Its Xpert HCV Viral Load Fingerstick assay remains one of the company's most important decentralized hepatitis products because it detects hepatitis C virus RNA directly from a fingerstick capillary whole-blood sample without requiring plasma preparation. The assay produces results in about one hour, allowing clinicians to diagnose active HCV infection and potentially begin treatment during a single patient visit, which is especially valuable in outreach clinics, emergency settings, and community screening programs. This product was the first CLIA-waived molecular test in the U.S. capable of directly detecting HCV RNA from fingerstick blood.

Cepheid markets its broader Xpert HCV viral load test menu, which offers quantitative hepatitis C monitoring on GeneXpert systems used in hospitals, laboratories, and decentralized testing sites. In sexual health diagnostics, the Xpert CT/NG assay is an important product following its expansion to include throat and rectal specimen testing, enabling rapid molecular detection of chlamydia and gonorrhea across multiple specimen types with high sensitivity and a fast turnaround time.

For emerging infectious diseases, Cepheid offers the Xpert Mpox test, designed for rapid molecular detection of monkeypox virus on GeneXpert instruments, supporting public health and hospital-based outbreak response. The company has also strengthened its respiratory testing menu with updated SARS-CoV-2 assays, including multi-target COVID molecular tests designed to maintain detection performance as viral variants evolve.

Additional menu expansion includes continued global rollout of Xpert HBV Viral Load for hepatitis B viral monitoring, broader use of Xpert Xpress combination respiratory panels covering COVID-19, influenza, RSV, and strep testing, and growing adoption of hospital-based syndromic panels that support faster infectious disease triage.

Cancer

Cepheid markets the Xpert Bladder Cancer Monitor in Europe as a noninvasive molecular assay for the surveillance of recurrent bladder cancer, using urine samples on the GeneXpert platform. The test delivers results in about 90 minutes and remains positioned as a complementary tool to cystoscopy, particularly for follow-up monitoring of patients with non-muscle invasive bladder cancer. Its strong negative predictive performance has been important in reducing unnecessary invasive procedures in selected surveillance settings, especially where rapid outpatient molecular assessment is needed.

In hematologic oncology, Cepheid offers Xpert NPM1 Mutation, a quantitative molecular assay that measures mutant NPM1 mRNA transcripts in peripheral blood or bone marrow from patients with acute myeloid leukemia. The test detects the major exon 12 mutation subtypes, including A, B, and D, and supports monitoring of measurable residual disease by providing standardized molecular quantification on GeneXpert systems. This assay is important in leukemia follow-up because it enables faster, decentralized molecular assessment compared with traditional reference-laboratory PCR workflows.

Cepheid's oncology menu has expanded through broader adoption of rapid molecular cancer assays on GeneXpert, including products used for hematologic malignancy monitoring, while its overall strategy remains focused on bringing fast PCR-based oncology and infectious disease testing closer to routine hospital workflows and decentralized care settings.

Danaher Corporation

Washington, DC

www.danaher.com

Table 14-8: Danaher Revenue History, Diagnostics Segment, 2023-2025 ($ million, estimated)

	2023	2024	2025
Total Diagnostics	9,577	9,787	9,941

Source: company reports, Kalorama Information

Danaher reported modest growth in diagnostics revenue in 2025, reaching approximately $9.9 billion compared with $9.8 billion in 2024. Growth was supported mainly by stronger performance in pathology diagnostics and acute care testing, particularly within Leica Biosystems, Radiometer, and Beckman Coulter Diagnostics. Geographic distribution of diagnostic sales remained broad, with North America representing the largest share, followed by Western Europe, high-growth markets, and other international regions.

Danaher has built one of the broadest diagnostics portfolios in the industry through a long series of acquisitions and internal expansion. Its major diagnostic businesses include Beckman Coulter Diagnostics, Cepheid, Leica Biosystems, Radiometer, and HemoCue, while related businesses such as SCIEX support analytical and clinical laboratory workflows. The company began developing its modern diagnostics platform with the acquisition of Radiometer in 2004 and expanded through additional acquisitions including Leica Microsystems, Beckman Coulter, Iris International, Aperio Technologies, HemoCue, and Cepheid. These businesses now serve core laboratory diagnostics, molecular diagnostics, pathology, urinalysis, and acute care testing markets.

Beckman Coulter is a leading provider of clinical diagnostics systems with a strong emphasis on automated core laboratory and high-throughput immunoassay testing. Its Access and UniCel DxI platforms, including the DxI 9000, support rapid and highly sensitive testing in hospital and reference laboratories, particularly in acute care environments. The company's cardiac marker menu includes high-sensitivity troponin I (hsTnI), which enables earlier and more precise detection of myocardial infarction, along with established troponin assays. For

heart failure assessment, Beckman Coulter offers BNP and next-generation NT-proBNP assays, the latter enhanced with improved antibody design, rapid turnaround times, and age-specific clinical interpretation. Additional markers such as CK-MB support evaluation of myocardial injury. These assays are optimized for speed, analytical performance, and integration into automated workflows, supporting timely clinical decision-making in cardiovascular care.

Cepheid is one of Danaher's most important molecular diagnostics assets. Since joining Danaher in 2016, Cepheid has continued expanding the GeneXpert platform, which is widely used for rapid molecular testing in infectious disease detection, hospital-acquired infections, tuberculosis, respiratory disease, sexual health testing, and selected oncology applications. The GeneXpert installed base remains one of the largest global molecular diagnostic footprints, supporting both hospital laboratories and decentralized testing environments.

Iris International strengthened Danaher's urinalysis business through advanced automated urine microscopy and chemistry systems. Its iRICELL platform integrates urine chemistry and digital microscopy into a fully automated workflow designed for high-volume laboratories. Proprietary digital flow morphology technology and auto-particle recognition software allow automated classification of urine particles while reducing manual microscopic review and improving consistency of results.

Danaher has also expanded through targeted acquisitions outside core diagnostics. Integrated DNA Technologies strengthened the company's molecular and genomic reagent capabilities, supplying oligonucleotides and nucleic acid components used in PCR, sequencing, gene editing, and diagnostic assay manufacturing. IDBS added scientific data management and laboratory informatics capabilities, while the acquisition of Abcam expanded Danaher's life sciences portfolio with antibodies, reagents, biomarkers, and assay technologies used in research and translational medicine. Danaher uses selective acquisitions to strengthen both its diagnostics and life sciences businesses while maintaining broad exposure across clinical, research, and applied markets.

Dexcom

San Diego, CA

www.dexcom.com

Table 14-9: Dexcom Revenue History, 2023-2025 ($ million)

	2023	2024	2025
Total Revenues	3,622	4,033	4,662

Source: company reports, Kalorama Information

Dexcom continued strong expansion in 2025, adding approximately 600,000 to 700,000 net new users during the year, excluding users of its over-the-counter Stelo platform. Total company revenue reached approximately $4.66 billion in 2025, up about 16% from $4.03 billion in 2024, driven primarily by higher disposable sensor volume, expanding international adoption, broader reimbursement coverage, and continued penetration in both intensive insulin and non-intensive insulin markets. Growth was supported by strong uptake of the Dexcom G7 platform, increasing pharmacy channel sales, and expanding direct consumer access.

Dexcom is focused exclusively on continuous glucose monitoring technology and manufactures products primarily in San Diego, California and Mesa, Arizona. Its CGM systems consist of a wearable sensor, transmitter, and display platform integrated with either a dedicated receiver, smartphone, or smartwatch. The sensor continuously measures interstitial glucose and transmits readings in real time, while software provides trend data, alerts, and predictive insights for hypoglycemia and hyperglycemia.

The company's legacy Dexcom G5 and G6 systems have largely been superseded commercially by the Dexcom G7, although G6 remains important because of compatibility with several installed insulin pump systems. Dexcom G6 provides factory-calibrated glucose monitoring without fingerstick calibration and remains widely used in automated insulin delivery platforms, including pump integrations. Dexcom G6 Pro also remains available for professional use, offering both blinded and unblinded clinical glucose monitoring over a 10-day wear period for physician-guided diabetes assessment.

Dexcom's principal growth platform is the Dexcom G7, which combines sensor and transmitter into a smaller all-in-one disposable device with a significantly shorter warm-up period, simplified insertion, and improved comfort. The G7 is available across North America, Europe, Asia Pacific, and selected Latin American markets, with reimbursement continuing to expand in both public and private payer channels. The system is integrated with multiple insulin delivery platforms, including Tandem's t:slim X2 pump, and supports direct connectivity to smartphones and Apple Watch without requiring smartphone relay.

In 2025 and early 2026, Dexcom also expanded availability of the Dexcom G7 15 Day system for adults, extending wear time and improving convenience for long-term users.

Dexcom also continues to expand beyond prescription diabetes care. Its Dexcom ONE+ platform, launched in multiple European markets including Spain, Belgium, and Poland, uses the G7 sensor architecture in a simplified lower-cost format designed for broader access. The company's over-the-counter platform, Stelo, became a major strategic addition as the first non-prescription glucose biosensor designed for people with type 2 diabetes not using insulin and for wellness-focused consumers seeking metabolic insights. Stelo sends glucose data directly to smartphones and has opened an entirely new commercial category for Dexcom in consumer biosensing.

The company's software is a major competitive strength. Dexcom CLARITY provides remote glucose pattern reporting for clinicians and patients, while newer digital tools now incorporate generative AI-based analytics that identify individualized glucose responses linked to meals, activity, sleep, and daily habits. This emerging software layer is designed to move Dexcom beyond glucose monitoring toward broader metabolic decision support. Dexcom STUDIO, the older reporting platform, has largely been replaced by CLARITY and app-based cloud reporting in most markets.

Dexcom positions itself for growth through expansion into hospital monitoring, non-intensive type 2 diabetes, international reimbursement gains, and broader biosensor applications beyond traditional diabetes management.

Exact Sciences

Madison, WI

www.exactsciences.com

Table 14-10: Exact Sciences Revenue History, 2023-2025 ($ million)

	2023	2024	2025
Total revenue	2,499	2,759	3,247

Source: company reports, Kalorama Information

Revenues increased in 2025 reached $3,247 million, demonstrating a 17.7% increase over 2024's $2,759 million. The company has continued to increase its revenues for its lead product, Cologuard. For 2025, the Cologuard test revenues grew to $2,530 million from 2024's $2,104 million. Revenues increased in 2025 due to an increase in the number of completed Cologuard tests and from new products. Precision Oncology revenues reached $717 million in 2025 up from $655 million in 2024.

Abbott Laboratories announced in late 2025 its agreement to acquire Exact Sciences in a transaction valued at approximately $21 billion, making it one of the largest diagnostics acquisitions in recent years. The acquisition closed in March 2026 following final regulatory review and completion of integration planning. Abbott will incorporate Exact Sciences into its diagnostics business to strengthen its position in cancer screening, molecular oncology, and precision medicine, adding major franchises such as Cologuard, Oncotype DX, hereditary cancer testing, and liquid biopsy assets. In 2026, the combined business is expected to focus on expanding colorectal cancer screening globally, accelerating development of blood-based cancer screening assays, broadening oncology menu integration across Abbott's global commercial infrastructure, and generating cross-platform growth through Abbott's large hospital and physician office customer base.

Exact Sciences was founded in 1995 following technology developed in collaboration with Mayo Clinic and has evolved into one of the leading molecular cancer diagnostics companies focused on screening, early detection, precision oncology, and minimal residual disease

monitoring. The company's initial breakthrough came with stool DNA testing for colorectal cancer, culminating in regulatory approval of Cologuard, which established a new noninvasive colorectal screening category. Exact Sciences has expanded Cologuard eligibility to average-risk adults beginning at age 45 and is now advancing its next-generation Cologuard Plus platform, designed to improve sensitivity for advanced precancerous lesions while maintaining strong specificity. Cologuard remains the company's largest revenue driver, supported by broad physician adoption, direct consumer awareness campaigns, and growing payer coverage.

Exact Sciences has a long-standing biomarker collaboration with Mayo Clinic across multiple cancer types, including pancreatic cancer, liver cancer, and other high-mortality malignancies. Earlier work demonstrated promising blood-based methylated DNA marker performance for pancreatic cancer detection, and this research has contributed to the company's broader multi-cancer early detection strategy. Although its hepatocellular carcinoma blood test program evolved more slowly than originally anticipated, Exact Sciences continues to develop blood-based screening and surveillance assays using combined genomic, epigenomic, and proteomic technologies.

A major strategic turning point came with the acquisition of Genomic Health, which added the globally established Oncotype DX franchise and significantly expanded Exact Sciences' international oncology presence. Oncotype DX is a major growth driver in breast, colon, and prostate cancer decision support, while the company continues expanding into therapy selection and genomic profiling. Its OncoExTra assay serves as a comprehensive tumor profiling platform using combined DNA and RNA sequencing to support therapy selection across solid tumors. The acquisition of OmicEra Diagnostics strengthened proteomic biomarker discovery capabilities, while the acquisition of Resolution Bioscience added liquid biopsy and circulating tumor DNA expertise that supports advanced precision oncology development.

Exact Sciences has broadened its hereditary and residual disease portfolio through products such as Riskguard hereditary cancer testing and Oncodetect, which supports recurrence monitoring after treatment using circulating tumor DNA. In 2025 and early 2026, the company continued integrating tissue profiling, liquid biopsy, hereditary testing, and recurrence monitoring into a unified oncology platform. It also maintains a licensing relationship with Freenome to support blood-based colorectal cancer screening development, reflecting continued strategic interest in blood-based screening beyond stool diagnostics.

Hologic, Inc.

Bedford, MA

www.hologic.com

Table 14-11: Hologic Revenue History, Diagnostic Product Revenue, 2023-2025 ($ million)

	2023	2024	2025
Total Dx	1,769	1,658	1,693

Source: company reports, Kalorama Information

Hologic diagnostic sales reached approximately $1,693 million in 2025. Diagnostic revenues increased 2.1% compared to 2024 due to an increase in the molecular diagnostics business which was driven by an increase in sales for BV/CV assays.

Hologic's diagnostics revenues are approximately 41.2% of the company's total sales with some 72.0% generated in the U.S., Europe 15.8%, Asia Pacific 6.1% and rest of world 6.1%.

Hologic, Inc. is active in several markets: diagnostic products, medical imaging systems, and surgical products. The company operates four core business units focused on diagnostics, breast health, gynecological surgical and skeletal health.

Hologic derives most of its diagnostics revenue from molecular testing platforms originally built through the acquisition of Gen-Probe, while maintaining global leadership in cervical cancer screening through the ThinPrep franchise. ThinPrep remains one of the most widely used liquid-based cytology systems worldwide, and the business has expanded further through integration with Aptima HPV molecular testing and digital cytology. Hologic's newer cytology strategy centers on the Genius Digital Diagnostics System, an AI-enabled platform that combines volumetric imaging and deep-learning analysis to improve cervical cancer screening efficiency and lesion detection. The system is increasingly being positioned alongside ThinPrep Pap testing and Aptima HPV assays as part of a fully integrated cervical screening workflow, particularly in higher-volume cytology laboratories.

PANTHER Molecular System

The PANTHER molecular platform is Hologic's molecular diagnostics portfolio. Originally developed to complement the higher-volume Tigris platform, PANTHER was designed for low- to mid-volume laboratories while retaining the same core target capture and transcription-mediated amplification technologies that became hallmarks of Gen-Probe systems. PANTHER uses capture oligomers, magnetic microparticles, and isothermal transcription-mediated amplification to deliver highly sensitive nucleic acid detection with full automation. The system offers primary tube sampling, random access loading, continuous sample and reagent loading, and the ability to run multiple assays from one specimen. Its compact design and broad menu have made PANTHER one of the most widely installed molecular systems in women's health and sexually transmitted infection testing globally. PANTHER can process large assay volumes with minimal hands-on labor while running multiple assay types simultaneously.

Sexually Transmitted Infections

Aptima remains the flagship assay brand on PANTHER. The assay menu includes chlamydia, gonorrhea, trichomoniasis, human papillomavirus, HPV genotyping, HIV viral load, hepatitis viral load assays, herpes simplex virus testing, and other sexually transmitted infection targets. Aptima Combo 2 remains one of the leading molecular assays for simultaneous detection of chlamydia and gonorrhea, and Hologic has expanded specimen claims to include clinician-collected and patient-collected throat and rectal swabs. Aptima Mycoplasma genitalium is an important differentiator because M. genitalium is difficult to culture and increasingly recognized as a clinically significant sexually transmitted pathogen. Hologic also markets Group B Streptococcus assays on PANTHER Fusion, expanding molecular testing for maternal and neonatal care.

Infectious Diseases

Hologic maintains a strong virology business through viral load assays on PANTHER. Aptima HIV-1 Quant and Aptima HIV-1 Quant Dx provide highly sensitive viral load monitoring and diagnostic capabilities, including dried blood spot testing that supports infant HIV diagnosis and decentralized testing programs in Africa and other international markets. Aptima HIV-1 Quant Dx remains notable because it supports both viral load monitoring and early infant diagnosis on one assay platform. Hologic also markets Aptima HCV Quant Dx

for hepatitis C viral load monitoring and confirmation of active infection, Aptima HBV Quant for hepatitis B viral load across genotypes A through H, and Aptima CMV Quant for transplant patient monitoring. These viral load assays allow laboratories to run HIV, HBV, HCV, and CMV in parallel on PANTHER, strengthening Hologic's position in centralized virology laboratories. Hologic offers its Aptima HCV Quant Dx assay on the PANTHER system to quantify hepatitis C viral load and confirm active HCV infection. The assay uses real-time transcription-mediated amplification to provide quantitative determination of sustained antiviral response across all major genotypes.

Hologic markets the Aptima Herpes Simplex Virus 1 & 2 molecular assay on the PANTHER system. The test, when used with swab specimens from anogenital skin lesions, can qualitatively detect and differentiate HSV-1 from HSV-2. Clinicians collect samples using a new Aptima Multitest Swab Specimen Collection Kit or commercially available viral transport media.

Hologic also provides additional marketing for the Aptima Combo 2 Assay for Chlamydia trachomatis and Neisseria gonorrhoeae. These additional claims allow for testing of both clinician- and patient-collected throat and rectal swabs.

Hologic offers the PANTHER Fusion Gastrointestinal bacterial assay and the expanded bacterial assay. The tests are designed to detect bacterial pathogens responsible for infectious gastroenteritis rapidly. The new GI pathogen detection test leverages rapid molecular technology and covers common bacterial causes of infectious gastroenteritis, including Salmonella, Campylobacter, Shigella, E. coli, Vibrio, Yersinia and Plesiomonas. The tests are run on the Panther Fusion System.

PANTHER Fusion

Hologic offers the PANTHER Fusion platform as a flexible molecular system that combines high-throughput automation with modular PCR testing. PANTHER Fusion extends existing PANTHER instruments by adding cartridge-based PCR capability to the high-volume liquid-reagent PANTHER workflow, allowing laboratories to run both large routine molecular workloads and lower-volume specialty assays on a single integrated platform. The PANTHER side is optimized for high-volume Aptima assays using transcription-mediated amplification, while the Fusion side uses real-time PCR cartridges for syndromic respiratory testing, hospital-acquired infection assays, transplant monitoring, and custom laboratory-

developed tests. This dual architecture is one of the platform's major advantages because laboratories can match test format to workload without adding separate instrumentation.

PANTHER Fusion respiratory testing is one of Hologic's strongest Fusion growth areas. The PANTHER Fusion SARS-CoV-2/Flu A/B/RSV assay provides simultaneous detection and differentiation of four major respiratory viruses from a single patient specimen using fully automated molecular testing. Hologic also expanded its respiratory workflow with the RespDirect collection kit, which simplifies sample preparation and enables direct specimen loading. Laboratories can run one, two, or all respiratory targets depending on clinical need, giving PANTHER Fusion a modular syndromic testing approach rather than requiring full fixed respiratory panels. This flexibility is important as respiratory testing volumes normalize after peak pandemic demand but continue to favor multiplex molecular workflows.

Outside North America, Hologic also offers respiratory testing through the Novodiag platform, where the Novodiag RESP-4 assay continues to detect SARS-CoV-2, influenza A, influenza B, and RSV in a fully automated format. The Novodiag system is particularly active in decentralized and near-patient molecular settings where lower throughput is needed. Together, PANTHER Fusion and Novodiag allow Hologic to serve both centralized and smaller laboratory respiratory testing markets.

A major strategic advantage of PANTHER Fusion is Open Access functionality, which continues to attract advanced molecular laboratories. Open Access allows CLIA-certified laboratories to develop and validate laboratory-developed tests directly on the fully automated PANTHER Fusion platform while running FDA-cleared or CE-marked assays simultaneously. The myAccess software supports protocol development, threshold setting, data interpretation, and automatic reporting to laboratory information systems. This capability has become increasingly valuable as laboratories seek flexible automation without purchasing separate open PCR systems.

PANTHER Fusion also remains important in transplant virology. The PANTHER Fusion EBV Quant assay supports Epstein-Barr virus monitoring in transplant patients using plasma and whole blood, while PANTHER Fusion BKV Quant measures BK virus in plasma and urine to help monitor transplant-associated viral complications. These assays strengthen Hologic's role in transplant monitoring, where quantitative viral load testing remains clinically important for immunocompromised patients.

The platform offers broad laboratory efficiency. Laboratories can combine women's health assays, virology, respiratory testing, hospital-acquired infection assays, transplant monitoring, and Open Access assays on a single system, capable of running up to 32 assay types simultaneously. Hologic's PANTHER Fusion is capable of processing up to 500 combined PANTHER Fusion and Aptima assays during a single 8-hour shift, which remains attractive for consolidated molecular laboratories.

Hologic's PANTHER Fusion strategy increasingly emphasizes menu expansion, respiratory flexibility, transplant virology, and laboratory consolidation, while future growth is expected from additional respiratory syndromic targets, broader adoption in hospital microbiology, and further expansion of laboratory-developed testing on automated PANTHER Fusion systems.

Cytology

Cytology is one of Hologic's strongest long-term franchises. ThinPrep continues to dominate liquid-based cervical cytology, especially when combined with Aptima HPV molecular assays. Hologic is a leading supplier in both Pap testing and HPV testing across Europe and North America. Clinical screening guidelines continue to support Pap testing in younger women and HPV co-testing in women aged 30 to 65. These guidelines support the strong utilization of ThinPrep and Aptima together. A major strategic development is the Genius Digital Diagnostics System, which adds AI-powered digital cytology analysis to the ThinPrep franchise. Genius combines volumetric imaging with deep-learning algorithms to identify clinically relevant abnormal cells and prioritize suspicious areas for cytotechnologist review. It is the first FDA-cleared digital cytology system combining artificial intelligence with volumetric imaging for cervical screening and is increasingly central to Hologic's digital cytology growth strategy.

Illumina

San Diego, CA

www.illumina.com

Table 14-12: Illumina Revenue History, 2023-2025 ($ million, not all revenues are for clinical products and services; estimated)

	2023	2024	2025
Total Revenues	4,504	4,372	4,343

Source: company reports, Kalorama Information

Illumina reported 2025 revenue of $4,343 million compared to $4,372 million in 2024. Core Illumina consumables increased in 2025 due to demand for high-throughput consumables from the transition to NovaSeq X, although core Illumina instruments decreased in 2025 due to lower demand.

Illumina offers its sequencing franchise, with a portfolio spanning benchtop, mid-throughput, and ultra-high-throughput platforms that support whole-genome sequencing, targeted resequencing, amplicon sequencing, copy-number analysis, structural variant detection, methylation studies, transcriptomics, and increasingly integrated multiomics applications. Its sequencing-by-synthesis (SBS) chemistry is the company's core competitive advantage, particularly against Thermo Fisher Scientific platforms and emerging long-read competitors. Illumina's installed base now spans research, clinical, public health, biopharma, and population genomics laboratories worldwide, with the company increasingly positioning its systems not only for sequencing output but also for integrated software, informatics, and AI-enabled genomic interpretation. Recent growth has been driven by the expansion of the NovaSeq X Series family, which offers significantly higher throughput, lower reagent consumption, reduced waste, and lower cost per genome than previous-generation systems, while the NovaSeq X Plus is capable of producing more than 20,000 whole genomes annually in large-scale genomic centers.

At the benchtop level, MiSeq is widely used for smaller laboratories requiring rapid turnaround and flexible low-volume sequencing, particularly for microbial genomics,

amplicon sequencing, and targeted oncology panels. The MiSeqDx is Illumina's flagship regulated benchtop clinical sequencer, featuring diagnostic workflows through integrated software for sample tracking, audit trails, user management, and clinical reporting. Regulatory availability has expanded across major global markets, including the United States, Europe, China, Canada, Australia, South Korea, Singapore, Thailand, and other Asia Pacific regions, supporting a growing ecosystem of in vitro diagnostic assay developers. Illumina's companion diagnostic leadership is growing, including extended RAS testing capabilities developed with Amgen for KRAS and NRAS mutation detection, which help oncology laboratories implement local precision oncology workflows.

Illumina offers the TruSight Oncology Comprehensive assay, one of the company's most strategically important clinical genomic products. The assay evaluates more than 500 genes and supports identification of actionable biomarkers, including NTRK fusions, RET alterations, MSI, and TMB, helping determine eligibility for targeted therapies such as Vitrakvi and Retevmo. In Japan, Illumina expanded the commercialization of TruSight Oncology following approval by the Ministry of Health, Labor and Welfare, strengthening its position in decentralized oncology testing. While TruSight Oncology 500 remains widely used in translational and pharmaceutical research, Illumina converts elements of this content into regulated clinical offerings across multiple geographies. Earlier assays, such as TruSight Tumor 170, are important in selected regional and laboratory-developed testing environments, particularly on the NextSeq 550Dx system.

In reproductive health, VeriSeq NIPT Solution v2 is a major CE-marked offering for noninvasive prenatal testing, allowing expanded screening for chromosomal and subchromosomal abnormalities beyond standard trisomy panels. The assay continues to gain adoption in Europe, the Middle East, Africa, and selected Asia Pacific markets as laboratories seek more automated high-throughput prenatal screening solutions. Illumina has a strong position in reproductive genomics through embryo screening and carrier screening workflows that are tied to its broader sequencing ecosystem.

The company's technology emphasizes multiomics. Illumina's Illumina Complete Long Reads provides synthetic long-read capability compatible with NovaSeq X, NovaSeq X Plus, and NovaSeq 6000 systems, enabling improved structural variant detection and phasing without requiring dedicated long-read instrumentation. This approach supports users seeking long-read genomic information while remaining within Illumina's SBS ecosystem. In single-cell biology, the 2024 acquisition of Fluent BioSciences strengthened Illumina's direct participation in simplified single-cell workflows by adding technology that reduces

instrument complexity and microfluidic dependence. Earlier collaborations with Bio-Rad Laboratories on single-cell sequencing also remain influential in laboratories that combine droplet partitioning with Illumina sequencing.

Illumina expanded its software and informatics partnerships to strengthen clinical interpretation and AI capabilities. Collaborations with QIAGEN provide the development of IVD kits on MiSeqDx and NextSeq 550Dx systems, while earlier oncology reporting partnerships with PierianDx helped establish structured variant interpretation workflows. In 2025, Illumina deepened its AI strategy through a partnership with Tempus AI to integrate genomic data generation with multimodal clinical data and machine-learning models to accelerate precision medicine adoption.

Strategically, Illumina has moved beyond pure sequencing toward proteomics and broader molecular profiling. The spin-off of GRAIL in 2024 marked a major restructuring after prolonged regulatory pressure surrounding the acquisition, allowing Illumina to refocus capital deployment. In 2025, Illumina advanced its multiomics strategy through the acquisition of SomaLogic, bringing high-plex proteomic analysis to its portfolio and strengthening its platform for integrated genomics-proteomics workflows. This complements the company's oncology and translational medicine strategy, where combined genomic and proteomic signatures are increasingly important for biomarker discovery.

Additional commercial expansion includes the partnership with Pillar Biosciences, enabling broader access to targeted oncology assays across Illumina sequencers. These assays strengthen decentralized oncology testing and support laboratories seeking faster targeted mutation analysis without requiring large comprehensive profiling runs.

China

Illumina is the leading global supplier of DNA sequencing systems, with its sequencing-by-synthesis technology continuing to dominate many research and clinical genomics laboratories worldwide. Its platforms are widely used in pharmaceutical research, drug discovery, translational medicine, oncology profiling, reproductive health, infectious disease surveillance, agricultural genomics, and consumer genomics. Although growth in China has become more complex because of procurement policies favoring domestic sequencing suppliers and rising competition from Chinese genomic instrument manufacturers, China is an important strategic market for Illumina, particularly in academic genomics, hospital-based oncology testing, reproductive health, and large-scale population sequencing programs.

Demand is strongest in oncology research, hereditary disease screening, reproductive testing, and noninvasive prenatal testing, although direct-to-consumer DNA testing has moderated compared with earlier years due to tighter regulatory oversight.

In China, Illumina's sequencing systems remain widely used in major reference laboratories and university hospitals for cancer genomics, inherited disease testing, and prenatal screening. The company has a large installed base of NovaSeq, NextSeq, and benchtop systems such as MiniSeq and MiSeq, which are frequently used in hereditary disease research and smaller clinical sequencing programs. Noninvasive prenatal testing remains one of the most established applications for Illumina technology in China, with many local laboratories using Illumina workflows for chromosomal aneuploidy screening and expanded reproductive genomics services.

Illumina's earlier collaboration with Boai NKY Medical Holdings is one of its notable China-focused initiatives in hereditary disease. The partnership was designed to combine Illumina sequencing hardware with NKY's local library-preparation chemistry and bioinformatics software to develop next-generation sequencing-based hereditary disease assays, particularly for inherited kidney disorders, aligned with the regulatory requirements of China's National Medical Products Administration. While no major public commercial launch from that collaboration has been highlighted, the program appears to have remained relevant as part of broader efforts to localize sequencing workflows for regulatory acceptance in China. Illumina's strategy in China increasingly emphasizes enabling local assay developers, integrating software, and supporting regulated diagnostic pathways rather than solely selling imported sequencing instruments.

More recently, Illumina has had to navigate stronger domestic competition from Chinese sequencing companies, especially as hospitals and public institutions increasingly evaluate locally manufactured alternatives for cost and procurement reasons. Even so, Illumina retains strong technical credibility in high-complexity oncology sequencing, reproductive genomics, and translational research, particularly where standardized global workflows and large international data compatibility remain important. The company's longer-term strategy in China now focuses on maintaining leadership in premium clinical sequencing applications, advanced oncology profiling, and multiomics research rather than relying solely on broad instrument expansion.

Leica Biosystems/Danaher

Buffalo Grove, IL

www.leicabiosystems.com

Leica Biosystems is a cancer diagnostics company and one of the global leaders in histopathology workflow solutions, with a portfolio that covers tissue processing, embedding, microtomy, staining, digital pathology, image analysis, and workflow software from biopsy through diagnosis. As part of Danaher Corporation, Leica Biosystems positions itself as a major integrated pathology provider focused on linking pathology more closely with radiology, surgery, and oncology, particularly as digital pathology adoption expands across clinical laboratories and cancer centers. Its strategy emphasizes workflow connectivity, automation, and AI-enabled pathology interpretation to support precision oncology and higher laboratory productivity.

Digital Pathology

Leica Biosystems markets a comprehensive digital pathology portfolio under its Aperio platform, including high-throughput systems such as the Aperio AT2 and Aperio GT 450, compact scanners such as the Aperio CS2 and Aperio LV1, and advanced multimodal systems such as the Aperio VERSA, which supports both brightfield and fluorescence imaging. The current commercial focus is on the Aperio GT 450 and GT 450 DX platforms, which are designed for high-volume clinical environments, offering faster scan speeds, large slide capacity, and scalable deployment across enterprise pathology networks. Leica has expanded its digital pathology system through Aperio eSlide Manager and associated viewing platforms, enabling remote case access, centralized workflow management, and interoperability with laboratory and hospital information systems. These capabilities support multi-site pathology operations and provide a foundation for integration of image analysis and AI-assisted workflows.

Tissue Staining

In tissue staining and advanced biomarker analysis, Leica Biosystems' acquisition of Cell IDx is important. The acquisition brought Cell IDx's UltraPlex multiplex staining technology

into Leica's research and translational pathology portfolio, allowing simultaneous visualization of multiple biomarkers on a single tissue section using both fluorescent and chromogenic multiplex immunohistochemistry. UltraPlex is designed to integrate directly with Leica's BOND RX automated staining platform, enabling high-throughput multiplex biomarker workflows that are increasingly important in immuno-oncology, tumor microenvironment analysis, and translational biomarker discovery.

The combination of UltraPlex and BOND RX allows researchers to detect three or more chromogenic markers on a single slide within a pathology workflow that remains compatible with standard laboratory practice. This has become increasingly relevant as pharmaceutical companies and cancer research centers demand multiplex tissue characterization to support companion diagnostics and immunotherapy development. Leica continues to expand this strategy through stronger integration of staining, imaging, and digital analysis so that multiplex workflows can move more efficiently from research into future clinical applications.

Lab Systems

Leica Biosystems focuses on histopathology workflow solutions through a product portfolio that spans specimen preparation, staining, imaging, and digital diagnosis. The company concentrates on integrating tissue processing, advanced staining, digital pathology, and workflow software into a unified pathology platform for cancer diagnostics. BOND-III is one of the company's core advanced staining systems, widely used for immunohistochemistry (IHC), in situ hybridization (ISH), and companion diagnostic workflows. The platform is valued for its high-throughput automation, assay consistency, and flexible menu support, particularly in oncology laboratories where standardized biomarker testing is critical for therapeutic decision-making.

For routine histology automation, Leica Biosystems markets the HistoCore SPECTRA Workstation, which integrates the HistoCore SPECTRA ST stainer and the HistoCore SPECTRA CV coverslipper into a single platform for medium- and high-volume pathology laboratories. The workstation facilitates continuous loading, automated reagent handling, and rapid slide throughput. Its integrated drying oven offers a major workflow advantage, allowing glass slides to dry in approximately five minutes, enabling them to move quickly to pathologist review and helping laboratories reduce turnaround time and improve daily workflow efficiency.

In digital pathology, Aperio LV1, a compact digital pathology platform designed for low-volume scanning, rapid consultation, and telepathology applications. The Aperio LV1 holds four slides and offers microscope-like navigation, along with live digital viewing, remote robotic control, and rapid slide access. Live View enables near-real-time telepathology, allowing remote slide viewing in under 15 seconds, making the system particularly useful for frozen-section support, satellite laboratories, and remote pathology consultation. It also functions as a low-volume whole-slide scanner, making it valuable in settings where laboratory space is limited but access to digital pathology is increasingly required.

More recently, Leica Biosystems expanded integration among its staining systems, digital scanners, and pathology software, enabling laboratories to move more seamlessly from slide preparation to digital review and AI-assisted analysis. This broader workflow integration is one of Leica's strongest competitive advantages as pathology laboratories increasingly adopt digital and computational pathology solutions.

Natera

Austin, TX

www.natera.com

Table 14-13: Natera Revenue History, 2023-2025 ($ million)

	2023	2024	2025
Total Natera Sales	1,078	1,697	2,306

Source: company reports, Kalorama Information

Natera reported very strong growth in 2025, with total revenues reaching approximately $2.31 billion, up from about $1.70 billion in 2024, reflecting continued progress in oncology, women's health, and transplant diagnostics. The strongest growth driver remained oncology, particularly the rising adoption of Signatera for molecular residual disease (MRD) assessment, recurrence monitoring, and treatment response tracking across multiple solid tumors. Natera, originally founded in 2003 as Gene Security Network and publicly listed on NASDAQ in 2015, has evolved from a reproductive genetics company into one of the most influential liquid biopsy and cell-free DNA diagnostics companies, while still maintaining a major position in non-invasive prenatal testing and transplant surveillance.

The company's core foundation is its proprietary multiplex PCR (mmPCR) platform, which enables simultaneous interrogation of thousands of genomic loci in a single reaction with very high analytical sensitivity. This platform is designed to detect both copy-number variants and single-nucleotide variants at very low circulating DNA concentrations, enabling detection of variants at approximately 0.01% variant allele frequency in plasma. Natera's bioinformatics segment, based on maximum-likelihood statistical modeling and individualized genomic interpretation, is paramount to its ability to generate highly sensitive, patient-specific assays. Together, these technologies support oncology MRD testing, transplant rejection surveillance, and reproductive genomics, while also helping assay customization for research and biopharma applications.

Signatera is Natera's flagship oncology product and differentiates itself from fixed-panel liquid biopsy assays by creating a personalized assay for each patient based on sequencing

of the individual tumor. Rather than using a generic mutation panel, Signatera typically tracks 16 or more patient-specific tumor variants and can expand to larger mutation sets for research applications. This personalized approach has made Signatera increasingly important in colorectal cancer, breast cancer, bladder cancer, lung cancer, and immunotherapy monitoring, with growing use in treatment selection and post-surgical surveillance. More recently, Natera introduced the ultra-sensitive Signatera Genome, which expands genomic coverage to improve sensitivity in very low disease burden settings and supports earlier molecular detection of recurrence.

In women's health, Natera is a major contributor in prenatal and reproductive genetics through its established prenatal portfolio. Panorama Prenatal Test is one of the leading non-invasive prenatal tests for fetal aneuploidy detection, screening chromosomes 13, 18, 21, X, and Y, while also supporting triploidy and selected microdeletion analysis. Natera's Vistara expands prenatal screening to include monogenic disease detection by analyzing fetal cfDNA for selected dominant single-gene disorders. Horizon Carrier Screen is a major carrier screening platform with a broad menu aligned with evolving clinical guidelines, covering hundreds of inherited disorders including cystic fibrosis, spinal muscular atrophy, fragile X syndrome, hemoglobinopathies, metabolic disorders, and many rare autosomal recessive conditions.

Natera strengthened this reproductive business significantly through its 2024 acquisition of reproductive health assets from Invitae, expanding both carrier screening and prenatal testing market share. Additional reproductive offerings include Anora for miscarriage analysis using SNP-based parental support technology, which detects aneuploidy, triploidy, copy number changes, uniparental disomy, and maternal cell contamination. Natera also offers preimplantation testing and prenatal paternity testing in selected markets The company has expanded into specialized prenatal assays such as Fetal Focus, designed for targeted inherited disease assessment covering cystic fibrosis, spinal muscular atrophy, alpha-thalassemia, beta-hemoglobinopathies, and sickle cell disease.

In transplant diagnostics, Prospera remains an important growth area. The assay measures donor-derived cell-free DNA to detect active organ rejection in transplant recipients. Its expanded cardiac transplant version, Prospera Heart with Donor Quantity Score, adds Donor Quantity Score (DQS) to improve discrimination of antibody-mediated and acute cellular rejection. Natera's distribution collaboration with One Lambda continues to augment transplant market penetration, especially in kidney transplantation, and there has been no major public indication that this arrangement has ended.

Internationally, Natera is engaged in strategic expansion through its collaboration with BGI Genomics, which includes the commercialization of Signatera in China and the development of reproductive health assays on BGI's DNBseq sequencing platform. This partnership is strategically relevant as China continues to expand oncology liquid biopsy and prenatal testing capacity. Natera has also expanded into early cancer detection research, although this remains earlier-stage compared with its highly commercialized MRD business.

Additionally, the company offers Natera's cfDNA-based fetal RhD assay, which is relevant in prenatal blood group management, and its collaboration with MyOme for integrated polygenic breast cancer risk assessment combining monogenic and polygenic risk factors.

Natera provides Zenith genomics, a next-generation whole genome sequencing assay that is designed to detect rare diseases. Zenith genomics was developed through a partnership with Natera and MyOme. The product provides enhanced resolution of hard-to-detect features that may indicate the presence of a rare disease through advanced sequencing and interpretation technology.

Natera's next phase of development is Signatera CDx, which is being positioned as a companion diagnostic intended to guide treatment decisions rather than only track disease status. In early 2026, Natera submitted the test for FDA premarket approval, marking a significant step toward regulatory clearance. The assay is designed to identify patients who are most likely to benefit from specific therapies, particularly in settings such as bladder cancer where MRD status can inform the use of immunotherapy. While it is not yet FDA-approved, the move toward a regulated companion diagnostic reflects a broader shift in molecular oncology, where liquid biopsy tests are evolving from monitoring tools into decision-making instruments that can directly influence treatment selection.

QIAGEN

Venlo, Netherlands

www.QIAGEN.com

Table 14-14: QIAGEN Revenue History, 2023-2025 ($ million)

	2023	2024	2025
Total Revenue	1,965	1,978	2,090

Source: company reports, Kalorama Information

QIAGEN reports total revenue of $2,090 million in 2025, compared with $1,978 million in 2024.

QIAGEN has expanded its global presence as part of a long-term growth strategy, with operations across Europe, North America, Asia, and other key international markets. The company offers a broad portfolio of consumable kits, instruments, and automation systems serving molecular diagnostics, applied testing, pharmaceutical development, biotechnology, and academic research. QIAGEN is widely recognized as a pioneer in DNA and RNA extraction technologies and continues to build on this foundation with integrated molecular workflow solutions.

QIAGEN has evolved into a leading molecular diagnostics company through a combination of internal innovation and strategic acquisitions. While historically focused on infectious disease testing, the company has expanded into oncology, precision medicine, and immune monitoring. Its clinical portfolio now offers applications including screening, diagnosis, prognosis, therapy selection, and disease monitoring.

QIAGEN maintains a strong position in immune response testing through its QuantiFERON platform, which is widely used in tuberculosis detection and is being expanded into broader immune-monitoring applications. The company continues to develop new assays and applications that leverage this technology, supporting both infectious disease and immunology-related testing.

In precision medicine, QIAGEN offers a growing portfolio of companion diagnostics and biomarker assays designed to guide targeted therapies. The company collaborates with numerous pharmaceutical and biotechnology partners to co-develop companion and complementary diagnostics that support treatment decisions across multiple cancer types. Its solutions include both tissue- and liquid biopsy–based approaches for molecular profiling.

QIAGEN's technology portfolio spans multiple molecular platforms, including PCR-based workflows, digital PCR, next-generation sequencing solutions through partnerships, universal reagent systems, and rapid syndromic testing with the QIAstat-Dx platform. These systems are designed to deliver flexible, scalable solutions for both centralized laboratories and near-patient settings.

As a leader in "Sample to Insight" solutions, QIAGEN integrates sample preparation, molecular analysis, and data interpretation into end-to-end workflows.

Tuberculosis.

QIAGEN has expanded its tuberculosis testing portfolio with the offering of the QIAreach QuantiFERON-TB test, a portable and decentralized solution designed to improve access to interferon-gamma release assay (IGRA) testing. The system uses whole blood samples to detect immune responses to Mycobacterium tuberculosis infection by measuring interferon-gamma produced by sensitized T cells. The QIAreach platform incorporates a digital lateral flow–based detection system that simplifies workflow and enables faster, easy-to-interpret results compared to traditional laboratory-based IGRA testing, for use in decentralized and resource-limited settings.

In addition, QIAGEN has expanded its molecular tuberculosis testing capabilities with the introduction of the QIAseq xHYB Mycobacterium tuberculosis panel. This next-generation sequencing–based assay enables targeted analysis of TB genetic material, supporting applications such as strain characterization and detection of drug resistance–associated mutations. The panel reflects QIAGEN's broader strategy to integrate sequencing technologies into infectious disease diagnostics and epidemiological surveillance.

Molecular Expansion

QIAGEN offers a broad molecular diagnostics portfolio centered on integrated "Sample to Insight" workflows that combine sample preparation, amplification, and analysis across multiple platforms. The company's portfolio includes automation systems such as QIAsymphony for sample preparation and assay setup, and QIAstat-Dx for rapid, multiplex syndromic testing in clinical and near-patient settings. QIAGEN continues to position these platforms as complementary solutions that address a wide range of laboratory needs, from centralized high-throughput testing to decentralized molecular diagnostics.

QIAGEN expanded its syndromic testing capabilities through the acquisition of STAT-Dx, whose cartridge-based molecular testing system was rebranded as QIAstat-Dx. This platform enables fully integrated, sample-to-answer molecular analysis using real-time PCR technology, with single-use cartridges that incorporate all necessary reagents and sample processing steps. The system is designed for ease of use and can deliver results in approximately one hour, supporting rapid diagnosis of infectious diseases in both laboratory and near-patient environments. The modular analyzer can be configured with multiple independent testing modules, allowing flexible throughput and workflow optimization.

The QIAstat-Dx portfolio has expanded with new panels and system enhancements, including higher-capacity configurations such as QIAstat-Dx Rise, which is designed to support increased testing volumes in mid- to high-throughput settings. The platform now includes multiplex respiratory panels capable of detecting a broad range of viral and bacterial pathogens, supporting syndromic testing for respiratory infections and improving clinical decision-making.

QIAGEN has also developed molecular testing solutions for viral load monitoring and transplant-related infections through its PCR-based assay portfolio. These assays are designed to support management of immunocompromised patients by enabling detection and quantification of clinically relevant viruses.

As part of its portfolio optimization strategy, QIAGEN has decided to discontinue its NeuMoDx integrated PCR systems, shifting its focus toward higher-growth areas such as syndromic testing with QIAstat-Dx, digital PCR with QIAcuity, and bioinformatics solutions. The company continues to support existing NeuMoDx customers while reallocating resources to its core molecular platforms.

Recent developments include regulatory clearance of expanded QIAstat-Dx respiratory panels, which enable multiplex detection of more than 20 pathogens, including SARS-CoV-2, in a single, fully integrated assay with results available in approximately one hour.

Precision Medicine / Companion Diagnostics

QIAGEN is a leader in precision medicine and has established a strong position through extensive collaborations with pharmaceutical and biotechnology companies to co-develop companion diagnostics. The company is engaged in numerous partnerships with major industry players, supporting the development of biomarker-driven tests that guide targeted therapies across oncology and other disease areas. These collaborations enable QIAGEN to expand its portfolio of companion and complementary diagnostics aligned with emerging precision therapies.

QIAGEN offers a broad menu of molecular diagnostics for cancer, including companion diagnostics designed to support therapy selection and disease management. Its solutions are supported by integrated molecular workflows, including automated sample preparation using the QIAsymphony platform and downstream PCR-based testing on systems such as the Rotor-Gene Q. The company has increasingly focused on flexible workflows that support both PCR and next-generation sequencing–based applications through universal reagent systems and partnerships.

QIAGEN has continued to expand its therascreen portfolio of PCR-based companion diagnostics. Recent additions include assays designed to detect clinically relevant mutations associated with targeted cancer therapies. These tests support the identification of actionable biomarkers in solid tumors, particularly in non-small cell lung cancer, where detecting resistance and activating mutations is critical for treatment selection.

The company has also secured regulatory approvals for companion diagnostics that guide the use of targeted therapies in oncology. These include PCR-based assays that detect specific gene mutations in tumor tissue samples, enabling the identification of patients who may benefit from precision therapies. QIAGEN's companion diagnostics are designed for use with formalin-fixed, paraffin-embedded tissue and integrate with its automated sample preparation and molecular testing platform. Recent developments include regulatory approvals for additional companion diagnostic assays designed to support targeted oncology therapies, as well as continued expansion of testing aligned with KRAS G12C inhibitor treatments. QIAGEN is also advancing a multi-platform strategy that integrates PCR-based

assays with broader sequencing workflows, enabling more comprehensive biomarker analysis in both tissue and liquid biopsy samples.

QIAGEN's QIAstat-Dx Rise is an automated syndromic testing system with automated cartridge loading and unloading. The company reports over 4,600 instruments placed globally so far.

Molecular Microbiology

QIAGEN's molecular diagnostics business includes its artus product line, originally developed through the acquisition of Gesellschaft für molekularbiologische Diagnostik und Entwicklung. The artus RealArt assay portfolio was designed for use with a variety of open PCR platforms, including Roche LightCycler, ABI TaqMan, and Rotor-Gene instruments. The portfolio includes a broad range of assays for detecting viral and bacterial pathogens, as well as applications in genotyping and veterinary diagnostics. While these assays established QIAGEN's early presence in molecular testing, the company has shifted its focus toward integrated, automated molecular solutions.

Building on its PCR foundation, QIAGEN has advanced its syndromic testing capabilities through the QIAstat-Dx platform, which provides fully integrated sample-to-answer molecular diagnostics via real-time PCR. The system enables processing of a wide range of sample types, including swabs and respiratory specimens, with minimal hands-on time and results available in approximately one hour. QIAstat-Dx is designed for both centralized laboratories and near-patient settings, offering flexible throughput through a modular analyzer configuration.

QIAGEN has expanded the QIAstat-Dx platform with new system enhancements and an expanding menu of syndromic panels. Recent updates include an enhanced analyzer configuration with improved software, connectivity, and workflow flexibility, supporting remote data access and integration with laboratory information systems. The platform has also expanded geographically, with broader adoption in Asia and other international markets.

The QIAstat-Dx test menu has grown significantly, with multiple syndromic panels designed to provide rapid diagnosis of infectious diseases. These include comprehensive respiratory panels that detect a wide range of viral and bacterial pathogens, gastrointestinal panels that target common causes of enteric infections, and focused respiratory virus panels to support targeted clinical decision-making. In addition, the platform has been expanded to include

panels for central nervous system infections, such as meningitis and encephalitis, further broadening its clinical utility.

Recent regulatory clearances have strengthened QIAGEN's position in syndromic testing, with multiple QIAstat-Dx panels approved for clinical use. These developments reflect the company's strategic focus on expanding rapid, multiplex molecular diagnostics and consolidating its leadership in syndromic testing.

Prenatal Testing

QIAGEN has collaborated with companies such as Natera to advance cell-free DNA–based testing workflows, particularly for applications like non-invasive prenatal testing. These efforts focused on integrating technologies for sample collection, preparation, and analysis to enable accurate detection of fetal DNA in maternal blood samples. QIAGEN's PAXgene cell-free DNA collection and stabilization technology plays a key role in preserving sample integrity and improving the reliability of downstream molecular analysis. While earlier collaborations included the development of sequencing-based workflows, QIAGEN's current strategy emphasizes enabling technologies and bioinformatics solutions that support flexible use across multiple next-generation sequencing platforms rather than reliance on a single proprietary system.

QIAGEN offers a portfolio of diagnostic solutions focused on reproductive health and disease prevention. This includes the PartoSure test, a rapid point-of-care assay used to assess the risk of spontaneous preterm birth in symptomatic patients. The test detects placental alpha-microglobulin-1 (PAMG-1) and provides rapid results using a noninvasive sampling procedure, supporting clinical decision-making in obstetric care.

PartoSure is part of QIAGEN's broader sexual and reproductive health portfolio, which also includes the AmniSure ROM Test for the detection of rupture of membranes and the Digene HC2 HPV Test for cervical cancer screening. In addition, QIAGEN supports non-invasive prenatal testing and broader genomic applications through its sample collection technologies and bioinformatics capabilities, positioning the company as an enabling partner in molecular diagnostics workflows rather than a primary provider of NIPT assays.

Next-Generation Sequencing

QIAGEN has expanded its next-generation sequencing (NGS) and bioinformatics portfolio offering applications in rare and inherited diseases through its QIAGEN Clinical Insight (QCI) platform. QCI provides advanced data interpretation and decision-support tools as part of an integrated "Sample to Insight" workflow, enabling analysis of genomic data generated from sequencing assays. The platform incorporates curated knowledge bases such as the Human Gene Mutation Database (HGMD), supporting identification of clinically relevant variants and inheritance patterns, and has continued to evolve as a key component of QIAGEN's precision medicine strategy.

QIAGEN has also developed a range of NGS library preparation and enrichment solutions under its QIAseq portfolio. These include technologies such as QIAseq FastSelect for efficient removal of ribosomal RNA, as well as expanded targeted DNA and RNA panels designed for oncology and rare disease applications. The company has introduced workflow-enhancing solutions such as normalization kits that simplify library preparation and improve consistency across samples, supporting automation and high-throughput sequencing environments.

More recently, QIAGEN has expanded its capabilities in advanced sequencing applications with the introduction of QIAseq xHYB Long Read Panels, designed to support long-read sequencing technologies and enable more comprehensive analysis of complex genomic regions and structural variants. In addition, RNA sequencing solutions such as the UPXome library kits support transcriptome analysis and gene expression profiling, further broadening the company's NGS portfolio.

Liquid Biopsy

QIAGEN has established a strong position in liquid biopsy by focusing on enabling technologies that support non-invasive genomic profiling of cancer. The company provides a comprehensive portfolio of solutions for the analysis of circulating biomarkers, including cell-free DNA (cfDNA), RNA, and extracellular vesicles. Rather than offering a single end-to-end diagnostic test, QIAGEN's strategy centers on providing integrated workflows that support sample collection, stabilization, purification, and downstream molecular analysis across multiple platforms.

A core component of QIAGEN's liquid biopsy portfolio is its sample preparation technology, including the QIAamp Circulating Nucleic Acid Kit, which is widely used for the isolation of circulating DNA and RNA from plasma. This is complemented by the PAXgene Blood ccfDNA Tube, which enables the collection and stabilization of whole blood samples while preserving circulating nucleic acid profiles during transport and storage. The continued expansion of PAXgene technology into both oncology and prenatal applications underscores its role as a key pre-analytical solution for liquid biopsy workflows. Together with automated processing on platforms such as QIAsymphony, these technologies provide a standardized workflow that supports reliable downstream molecular testing.

QIAGEN has also developed integrated solutions for next-generation sequencing–based liquid biopsy analysis. These include workflows that combine cfDNA extraction, library preparation, and targeted sequencing using QIAseq technologies, along with associated bioinformatics tools for data analysis and interpretation. Recent developments include expanded support for advanced sequencing approaches, such as long-read technologies, which enable improved analysis of complex genomic regions and structural variants.

In addition to cfDNA-based approaches, QIAGEN offers solutions for the analysis of extracellular vesicles and RNA biomarkers, including kits for exosome isolation and total RNA purification from biofluids such as plasma and urine. These technologies support emerging multi-analyte liquid biopsy applications in cancer research and biomarker discovery.

Cervical Cancer

QIAGEN is a global provider of HPV screening technologies, with a portfolio that spans both established and emerging molecular approaches to cervical cancer screening. The company has developed solutions for use in a wide range of settings, from high-throughput clinical laboratories to low-resource environments. Its careHPV test supports cervical cancer screening programs in resource-limited regions, while its broader molecular portfolio addresses increasing demand for more precise risk stratification and early detection.

QIAGEN has expanded its HPV testing portfolio with PCR-based assays such as the QIAscreen HPV PCR Test, which detects multiple high-risk HPV genotypes associated with cervical cancer. The assay supports both screening and genotyping and is designed for use with clinician-collected and self-collected samples, reflecting growing adoption of self-sampling approaches in cervical cancer screening programs. The test is compatible with

QIAGEN's PCR workflows, including Rotor-Gene Q systems and other open-platform configurations.

In addition, QIAGEN offers advanced molecular solutions, such as methylation-based assays, to support risk stratification following a positive HPV test. These technologies enable the identification of patients at higher risk of progressing to cervical cancer, supporting more personalized screening and follow-up strategies.

The company's established digene Hybrid Capture 2 (HC2) HPV Test remains widely used in screening programs, particularly in settings where established workflows are in place. However, QIAGEN's strategy has shifted toward expanding PCR-based and molecular testing solutions that offer improved sensitivity, specificity, and genotyping capabilities.

Expansion

QIAGEN continues to expand its portfolio through a combination of internal development and strategic partnerships, particularly in precision medicine and immuno-oncology. The company has entered into collaborations to advance companion diagnostics and biomarker discovery, including agreements granting access to technologies for profiling T-cell and B-cell receptor repertoires via next-generation sequencing. These capabilities augment the development of immune-based diagnostics and enhance QIAGEN's position in immuno-oncology research.

QIAGEN has also strengthened its global infrastructure, including by expanding its development and manufacturing footprint. The establishment of advanced facilities in the United Kingdom supports ongoing innovation in molecular diagnostics and assay development, reinforcing the company's role in global diagnostic innovation.

The company is building partnerships in precision oncology, including collaborations to advance companion diagnostics and integrated testing solutions. These efforts include the development of assays for use in both laboratory-developed and kit-based formats, supporting broader adoption of biomarker-driven therapies.

QIAGEN has also expanded its geographic presence, including initiatives to strengthen its footprint in the Middle East, where it supports public health programs such as tuberculosis screening through the deployment of QuantiFERON-based testing solutions.

Recent product developments include continued expansion of the QIAstat-Dx syndromic testing platform, including the introduction of targeted gastrointestinal panels designed to detect a defined set of clinically relevant pathogens. These smaller panel configurations complement broader multiplex assays and reflect increasing demand for flexible, cost-effective syndromic testing.

In addition, QIAGEN has expanded its collaborations in molecular diagnostics and precision oncology, including partnerships to develop next-generation sequencing–based panels for hematologic malignancies and to advance digital PCR–based oncology assays. These efforts combine QIAGEN's expertise in sample preparation, molecular technologies, and digital PCR platforms with partner capabilities in assay development, supporting both tissue- and liquid biopsy–based applications.

QuidelOrtho Corporation

San Diego, CA

www.quidelortho.com

Table 14-15: QuidelOrtho Revenue History, 2023-2025 ($ million)

	2023	2024	2025
Total revenues	2,999	2,782	2,732

Source: company reports, Kalorama Information

Labs revenue increased 6% compared to 2024 due to growth in reagents, consumables and services. However, instrument revenue declined. Immunohistology revenues increased due to reagent growth. Donor screening decreased 54% due to the wind-down of the U.S. donor screening business. POC revenue decreased 13% due to the decrease in sales of QuikVue SARS and Sofia SARS Antigen assays. Molecular diagnostics increased 10%, driven by higher SAVANNA revenue.

The following is a breakdown of QuidelOrtho's revenues as provided by the company.

Table 14-16: QuidelOrtho Diagnostic Revenues, by Segment, 2023-2025 ($ million, estimated)

Segment	2023	2024	2025	YoY Growth 2024-2025
Core Lab	1,426	1,427	1,506	5.6%
Point of Care	892	694	602	-13.3%
Donor Screening	136	115	53	-53.9%
Immunohematology	512	522	544	4.2%
Molecular	33	24	27	12.5%
Total	**2,999**	**2,782**	**2,732**	**-1.8%**

Source: Kalorama Information

QuidelOrtho Corporation markets a broad portfolio of diagnostic products spanning infectious disease, women's health, cardiac biomarkers, gastrointestinal testing, immunohematology, and clinical laboratory diagnostics. Since the merger of Quidel and Ortho Clinical Diagnostics, the company has expanded from a primarily rapid-test business into a diversified diagnostics supplier serving physician offices, hospitals, urgent care centers, clinical laboratories, reference laboratories, retail clinics, and wellness screening programs. Its strongest region is the United States through direct sales and distributor networks, while international sales continue across Europe, Japan, Latin America, and selected Asia Pacific markets, with respiratory testing, cardiac biomarkers, and laboratory automation remaining major growth drivers.

In 2025, QuidelOrtho announced a strategic shift in its molecular diagnostics strategy, discontinuing development of its Savanna platform and instead planning to acquire LEX Diagnostics following FDA clearance. The LEX system is designed to deliver ultra-fast PCR-based molecular testing for respiratory infections in decentralized healthcare settings. At the same time, the company continues to expand the test menu available on its VITROS laboratory platforms and strengthen its position across point-of-care testing, core laboratory diagnostics, and transfusion medicine.

Immunoassays

QuidelOrtho Corporation markets a broad mix of point-of-care and laboratory immunoassays across rapid-testing and core laboratory platforms. Its rapid immunoassay brands include QuikVue, Sofia 2, D3 Direct Detection, and Thyretain. These tests for influenza, RSV, SARS-CoV-2, Group A Strep, fecal occult blood, pregnancy, thyroid disease, bacterial vaginosis, infectious mononucleosis, HSV, H. pylori, and selected sexually transmitted infections. The Sofia platform is the company's leading POC patient immunoassay system, with respiratory testing continuing to drive major volume.

QuidelOrtho offers VITROS XT 7600, VITROS 5600, VITROS 4600, and VITROS 3600 in the core laboratories for chemistry, immunodiagnostics, and integrated testing. The VITROS menu provides routine chemistry, special chemistry, proteins, therapeutic drug monitoring, toxicology, endocrine assays, infectious disease serology, cardiology markers, and oncology immunoassays. Enhanced chemiluminescence is paramount to the immunodiagnostic systems, supporting tests in thyroid function, reproductive endocrinology, anemia,

metabolism, infectious disease, and tumor markers, including CA125, CEA, alpha-fetoprotein, and CA15-3.

The company is expanding through its MicroTip Partnership Assay program, which allows third-party assays to run on VITROS analyzers through collaborations with Diazyme Laboratories, ARK Diagnostics, and Sekisui Diagnostics. This program adds esoteric assays such as free light chains for plasma cell disorders, D-dimer, toxicology assays including fentanyl, and specialty chemistry assays without requiring QuidelOrtho to internally develop every assay.

QuidelOrtho offers the VITROS High Sensitivity Troponin I Assay, which supports rapid rule-out and rule-in of myocardial infarction across multiple VITROS systems. The VITROS NT-proBNP II Assay is designed for heart failure assessment, while the VITROS NEPHROCHECK is an automated urinary biomarker test for acute kidney injury risk using TIMP-2 and IGFBP-7 biomarkers. Infectious disease immunoassays remain broad and include hepatitis B markers, HIV combination testing, syphilis serology, and other blood-borne infection assays across automated VITROS systems.

Rapid Immunoassays

QuidelOrtho markets a broad point-of-care immunoassay portfolio built around the Sofia 2 platform, which is one of the company's most important near-patient testing systems. Earlier acquisitions, such as the ocular diagnostics products acquired from RPS Diagnostics, remain part of QuidelOrtho's specialty rapid test portfolio, including InflammaDry, which detects elevated MMP-9 as an inflammatory marker associated with dry eye disease, and AdenoPlus, which helps differentiate adenoviral conjunctivitis from other causes of acute conjunctivitis. These products are FDA-cleared and support ophthalmology office testing, although they represent a smaller specialty segment compared with respiratory diagnostics.

The Sofia platform has evolved into QuidelOrtho's core fluorescent immunoassay system for POC testing, combining fluorescent lateral flow chemistry, automated interpretation, connectivity, barcode scanning, and electronic reporting. Compared with visually read lateral flow assays, Sofia provides instrument-read results that reduce subjective interpretation and improve consistency. Virena continues to provide real-time de-identified reporting from connected Sofia analyzers, supporting infectious disease surveillance across healthcare networks.

Current Sofia testing is heavily concentrated in respiratory disease, including influenza A+B, RSV, SARS-CoV-2, Group A Strep, and combination respiratory panels. The Sofia 2 SARS Antigen FIA is one of the best-known antigen assays on the platform and was notable as the first COVID-19 antigen assay to receive de novo authorization through the FDA's traditional review pathway. QuidelOrtho also markets the CLIA-waived QuickVue COVID-19 Test, which received expanded FDA clearance for both home and professional use and remains part of its OTC respiratory strategy.

Additionally, Sofia provides specialty assays, including Lyme disease testing through Sofia Lyme FIA and Sofia 2 Lyme+ FIA, as well as Sofia Vitamin D FIA, which is one of the few quantitative assays on the Sofia platform. Earlier menus also included Legionella and pneumococcal antigen testing, supporting decentralized infectious disease diagnosis.

QuidelOrtho offers the Triage MeterPro business, including the Triage True High-Sensitivity Troponin I Test for rapid assessment of myocardial infarction in emergency and POC settings. This fluorescence immunoassay provides results in approximately 20 minutes and strengthens QuidelOrtho's position in acute care diagnostics.

The company has continued to integrate specialty assay collaborations into its broader menu. The 2025 collaboration with BÜHLMANN Laboratories added fecal assays, including fCAL turbo and fecal pancreatic elastase testing, to automated laboratory systems to support inflammatory bowel disease differentiation and pancreatic insufficiency assessment.

The Solana Business

QuidelOrtho offers the AmpliVue non-instrumented system for lower-volume, moderately complex labs, and Lyra reagents for higher throughput, highly complex laboratories that are compatible with existing PCR infrastructure.

The Solana molecular platform leverages QuidelOrtho's Helicase-Dependent Amplification (HDA) technology, and in some tests a Reverse-Transcriptase HDA that is resident in QuidelOrtho's AmpliVue molecular product line to generate a fast test result. Solana can process up to 12 patient samples in each 45-minute run.

The Solana molecular platform processes up to 12 different assays or samples in each batched run, and the menu for the instrument also includes Quidel's Influenza A+B, Strep

Complete (Groups A+C/G), RSV+hMPV, HSV 1+2/VZV, Trichomonas, and C. difficile tests.

QuidelOrtho provides the Solana RSV + hMPV assay, which can detect and differentiate between respiratory syncytial virus and human metapneumovirus. The assay detects viral RNA from nasal and nasopharyngeal swabs and runs on the firm's Solana molecular testing instrument. It requires no upfront RNA extraction and yields results in approximately 45 minutes. The RSV and hMPV assay also uses a novel reverse-transcriptase HDA that is used in Quidel's AmpliVue molecular product line to generate fast and accurate test results

QuidelOrtho markets its Solana GBS Assay for the direct, qualitative detection of Group B Streptococcus from enriched broth cultures of specimens from antepartum women. The Solana GBS Assay is an easy-to-use molecular diagnostic test that generates accurate results from either LIM or Carrot enrichment broth cultures of vaginal/rectal swabs from antepartum women after 18 to 24 hours of incubation.

QuidelOrtho also markets the Solana Bordetella Complete Assay, a molecular diagnostic assay to detect bacterial strains that cause whooping cough. The assay also detects and differentiates Bordetella pertussis and Bordetella parapertussis in nasopharyngeal swabs. The test runs on QuidelOrtho's Solana system, which uses helicase-dependent amplification and processes up to 12 samples per batched run.

Blood Bank

QuidelOrtho is one of the major global suppliers in transfusion medicine, building on more than 75 years of immunohematology development dating back to early blood typing innovations under the Ortho Clinical Diagnostics legacy. The company provides blood bank automation, serology reagents, and transfusion workflow software, serving hospitals, donor centers, and reference laboratories worldwide. Its transfusion medicine portfolio focuses on blood grouping, antibody screening, compatibility testing, donor typing, and extended antigen phenotyping, with ongoing emphasis on laboratory automation, workflow standardization, and blood safety.

The company markets ORTHO Sera blood-grouping reagents for extended-phenotype testing, maintaining one of the broadest antisera menus available to immunohematology laboratories in the United States. These reagents support detailed antigen characterization beyond routine ABO/Rh typing and remain important in complex transfusion cases, antibody

investigations, and rare donor matching. Extended phenotyping is increasingly relevant as laboratories seek better compatibility for chronically transfused patients, including oncology and sickle cell populations.

ORTHO VISION and ORTHO VISION Max are flagship immunohematology analyzers for blood typing, antibody screening, crossmatching, and donor testing. These systems support gel-based automation, reduce manual handling, and improve consistency in transfusion laboratories. QuidelOrtho continues to expand software integration through ORTHO CONNECT, which centralizes workflows across multiple instruments and hospital sites while enabling a single, validated integration with laboratory information systems. ORTHO CONNECT remains strategically important because blood bank laboratories increasingly require centralized oversight, remote result review, and standardized data handling across healthcare networks.

QuidelOrtho is focusing on strengthening automation in rare antigen phenotyping and advanced blood bank workflow efficiency. These areas expected to remain important as transfusion services face staffing shortages and increasing complexity of compatibility testing.

Radiometer A/S / Danaher

Copenhagen, Denmark

www.radiometer.com

Radiometer, founded in 1935, is a global pioneer in acute care diagnostics and blood gas analysis. The company introduced the world's first commercially available blood gas analyzer in 1954, and it continues to be one of the strongest global suppliers of acute care testing systems used in hospitals, emergency departments, intensive care units, operating rooms, and clinical laboratories in more than 130 countries.

Radiometer develops, manufactures, and markets solutions for blood gas analysis, blood sampling, acute care immunoassays, transcutaneous monitoring, and related IT management systems. Its major brands include ABL90 FLEX PLUS, ABL800 FLEX, AQT90 FLEX, TCM5 FLEX, AQURE, PICO, CLINITUBES, and QUALICHECK. Through ownership of HemoCue, Radiometer also provides decentralized hemoglobin and glucose testing.

The company is a leader in acute care workflow automation, with its ABL analyzers designed to rapidly deliver blood gas, electrolytes, metabolites, and co-oximetry parameters directly at the point of care. Ongoing development has focused on faster cartridge handling, enhanced usability, and improved connectivity, as well as tighter integration with hospital information systems via the established AQURE platform. AQURE provides centralized management of quality control, operator competency, and device oversight across distributed testing environments, supporting compliance and standardization. These capabilities have become increasingly important as hospitals seek to manage growing networks of point-of-care devices under unified quality and data governance frameworks.

Radiometer offers transcutaneous monitoring through its TCM platform, which enables noninvasive measurement of oxygen and carbon dioxide using skin-based sensors. These systems remain particularly important in neonatal intensive care, as well as in respiratory and selected critical care applications where continuous monitoring is required without repeated blood sampling. Ongoing enhancements focus on improving connectivity and interoperability with bedside monitoring systems and the hospital information infrastructure, enabling transcutaneous data to be more effectively integrated into patient monitoring workflows and clinical decision-making.

The AQT platform is offered for rapid cardiac and inflammatory markers in emergency settings, including troponin, D-dimer, CRP, and NT-proBNP.

Critical Care

Radiometer focuses on delivering laboratory-quality acute-care testing at the point of care through cassette-based analyzers, integrated blood-sampling systems, and centralized IT connectivity. Radiometer's operations in Denmark are through Radiometer Medical ApS. The company's strategy emphasizes rapid critical care testing with minimal operator complexity, especially in ICUs, NICUs, emergency departments, operating rooms, and decentralized hospital testing sites.

Its flagship blood gas systems is the ABL90 FLEX PLUS and ABL800 FLEX platforms. The ABL90 FLEX PLUS continues to be one of the most advanced compact blood gas analyzers in acute care, measuring up to 19 parameters from only 65 µL of whole blood in approximately 35 seconds. Its menu includes blood gases, electrolytes, metabolites, co-oximetry, bilirubin, creatinine, and urea, making it one of the broadest compact critical care menus available. This wide panel is especially valuable because clinicians can obtain renal function markers such as creatinine and urea directly at the bedside, together with immediate blood gas results, reducing delays in acute decision-making.

The ABL800 FLEX PLUS is Radiometer's major platform, providing up to 18 STAT parameters on a single sample with high-throughput automated handling and Drop'n Go functionality that allows staff to load samples and go. This is highly valuable in emergency departments and larger critical care laboratories where rapid throughput and minimal staff interruption are important. Smaller systems such as ABL80 FLEX and ABL9 are used by lower-volume departments and satellite testing locations, with ABL9 particularly suited to critical care units that perform only limited daily blood gas volumes.

The company's TCM5 is a product for neonatal, pediatric, adult, sleep, and respiratory monitoring. The system continuously measures transcutaneous oxygen and carbon dioxide along with pulse oximetry, perfusion index, and pulse rate using integrated Masimo technology. The TCM5 FLEX version is particularly important in neonatal intensive care because it allows continuous respiratory assessment without repeated blood draws, while the TCM5 BASIC version is used more frequently in sleep clinics and home respiratory care.

Radiometer has expanded digital clinical support through collaboration with Etiometry. The partnership, first launched in 2022 and expanded commercially in 2024, remains active and focuses on integrating acute care analyzer data with predictive clinical decision-support tools, especially in neonatal intensive care and other high-acuity hospital settings. This reflects Radiometer's broader strategy of moving beyond analyzers alone toward integrated acute care decision support and workflow optimization.

Immunoassays

Radiometer entered the immunoassay market through its 2006 acquisition of Innotrac Diagnostics, which provided the core technology behind Radiometer's acute care immunoassay platform. That acquisition introduced proprietary dry chemistry and time-resolved fluorescence capabilities that remain central to the AQT90 FLEX system. Since its launch, AQT90 FLEX has become one of the company's most important acute care immunoassay platforms, designed for both near-patient and laboratory use where rapid quantitative biomarker testing is needed.

The AQT90 FLEX fully automates the immunoassay process from whole blood aspiration through reagent handling, incubation, fluorescence detection, and result generation, minimizing manual preparation and allowing quantitative results directly from whole blood in approximately 11 to 21 minutes, depending on the assay. The analyzer remains widely used in emergency departments, chest pain units, and critical care settings because it delivers laboratory-quality quantitative results without requiring centrifugation or extensive sample preparation.

The current test menu includes major acute care biomarkers such as troponin I, CK-MB, myoglobin, NT-proBNP, CRP, β-hCG, D-dimer, procalcitonin, and creatinine. These assays support rapid assessment of myocardial infarction, heart failure, thromboembolic disease, infection, pregnancy-related emergencies, and renal function in acute care environments. Recent clinical emphasis has increasingly centered on cardiac biomarkers, inflammatory markers, and sepsis support, where rapid decision-making is essential.

The AQT90 FLEX PCT remains particularly important because it provides quantitative procalcitonin measurement directly from whole blood or plasma without prehandling, supporting early sepsis evaluation and antibiotic stewardship programs. Results are available in under 21 minutes, allowing faster clinical intervention in emergency and intensive care settings. Creatinine testing on the AQT90 FLEX also adds renal assessment capability,

helping broaden the analyzer's role in acute care decision-making beyond traditional cardiac testing. Overall, Radiometer's immunoassay business continues to complement its blood gas franchise by adding rapid biomarker analysis to critical care workflows.

HemoCue

HemoCue is a global provider of point-of-care hemoglobin testing, particularly through the widely used HemoCue Hb 201+ Analyzer, which remains extensively deployed in hospitals, blood donation centers, maternal health programs, field screening initiatives, and community anemia programs worldwide. As part of Radiometer, HemoCue offers decentralized testing that delivers laboratory-quality hemoglobin results from capillary, venous, or arterial blood within seconds, supporting both clinical diagnosis and public health screening.

To strengthen digital anemia management, HemoCue offers HealthTrender Anemia, a connected solution designed for real-time population monitoring and program management. The system uses the HemoCue BT Connect, attached to the Hb 201+ Analyzer, enabling Bluetooth transfer of hemoglobin results to a mobile application. Users can add demographic and anthropometric information such as age, gender, location, weight, and height, after which data are uploaded securely to a cloud-based platform. Offline functionality remains important for rural and field programs because results are stored locally until connectivity is restored, preventing loss of screening data.

The HealthTrender web platform provides dashboards, statistical reporting, and program analytics, making it especially valuable for ministries of health, NGOs, and large anemia surveillance programs where rapid field data aggregation is essential. This digital integration has strengthened HemoCue's role beyond single-patient testing by supporting broader anemia intervention programs, particularly in maternal and child health and nutritional surveillance.

HemoCue's 2024 collaboration with Novo Nordisk, provided placement of HemoCue's HbA1c 501 systems in more than 400 clinics across approximately 30 countries in Africa, Latin America, and Southeast Asia. This initiative focuses on improving access to point-of-care HbA1c testing for children with type 1 diabetes, expanding HemoCue's role from anemia screening into diabetes monitoring in underserved healthcare settings. Together, these developments reinforce HemoCue's position as a major provider of decentralized hematology and metabolic point-of-care diagnostics

Transcutaneous Monitoring

Radiometer Medical ApS partnered with Perimed AB to accelerate and expand the distribution of the Perimed PeriFlux 6000 tcp02 standalone system. The PeriFlux 6000 tcp02 standalone system is the latest generation of transcutaneous monitoring systems and will be an addition to Radiometer's portfolio, designed to provide non-invasive measurements of oxygenation status. The PeriFlux 6000 tcp02 standalone system provides health care professionals with a reliable, easy-to-use tool to support wound-healing predictions and will replace Radiometer's TCM400. The partnership is active and longstanding.

Revvity

Waltham, MA

www.revvity.com

Table 14-17: Revvity Revenue History, 2023-2025 ($ million, estimated)

	2023	2024	2025
Total Diagnostics	1,458	1,356	1,431

Source: company reports, Kalorama Information

Diagnostic revenue for 2025 increased $75 million due to an increase in immunodiagnostics and an increase in reproductive health revenue.

Revvity, Inc. is a global provider of health science technologies and services headquartered in Waltham, Massachusetts, with approximately 11,000 employees. The company operates through two primary segments, Life Sciences and Diagnostics, following the strategic transformation of its legacy PerkinElmer portfolio. Revvity's Diagnostics business is focused on reproductive health, newborn screening, infectious disease testing, autoimmune diagnostics, and selected genomic applications, supported by a broad portfolio of instruments, reagents, assay platforms, and informatics solutions. The company maintains a strong leadership position in prenatal and newborn screening, with platforms such as the DELFIA Xpress system that support first- and second-trimester screening workflows and are integrated with LifeCycle software for data interpretation and laboratory management. Revvity continues to expand this leadership in 2026 through growth in multiplex newborn screening, particularly with assays such as the EONIS SCID-SMA test and the EONIS Q system, which streamline high-throughput molecular screening in public health laboratories.

Through its EUROIMMUN business, Revvity has strengthened its position in autoimmune and infectious disease diagnostics by offering advanced immunofluorescence and immunoassay solutions. The EUROPattern system, used with IFA Mosaic assays, enables automated digital interpretation of antibody patterns such as ANCA, supporting the diagnosis of autoimmune diseases, including vasculitis. EUROIMMUN's BIOCHIP technology

enables multiplex detection in a single reaction field, allowing simultaneous pattern recognition and monospecific confirmation of antibodies such as PR3, MPO, and GBM. These capabilities are further enhanced by automation and AI-assisted image analysis, reflecting Revvity's broader 2026 strategy of embedding artificial intelligence into diagnostic workflows to improve accuracy, standardization, and laboratory efficiency. Additionally, the company continues to expand its specialty immunodiagnostics portfolio through chemiluminescence and ELISA-based assays across endocrinology, autoimmune disease, infectious disease, and neurology, supported by platforms such as the IDS i20 random-access analyzer, which enables multi-disciplinary testing on a single system.

In molecular and genomics workflows, Revvity offers automated sample preparation solutions through its Chemagic platform portfolio, including the Chemagic 360 and the integrated Chemagic Prime system. These platforms automate nucleic acid for PCR and next-generation sequencing applications, utilizing magnetic rod-based separation to improve yield and consistency across a wide range of sample types. In 2026, Revvity has further expanded its automation strategy by introducing new intelligent liquid-handling and workflow solutions, including compact systems designed to increase flexibility, reduce manual intervention, and support scalable laboratory operations. These developments reinforce the company's focus on fully automated, sample-to-answer workflows aligned with the needs of high-throughput and decentralized testing environments.

Revvity also maintains a strong presence in infectious disease diagnostics through products such as the T-SPOT.TB test, an interferon-gamma release assay used for the detection of latent tuberculosis infection. The company has enhanced automation of this workflow with liquid-handling platforms such as the Auto-Pure 2400 system, improving throughput and reproducibility in clinical laboratories. Across its diagnostics portfolio, Revvity is increasingly aligning with precision medicine by expanding into companion diagnostics and collaborating with biopharmaceutical partners, while also advancing digital and informatics capabilities through its software platform.

Roche Diagnostics

Indianapolis, IN

www.roche.com

Table 14-18: Roche Revenue History, 2023-2025 (CHF million)

	2023	2024	2025
Roche Diagnostics	14,451	14,324	13,847

Source: company reports, Kalorama Information

In 2025, Roche Diagnostics reached revenues of CHF 13,847 million.

Table 14-19: Roche Diagnostic Revenues, by Segment, 2023-2025 (CHF million)

Segment	2023	2024	2025	YoY Growth 2024-2025
Core Lab	7,750	8,004	7,614	-4.9%
Molecular Lab	2,567	2,590	2,527	-2.4%
Near Patient Care	2,746	2,167	1,983	-8.5%
Pathology Lab	1,388	1,563	1,723	10.2%
Total	**14,451**	**14,324**	**13,847**	**-3.3%**

Source: company reports, Kalorama Information

For the full year of 2025, Roche Diagnostics revenues decreased by -3% in CHF. North American sales increased 9% in 2025; EMEA sales increased 6% in 2025. Asia Pacific sales decreased by 12%, and Latin American sales increased by 11% in 2025.

Roche is the global leader in clinical diagnostics, maintaining a significant lead over competitors with revenues that continue to exceed those of other major IVD companies by a

wide margin. The company holds a dominant position across core laboratory diagnostics, molecular testing, and tissue-based cancer diagnostics through its Roche Diagnostics and Roche Tissue Diagnostics divisions. Roche is also a key player in personalized healthcare, integrating diagnostics with therapeutics to support targeted treatment strategies, particularly in oncology and chronic disease management. Its long-standing leadership in diabetes care, despite increased competition from continuous glucose monitoring (CGM) specialists, is supported by its Accu-Chek franchise and ongoing investments in next-generation glucose monitoring technologies.

In point-of-care testing, Roche strengthened its decentralized diagnostics strategy through the acquisition of select assets from LumiraDx, focused on POC platform technology. This move enhances Roche's ability to deliver rapid, near-patient testing solutions across immunoassay and clinical chemistry applications, aligning with the broader industry shift toward decentralized care and faster clinical decision-making. The integration of LumiraDx's technology is expected to expand Roche's footprint in urgent care settings, physician offices, and community-based testing environments.

Roche is investing in its diagnostics and diabetes care infrastructure, including its established manufacturing and operations in Indianapolis, a key North American hub. The company maintains large-scale production of Accu-Chek blood glucose monitoring products and continues to enhance its capabilities through investments in automation, digital connectivity, and integrated diabetes management solutions. While Roche is actively developing and evaluating continuous glucose monitoring technologies through partnerships and internal innovation, it has not established large-scale CGM manufacturing in the United States. Its current strategy emphasizes connected care platforms, data integration, and expansion of its core glucose monitoring portfolio rather than major standalone CGM production facilities.

Roche continues to advance its diagnostics portfolio by increasing its focus on automation, digital integration, and menu expansion across molecular and immunodiagnostics platforms. The company is expanding the use of AI and data-driven tools to enhance workflow efficiency, particularly in digital pathology and clinical decision support. Roche's strategy concentrates on connecting diagnostics with therapeutics, reinforcing its leadership in personalized medicine while continuing to scale both centralized laboratory systems and decentralized testing solutions.

Hematology

Roche's cobas m 511 integrated digital hematology analyzer is a system that consolidates multiple steps of the complete blood count (CBC) process into a single automated workflow. The platform brings together cell counting, digital morphology, and classification, minimizing the need for manual slide preparation and microscopic review. Automating smear preparation, staining, imaging, and analysis enables laboratories to improve operational efficiency while maintaining consistent and reproducible results across routine and more complex testing environments.

The system uses Roche's digital morphology approach to capture high-resolution images of blood cells and apply advanced analytical algorithms to identify and classify white blood cells, red blood cells, and platelets. It provides a full CBC with 5-part differential and reticulocyte count, along with detailed morphological evaluation that traditionally required manual microscopy. This digitized workflow provides remote review, standardized interpretation, and improved traceability, which are increasingly important for quality control and multi-site laboratory operations.

Roche continues to advance the cobas m 511 through software and connectivity enhancements that align with its broader laboratory automation strategy. Improved integration with laboratory information systems and automation solutions provides more efficient data handling and workflow coordination within centralized laboratories. Ongoing refinement of algorithm-based classification and decision-support tools is further strengthening the system's role in AI-assisted hematology, helping laboratories address growing test volumes and staffing challenges while maintaining diagnostic reliability.

Immunoassays

Roche's cobas and Elecsys immunoassay portfolio sports one of the most comprehensive centralized IVD testing platforms, covering a broad range of clinical areas including infectious disease, cardiology, oncology, fertility and maternal health, endocrinology, neurology, bone and rheumatoid markers, and critical care. The menu is built on Roche's electrochemiluminescence (ECL) technology, which is widely used for its high sensitivity, precision, and scalability across laboratory settings. These assays run on Roche's cobas e systems, including the cobas e 402, cobas e 801, and cobas pro integrated solutions, supporting testing from mid-volume laboratories to high-throughput core lab environments.

Roche's infectious disease immunoassays, offers a broad serology and antigen/antibody testing menu that includes hepatitis A, B, and C, HIV, syphilis, HSV, CMV, rubella, toxoplasma, and HTLV. Advanced assays such as Elecsys HCV Duo and HIV combination tests enable simultaneous detection of antigens and antibodies, improving early detection and diagnostic accuracy. In critical care, the Elecsys BRAHMS PCT assay continues to provide sepsis risk assessment and antibiotic stewardship, while Roche's cardiac menu includes high-sensitivity troponin assays designed for rapid and precise detection of myocardial injury.

Roche's high-throughput immunoassay capability is represented by systems such as the cobas e 801 module, which delivers high testing capacity with a large number of onboard reagents, enabling laboratories to consolidate testing and improve operational efficiency. The company continues to enhance workflow automation, reagent management, and system connectivity, supporting integration into fully automated laboratory environments.

Roche has expanded its immunoassay portfolio in neurology with the introduction of blood-based Alzheimer's biomarkers, including the Elecsys pTau181 plasma assay to identify amyloid pathology and the Elecsys ApoE4 test to assess genetic risk. It tests for These assays complement existing cerebrospinal fluid (CSF) tests, such as beta-amyloid and phosphorylated tau, and reflect a broader shift toward minimally invasive, high-throughput testing that can be performed on existing cobas e platforms. This transition toward blood-based biomarkers supports earlier detection and wider clinical adoption of neurodegenerative disease testing.

The company also offers the Elecsys Neurofilament Light Chain (NfL) test, a blood test that detects neuroaxonal damage associated with neuroinflammation. It is a quantitative immunoassay that measures neurofilament light chain protein concentrations in plasma. The test is CE marked and is performed on the cobas instruments. The test aims to deliver reliable insights into relapsing-remitting multiple sclerosis

Roche has also strengthened its women's health testing portfolio, including the Elecsys sFlt-1/PlGF ratio, which is used to assess the risk of preeclampsia and support clinical decision-making in pregnancy management. In fertility testing, assays such as anti-Müllerian hormone (AMH) continue to be widely used to evaluate ovarian reserve.

HIV

Roche is focusing on improving access, automation, and clinical monitoring across both centralized and decentralized settings. The cobas Plasma Separation Card, an important component of this strategy, enables the collection of small blood samples via fingerstick for HIV viral load testing without the need for cold-chain transport. This approach provides access to quantitative HIV-1 testing in remote and resource-limited settings, while maintaining compatibility with Roche's high-throughput molecular systems, including the cobas 6800 and cobas 8800 platforms. The card also provides expanded access to testing through global health programs and aligns with ongoing efforts to improve early diagnosis and viral load monitoring.

Roche's HIV molecular testing portfolio features its automated PCR-based systems, particularly the cobas 6800/8800 platforms, which provide high-throughput, fully integrated sample-to-result viral load testing. These systems offer large-scale screening and treatment-monitoring programs, delivering consistent, standardized results across centralized laboratories. In 2025 and 2026, Roche has further strengthened this offering with enhancements to system performance, workflow flexibility, and connectivity, along with continued use of dual-target HIV-1 viral load assays designed to improve detection across diverse viral subtypes.

Roche has also expanded its HIV assay menu by adding a qualitative nucleic acid test that detects and differentiates HIV-1 and HIV-2, supporting earlier diagnosis and improved clinical decision-making. This complements Roche's established immunoassay portfolio, including combination antigen and antibody tests that enable early detection of infection and are widely used in screening and diagnostic settings.

Roche's broader HIV strategy emphasizes integrated solutions that combine innovative sample collection methods, high-throughput molecular testing, and sensitive immunoassays. The company continues to support global access initiatives and public-private partnerships aimed at expanding HIV testing, improving linkage to care, and enabling effective monitoring of treatment response.

Molecular Expansion

Roche has expanded its molecular diagnostics portfolio through the integration of the former GenMark ePlex platform, now marketed as the cobas eplex system. The system provides

automated, sample-to-answer multiplex testing with integrated quality control and data management, supporting syndromic panels for respiratory and bloodstream infections. Its test menu includes panels that can identify a broad range of bacterial and viral pathogens, as well as key antimicrobial resistance markers, enabling faster, more targeted treatment decisions, particularly in sepsis and acute care settings.

A major area of innovation in 2025 and 2026 is Roche's introduction of TAGS (temperature-activated generation of signal) technology, which enables greater multiplexing within existing PCR systems. The first implementation of this technology has been applied to respiratory testing with assays such as the cobas Respiratory 4-flex and expanded cobas Respiratory flex tests, which allow simultaneous detection of multiple respiratory viruses, including SARS-CoV-2, influenza A and B, and RSV, along with additional respiratory targets. These assays are designed to run on the cobas 5800, 6800, and 8800 systems, allowing laboratories to scale testing from routine to high-throughput environments while maintaining consistent assay performance.

Roche's current molecular strategy is a move toward flexible, customizable multiplex testing. Laboratories can tailor testing panels based on clinical needs, seasonal trends, or patient populations, while digital reflex capabilities enable additional targets to be analyzed automatically from the same sample, without requiring repeat sample collection or processing. This approach improves workflow efficiency, reduces unnecessary testing, and supports faster clinical decision-making.

Additionally, Roche expanded the clinical utility of the cobas eplex system by introducing broader syndromic panels and enhanced pathogen coverage, including improved detection of bloodstream infections and integrated antimicrobial resistance marker identification. The system is positioned to support faster turnaround times in acute care environments, complementing Roche's high-throughput molecular platforms.

Together, the cobas eplex system and TAGS-enabled assays form part of Roche's broader molecular diagnostics strategy, which spans rapid syndromic testing, scalable high-throughput PCR, and flexible multiplex assay design.

Core Molecular

The cobas 6800 and cobas 8800 systems are Roche's flagship high-throughput molecular platforms, providing fully integrated, automated sample-to-result solutions for routine and

large-scale testing. These systems offer a wide range of applications, including viral load monitoring, blood donor screening, women's health, and infectious disease diagnostics. Built on real-time PCR technology, they enable continuous, random-access processing with minimal manual intervention, eliminating the need for pre-sorting and allowing multiple assays to run simultaneously within the same workflow. The systems are designed for extended walk-away operation, supporting several hours of unattended processing while maintaining high throughput and consistent performance across centralized laboratory environments. Roche's global installed base has continued to expand, reflecting strong adoption in national screening programs and large reference laboratories.

Roche's molecular menu on the cobas 6800/8800 platforms includes assays for HIV-1 viral load and qualitative HIV-1/HIV-2 detection, hepatitis B and C, cytomegalovirus, human papillomavirus, and chlamydia/gonorrhea. The systems also provide blood screening assays such as cobas MPX, along with tests for West Nile virus and hepatitis E, enabling comprehensive donor screening. Additionally, Roche expanded its infectious disease menu to include assays for emerging pathogens such as monkeypox (MPXV) and malaria, supporting broader public health and blood safety applications.

The cobas c 703 is part of Roche's cobas pro integrated solutions and serves as a high-throughput clinical chemistry module designed for large core laboratories. It is positioned alongside the cobas e 801 immunoassay module to create a consolidated, fully automated core lab system capable of handling high sample volumes with minimal manual intervention.

The cobas c 703 is designed to deliver very high throughput for routine and specialty chemistry testing, supporting a broad test menu that includes general chemistry, therapeutic drug monitoring, drugs of abuse, and specific proteins. The system emphasizes continuous loading, high onboard reagent capacity, and automated maintenance functions, allowing laboratories to maintain an uninterrupted workflow and reduce downtime. It also supports standardized reagent packaging and calibration processes, helping improve consistency across laboratory networks.

A key strength of the cobas c 703 is its integration within Roche's overall automation ecosystem. When connected to pre-analytical systems and track-based automation, the analyzer supports fully automated sample handling from loading through result reporting. The platform is also integrated with Roche's informatics and middleware solutions, enabling centralized data management, workflow optimization, and remote monitoring of system performance.

In 2025 and 2026, Roche introduced next-generation enhancements to the cobas 6800/8800 systems that significantly improve throughput, flexibility, and workflow efficiency. Updated system configurations and software enable more assays to run within the same workflow and support more flexible test scheduling, including the ability to run multiple assay types simultaneously from the same sample stream. These enhancements also enable laboratories to run both in vitro diagnostic and laboratory-developed tests within a unified workflow, improving operational efficiency and resource utilization.

Roche has also advanced multiplex molecular testing on these platforms by integrating newer technologies that enable the detection of multiple targets in a single assay. This enables more flexible, customizable testing strategies, particularly in respiratory diagnostics, where laboratories can tailor testing to clinical need or seasonal demand.

Roche offers rapid molecular testing through the cobas liat platform, including multiplex assays for SARS-CoV-2, influenza A/B, and RSV, delivering results in approximately 20 minutes. Together, these platforms form a tiered molecular testing strategy, with cobas liat addressing near-patient needs and cobas 6800/8800 supporting centralized, high-volume laboratories.

Digital PCR

The digital PCR segment is becoming increasingly competitive, with Roche advancing its position alongside established players such as Bio-Rad and Thermo Fisher Scientific. Roche has been developing a multi-channel digital PCR platform, designed to expand multiplexing capabilities and improve the detection of low-abundance targets, reflecting growing demand for highly sensitive nucleic acid quantification in oncology, infectious disease, and translational research.

Roche's primary entry in this space is the Digital LightCycler System, a digital PCR platform designed for precise and absolute quantification of DNA and RNA without the need for standard curves. The system supports high-sensitivity detection of rare mutations and low-level viral loads, making it particularly relevant for applications such as minimal residual disease monitoring, liquid biopsy, and infectious disease research. Roche's system provides an enhanced platform with improved multiplexing, workflow automation, and data analysis capabilities, positioning it for broader use in both research and, over time, clinical environments.

Roche offers the LightCycler PRO System, a next-generation quantitative PCR platform that complements its digital PCR offering. The system is designed to deliver improved thermal performance, faster cycling times, and enhanced data precision, supporting a wide range of molecular testing applications. While primarily positioned for research and advanced laboratory use, it reflects Roche's continued investment in high-performance PCR technologies across both qPCR and digital PCR segments.

Diabetes Care

Roche Diabetes Care is an established player in diabetes management, with a long history in blood glucose monitoring and a presence across global markets. Under the Accu-Chek brand, Roche offers a range of connected solutions that integrate glucose monitoring, data management, and digital health tools to support therapy decisions. The company's strategy has increasingly shifted toward connected care, combining devices, software, and services to enable more personalized and data-driven diabetes management.

Roche's core blood glucose monitoring portfolio centers on systems such as the Accu-Chek Guide platform, which remains widely used for self-monitoring. The system includes user-focused design features such as spill-resistant strip packaging, simplified blood application, and automated data capture. Results are transmitted via Bluetooth to Roche's digital platforms, allowing patients, caregivers, and healthcare providers to access and share glucose data in real time.

The mySugr platform was acquired by Roche and is a central component of its digital diabetes portfolio. The app supports logging, coaching, and data visualization, and integrates with Accu-Chek devices to provide a more comprehensive view of glucose trends and therapy management. Roche expanded digital coaching, remote support, and subscription-style supply models that bundle devices, test strips, and digital services.

The Accu-Chek SmartGuide CGM system represents a recent product introduction from Roche, first launched in 2024 and expanded commercially through 2025. By 2026, the system is in the early stages of broader market adoption, positioning it as a next-generation continuous glucose monitoring platform rather than a newly introduced product. This next-generation platform provides continuous, real-time glucose readings and predictive insights, enabling users to anticipate and better manage glucose level fluctuations. The system includes a wearable sensor with extended wear time and mobile applications that forecast glucose trends, supporting more proactive disease management. Integration of SmartGuide

with Roche's digital system, particularly the mySugr platform, consolidates glucose data, lifestyle inputs, and therapy information into a unified interface, improving usability and clinical insight. Roche has also expanded interoperability, enabling its CGM and connected devices to integrate with external data platforms, supporting a more flexible and connected approach to diabetes management.

Coagulation

Since 1993, CoaguChek systems from Roche have set the standard in point-of-care INR testing for patients on oral anticoagulant therapy. According to Roche, CoaguChek is a market leader, with over 1 million CoaguChek XS meters in use worldwide and over 250,000 CoaguChek XS PT test strips used per day. Nine of the top 10 U.S. integrated health networks (IHNs) have chosen CoaguChek technology.

Roche offers the CoaguChek XS mPOC app for use with the CoaguChek XS meter. The app makes the Bluetooth-enabled PT/INR reporting offered by CoaguChek Patient Services more convenient and accessible by allowing patients to use their own iOS device (iPhone or iPad). The app is available exclusively to patients who test PT/INR, with support from CoaguChek Patient Services. Wireless-enabled patient self-testing with CoaguChek Patient Services enables HCPs to confidently monitor reported PT/INR data remotely.

Roche markets its multiplex Factor II and Factor V test for use on the Cobas 4800 system, which performs real-time PCR analysis for mid- to high-volume labs. Roche noted that the clearance expands the cobas 4800 system's menu and enables labs to consolidate genomics, oncology, microbiology, and virology testing on a single platform. Roche added the Cobas t 511 and Cobas t 711 coagulation analyzers, which are suitable for central labs performing coagulation and thrombophilia testing.

cobas Liat System – POC

Utilizing PCR technology, the cobas Liat System fully automates the testing process, simplifies workflow and enables healthcare professionals to perform molecular testing in a variety of settings with minimal training. The Liat system performs real-time PCR in a tube-based format, using spatial thermal cycling to enable results in 20 minutes or less.

Roche offers the CLIA-waived molecular cobas Influenza A/B & RSV test for use on the cobas Liat System. The cobas Influenza A/B & RSV test provides lab-quality PCR results for flu and RSV in about 20 minutes, supporting a prompt, confident diagnosis to patients.

The cobas Influenza A/B & RSV test uses real-time PCR technology to detect and differentiate influenza A virus RNA, influenza B virus RNA and respiratory syncytial virus (RSV) RNA in about 20 minutes.

Roche sells the cobas Liat PCR System with four assays into CE-markets, including a 20-minute real-time PCR nucleic acid test to detect Clostridium difficile (C. diff), the cobas Influenza A/B, cobas Strep A, and cobas Influenza A/B & RSV. These assays have been approved by the FDA and are CLIA waived.

Roche offers the cobas MRSA/SA test for use on the Liat PCR point-of-care platform. The test simultaneously detects MRSA and SA from a single sample in less than 30 minutes. The MRSA/SA test is the fifth Cobas assay for use on the Liat PCR system.

Roche offers FDA- and CLIA-waived cobas liat sexually transmitted infection multiplex assay panels, called the Liat Triplex Point-of-Care STI Test. The panels include tests for chlamydia, gonorrhea, and Mycoplasma genitalium, which are identified from a single sample. The cobas liat CT, NG, and MG STI assays further expand and complement the company's portfolio of point-of-care diagnostic solutions.

Roche marketed its first POC test to diagnose Bordetella infections, including whooping cough. The test detects Bordetella infections and also differentiates between three key species: pertussis, Para pertussis, and B. holmessii. The test is run on the cobas liat system and delivers results in about 20 minutes.

HPV

In June 2023, the WHO provided prequalification for Roche's cobas HPV test for use on the cobas 6800/8800. This expands the availability of this HPV screening tool in countries that rely on the global organization's list in making purchases.

Roche markets its HPV self-collection solution. This HPV self-collection solution provides easy screening for patients, with samples sent to a laboratory for analysis using Roche's cobas molecular instrument.

Blood Bank

Roche's blood banking and donor screening business is a highly automated, integrated workflow that combines NAT, serology, pre-analytics, and informatics to support high-throughput donor screening laboratories. The company has a leading position in global blood and plasma molecular screening, with decades of real-time PCR expertise and expanding connectivity across molecular and immunoassay platforms to streamline operations and improve traceability. Its systems emphasize full sample-to-result automation, bidirectional data flow, and scalable throughput suited to national and regional blood services.

Roche's cobas MPX assay is a multiplex NAT solution for donor screening on the cobas 6800 and cobas 8800 Systems, enabling simultaneous detection of HIV-1, HIV-2, HBV, and HCV from a single sample using dual-target strategies that enhance sensitivity and reduce the need for supplemental discriminatory testing. These systems are among the highest-throughput molecular platforms, offering extended walk-away times, continuous loading, and improved workflow efficiency. Enhancements across the cobas 5800/6800/8800 family have focused on expanded menu flexibility, improved automation, and broader adoption of high-plex PCR technologies to support evolving screening demands, including preparedness for emerging pathogens.

Roche has expanded its cobas pro integrated solution, which combines clinical chemistry and immunoassay capabilities for large-scale infectious disease screening. The platform offers high-volume donor testing with assays such as Elecsys HIV Duo, which differentiates HIV antigen and antibody responses, along with an expanded menu covering hepatitis, syphilis, and other transfusion-relevant infections. Ongoing menu development has emphasized improved sensitivity, reduced turnaround times, and harmonization with molecular screening workflows.

Roche has also strengthened its blood screening portfolio through the development of pre-analytical automation and digital solutions, including sample handling systems, workflow optimization software, and connectivity tools that link donor screening instruments with laboratory information systems. In addition, the company continues to support dried-blood and remote-collection approaches, such as plasma separation cards, to expand access to molecular testing in decentralized or resource-limited settings.

Transplant Medicine

Roche offers a comprehensive cytomegalovirus (CMV) molecular testing portfolio, with ongoing transition from legacy platforms to its newer high-throughput cobas systems. The cobas AmpliPrep/cobas TaqMan CMV Test established itself as one of the first standardized in vitro diagnostic assays aligned to the World Health Organization (WHO) International Standard, enabling consistent viral load monitoring across laboratories and supporting clinical management of transplant patients. While this system remains in use in some laboratories, Roche has increasingly shifted its focus toward its newer-generation platforms.

Roche's cobas CMV assay is now positioned on the fully automated cobas 6800 and cobas 8800 Systems, delivering higher throughput, improved workflow automation, and enhanced standardization for quantitative CMV DNA testing. The assay is used to monitor viral load in recipients of solid-organ and hematopoietic stem cell transplants undergoing antiviral therapy, supporting earlier intervention and more precise treatment management. The system allows simultaneous processing of CMV alongside other viral load assays such as HIV-1, HBV, and HCV, enabling consolidated testing on a single integrated platform.

Company updates through 2026 emphasize improved assay sensitivity at low viral loads, expanded calibration traceability to international standards, and greater harmonization across laboratories. Roche has also enhanced multiplexing efficiency and workflow flexibility on the cobas 5800/6800/8800 family, allowing laboratories to balance transplant monitoring with infectious disease testing on shared instrumentation.

In addition, Roche is advancing its broader molecular offerings with the integration of higher-plex PCR capabilities and the development of digital PCR technologies, which are expected to further improve precision in viral load quantification for transplant management over time. Connectivity and data management tools have also been strengthened, enabling closer integration with hospital information systems and supporting longitudinal patient monitoring.

Sequencing and Mass Spectrometry

Roche expanded its presence in mass spectrometry and next-generation sequencing workflows, building on earlier introductions while advancing automation, menu development, and integration with core laboratory systems. The cobas mass spectrometry solution includes the cobas i 601 analyzer, which represents Roche's entry into routine clinical mass spec with an emphasis on standardization, ease of use, and full laboratory

automation. The Ionify reagent packs initially focused on steroid hormone testing, and the menu has since expanded to include additional endocrinology and therapeutic drug monitoring assays, with ongoing development aimed at bringing more complex mass spectrometry applications into routine clinical use without requiring highly specialized expertise.

Roche offers its mass spectrometry platform as part of an integrated core lab system, linking sample preparation, analysis, and data management with existing cobas automation and IT infrastructure. Enhancements are focused on improving throughput, reducing manual steps, and enabling scalable deployment in high-volume laboratories. The company continues to emphasize standardized workflows and ready-to-use reagent kits to differentiate its offering from traditional, more complex mass spectrometry systems.

Roche has advanced its SBX technology as part of a broader strategy to enter the next-generation sequencing market with a differentiated approach. SBX is designed to improve sequencing performance by converting nucleic acid sequences into expanded molecular constructs, enabling highly accurate signal detection and efficient data generation. The technology is in an advanced development phase, with ongoing efforts focused on improving read accuracy, scalability, and workflow efficiency for both research and future clinical applications, particularly in oncology and infectious disease. Roche is positioning SBX alongside its established PCR and digital PCR capabilities to create a multi-technology portfolio spanning targeted molecular testing through to high-throughput sequencing. This approach reflects a broader strategy to bring advanced genomic technologies into more automated, standardized, and clinically accessible laboratory workflows.

Cancer Companion Testing

Roche offers its companion diagnostics and precision oncology portfolio, strengthening its position in tissue-based diagnostics and targeted therapy selection. The company offers a companion diagnostic to identify patients with HER2-low metastatic breast cancer who may benefit from treatment with Enhertu, reflecting the growing importance of refined biomarker stratification beyond traditional HER2-positive classifications. Roche enhanced its HER2 testing portfolio with improved assay sensitivity and digital pathology integration to support more precise patient identification.

Roche's VENTANA CLDN18 RxDx Assay is a valuable addition in gastrointestinal oncology as the first immunohistochemistry-based companion diagnostic for determining

CLDN18 expression in gastric and gastroesophageal junction cancers, supporting patient selection for targeted therapies such as zolbetuximab. Similarly, the VENTANA FOLR1 RxDx Assay has expanded access to folate receptor alpha testing in ovarian cancer, enabling identification of patients eligible for antibody-drug conjugate therapies such as mirvetuximab soravtansine. Roche continues to focus its companion diagnostic menu in solid tumors, with ongoing development in lung, breast, and gynecologic cancers.

Roche markets its digital pathology and AI-enabled diagnostics. The VENTANA TROP2 RxDx assay, combined with an AI-driven image analysis algorithm, represents a move toward integrated companion diagnostics that combine tissue staining with computational interpretation. This approach is designed to improve reproducibility and standardization in biomarker scoring and is expected to be extended to additional biomarkers and tumor types. Further development of AI-assisted companion diagnostics and expanded regulatory submissions across multiple oncology indications is expected during the forecast period.

Roche's VENTANA MET RxDx Assay identifies patients with non-squamous non-small cell lung cancer who are eligible for MET-targeted therapies, reinforcing the company's strong presence in lung oncology biomarker testing. Roche offers a comprehensive lung cancer testing portfolio that includes MET, PD-L1, ALK, ROS1, and other biomarkers, often integrated with digital pathology workflows.

Information Technology

Roche was awarded the CE mark for its Navify Mutation Profiler clinical software that provides annotation, interpretation, and clinical reporting of next-generation sequencing tests for cancer. Along with it, Roche launched Navify Therapy Matcher, an optional clinical decision support app that helps clinicians link clinically actionable mutations to therapy options.

Roche offers the cobas infinity edge, a secure, cloud-based platform for integrating and managing POC data in the clinical setting.

Roche Tissue Diagnostics

Tucson, AZ

www.diagnostics.roche.com

Roche Tissue Diagnostics, a division of Roche, offers a portfolio of automated tissue diagnostics systems, reagents, and digital pathology solutions, with a strong emphasis on workflow integration, AI-enabled analysis, and precision oncology. The company's VENTANA platform provides automated tissue processing and slide staining for cancer diagnostics, supporting both immunohistochemistry (IHC) and in situ hybridization (ISH) applications in clinical labs.

The BenchMark ULTRA and the newer BenchMark ULTRA PLUS systems are now the main platforms, offering true random-access processing, enabling laboratories to run STAT and routine samples simultaneously without batching. These systems provide enhanced throughput, improved reagent management, and greater standardization of staining quality, while maintaining flexibility for complex protocols. The BenchMark Special Stains platform is a fully automated histochemical staining process with walk-away capability, integrated baking through staining, and seamless connectivity to laboratory workflow solutions and remote support tools.

Roche has significantly expanded its digital pathology system, including high-throughput slide scanners such as the VENTANA DP 200 and next-generation scanning systems designed for higher capacity and faster image acquisition. These are integrated with the uPath enterprise software platform, which enables image management, case review, collaboration, and remote diagnostics. Roche's digital pathology offering is enhanced by expanded AI-powered image analysis algorithms that support biomarkers such as HER2, PD-L1, Ki-67, and other oncology markers, improving reproducibility and diagnostic confidence.

Roche offers its assay menu across IHC, ISH, and multiplex staining, including companion diagnostics aligned with targeted therapies in oncology. Multiplex and advanced staining capabilities are being further developed to support more complex biomarker profiling within a single tissue sample, reflecting the growing demand for precision medicine.

Immunohistochemistry - IHC

Roche markets the anti-p504s (SP116) Rabbit Monoclonal Primary Antibody2 for prostate cancer diagnosis. This antibody has been validated for use in a dual stain with the VENTANA Basal Cell Cocktail (34ßE12+p63), on a single slide, to aid in distinguishing morphologically difficult cases as benign, atypical or cancerous on a single slide. The assay is an in vitro diagnostic (IVD) primary antibody for use on the VENTANA BenchMark IHC/ISH series of automated slide stainers.

Roche Tissue Diagnostics uses its OptiView DAB detection technology to develop new immunohistochemistry (IHC)-based diagnostic tests. Roche Tissue Diagnostics received FDA clearance to market the VENTANA MMR IHC Panel, which provides a group of immunohistochemistry (IHC) tests for patients diagnosed with colorectal cancer. The tests detect specific proteins associated with a DNA repair mechanism called mismatch repair (MMR) and help differentiate between sporadic colorectal cancer and probable Lynch syndrome, a hereditary form of colorectal cancer. About 3 percent of colorectal cancers are associated with Lynch syndrome. The panel of five assays includes four that target MMR proteins MLH1, MSH2, MSH6 and PMS2, as well as the VENTANA BRAF V600E (VE1) assay. According to Roche Tissue Diagnostics, this is the first FDA clearance of an IHC panel of this type.

Roche Tissue Diagnostics offers the VENTANA DP 200 high-speed slide scanner for digital pathology.

Additional features of the VENTANA DP 200 include scan speed of less than 49 seconds for 15-by-15-millimeter scan area, and the application of a unique International Color Consortium (ICC) color profile to each image to ensure that the digital image closely matches colors observed under a microscope. The VENTANA DP 200 is also Digital Imaging and Communications in Medicine (DICOM) Standard compatible and integrates with Image Management Servers, including VENTANA Virtuoso software.

Roche has expanded its digital pathology portfolio beyond the VENTANA DP 200 slide scanner, a clinical whole slide imaging system designed for routine diagnostic use that enables high-resolution digitization of glass slides and supports pathologists in reviewing and interpreting cases for primary diagnosis. The portfolio now includes the higher-throughput VENTANA DP 600 slide scanner for larger laboratories requiring greater capacity and faster turnaround times, along with the navify digital pathology platform, which provides image

management, case workflow, reporting, and integration with laboratory information systems to support scalable and remote review environments. Roche has also built out a broader digital system that incorporates AI-enabled image analysis for biomarkers such as HER2, PD-L1, ER, PR, and Ki-67 and links digital pathology with its companion diagnostics and staining platforms, positioning the company toward a more connected, standardized, and data-driven pathology workflow.

Roche also offers the VENTANA HER2 Dual ISH DNA Probe Cocktail assay for the detection of the HER2 biomarker in breast and gastric cancer. HER2 - human epidermal growth factor receptor 2 - is an important biomarker found in breast and gastric cancers. Roche reported that the assay is designed to be completed within the same day, providing clinicians the ability to get results back quicker than the most common methods of confirmatory testing for HER2. Results can be read using light microscopy, eliminating the need for a specialized fluorescence microscope. Further, Roche claims to be the only provider of a fully automated brightfield Dual ISH solution for the detection of HER2 amplification. The brightfield assay is fully automated on the BenchMark IHC/ISH instruments. The test is being launched in Europe, the Middle East, Africa, Latin America and Asia Pacific.

Roche offers the Ventana Kappa and Lambda Dual ISH mRNA Probe Cocktail. The test is designed to help pathologists differentiate a B-cell malignancy from a normal response to infection. The product was CE marked in June 2024.

Cervical Cancer Screening

The CINtec Cytology tests are used in determining which women are at higher risk of developing cervical cancer. Roche Tissue Diagnostics offer a complete menu of cervical cancer tests the cobas HPV Test for screening, and the CINtec PLUS Cytology and CINtec Histology for triage and diagnosis.

Roche markets the CINtec histology test to detect high-grade cervical disease in women who have had a tissue biopsy. Pathologists can use CINtec test along with hematoxylin & eosin (H&E) staining to identify women for providing treatment for cervical pre-cancer.

CINtec histology test offers conclusive visual confirmation whether the pre-cancerous lesions are present or absent. CINtec histology test adds to the firm's cervical cancer portfolio, which also comprises cobas HPV test and CINtec Plus cytology test.

Companion Diagnostics

Roche Tissue Diagnostics markets the PD-L1 Assay as a complementary diagnostic for Genentech's PD-L1 inhibitor Tecentriq, which was subsequently approved to treat lung cancer. The test gauges PD-L1 expression in tumor and immune cells

The Ventana PD-L1 assay is run on the Ventana BenchMark Ultra instrument. It evaluates a patient's PD-L1 status using tumor and immune cell staining and scoring within the tumor microenvironment. PD-L1 is a protein involved in the suppression of the immune system and understanding its expression in tumors could help with identifying those patients who are most appropriate for treatment with an immunotherapy. Ventana reported it is pursuing regulatory approval of the Ventana PD-L1 assay for use with other cancers in the U.S. and internationally.

Roche markets the Ventana ALK CDx assay as a companion diagnostic to identify ALK-positive (NSCLC patients eligible for treatment with the Roche medicine ALECENSA (alectinib). The Ventana ALK CDx Assay is the only FDA-approved test as a companion diagnostic for ALECENSA. The VENTANA ALK CDx Assay is intended for the qualitative detection of the anaplastic lymphoma kinase protein in formalin-fixed, paraffin-embedded (FFPE) NSCLC tissue stained with a BenchMark XT or BenchMark ULTRA automated staining instrument. It is also indicated as an aid in identifying patients eligible for treatment with XALKORI (crizotinib), ZYKADIA (ceritinib) or ALECENSA (alectinib).

Roche provides VENTANA PD-L1 Assay in CE markets. It aids in identifying triple-negative breast cancer patients eligible for treatment with Tecentriq (atezolizumab) plus chemotherapy (nab-paclitaxel). Assessment of PD-L1 biomarker status on tumor-infiltrating immune cells with the assay is essential for identifying those patients most likely to benefit from the treatment.

Roche offers the Ventana PD-L1 Assay as a companion diagnostic to identify NSCLC patients that would benefit from treatment with Libtayo offered by Regeneron.

Roche, through its Ventana portfolio, continues to expand its leadership in companion diagnostics with the introduction of multiple new immunohistochemistry-based assays aligned with targeted oncology therapies. The VENTANA CLDN18 (43-14A) RxDx Assay is an FDA-approved companion diagnostic designed to identify CLDN18.2 protein expression in patients with gastric or gastroesophageal junction adenocarcinoma who may be eligible for treatment with zolbetuximab (VYLOY).

Roche also offers an expanded indication of its PATHWAY anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody assay to support assessment of HER2 status in biliary tract cancer, enabling identification of patients eligible for HER2-targeted therapies such as zanidatamab (ZIIHERA).

In addition, Roche offers the VENTANA FOLR1 RxDx Assay, an immunohistochemistry-based companion diagnostic intended to identify patients with epithelial ovarian cancer who may benefit from treatment with mirvetuximab soravtansine (ELAHERE). These developments highlight Roche's continued focus on expanding its companion diagnostic portfolio to support precision oncology across multiple tumor types.

Siemens Healthineers (Siemens)

Deerfield, IL

www.siemens.com/diagnostics

Table 14-20: Siemens Healthineers Revenue History, 2023-2025 (€ million)

	2023	2024	2025
Total	€8,286	€8,678	€9,156

Source: company reports, Kalorama Information

Total revenue for diagnostics was €9,156 million for 2025. There was moderate growth in most segments during 2025. The company is still feeling the effects of a reduction in COVID-19 revenues. However, there was an increased demand for routine tests in 2025. Excluding COVID-19 revenues, the diagnostic segment increased 2.1%. In 2024, Siemens's revenue generated 42% in the Americas, 33% in the EMEA, and 24% in the Asia Pacific including China.

Siemens Healthineers and 24ed beyond its earlier Strategy 2025 framework and is now operating under a newer strategic phase focused on expanding leadership in imaging, diagnostics, precision therapy, and digitally enabled healthcare. Within this structure, Diagnostics continues as a core business with its own operating direction, while the company's broader portfolio increasingly emphasizes artificial intelligence, workflow efficiency, and integrated care pathways across the healthcare continuum. Earlier initiatives such as the integration of the epoc blood gas portfolio are offered in point-of-care testing, but Fast Track Diagnostics is no longer a central growth platform following the company's decision to wind down that unit. Siemens Healthineers' diagnostics business currently spans laboratory diagnostics and point-of-care testing, including clinical chemistry, immunoassay, hematology, hemostasis, urinalysis, automation, informatics, and blood gas analysis. The company's overall business is best described today as being organized around imaging, diagnostics, cancer care, and minimally invasive therapies, supported by digital technologies and AI rather than by the older historical framing that included hearing aids and legacy acquisitions as defining elements.

Core Lab

Siemens offers its complete core lab testing solution the CE Marked and FDA cleared Atellica system consists of scalable immunoassay and chemistry analyzers and can operate as a stand-alone system or connect to Aptio Automation. The Atellica Portfolio includes: Atellica Solution (automation-ready immunoassay, and clinical chemistry analyzers), Atellica 1500 Automated Urinalysis System (fully digital, automated urinalysis system), Atellica NEPH 630 System (mid-volume, dedicated nephelometric system for specialty protein testing), Atellica COAG 360 System (fully automated high-volume coagulation system that unifies five testing methodologies), Atellica MDX 160 System (flexible, automated molecular system for multiple sample types), and Atellica PM 1.0 Software (process management software to optimize lab operations through data analytics and visualization).

Siemens' Atellica MDX 160 Molecular System allows users to automate and integrate LDTs With IVD Kits on multiple sample types. Atellica MDX 160 Sample Prep is a flexible, automated sample preparation solution with maximum productivity for multiple specimen types.

The company continues to expand the test menu. Siemens Healthineers added two high-Sensitivity Troponin I assays (TnIH) for Siemens' Atellica (immunoassay and clinical chemistry analyzer) and ADVIA Centaur XP/XPT (immunoassay system). The high-sensitivity performance of the two TnIH assays enables detection of lower levels of troponin at significantly improved precision at the 99th percentile and detects smaller changes in a patient's troponin level during repeated testing.

Siemens markets the Atellica IM BRAHMS PCT (procalcitonin) Assay for ER and ICU use of sepsis assessment, assigning mortality risk and antibiotic therapy decision-making.

Siemens also markets the Dimension Hemoglobin A1c turbidimetric inhibition assay for measuring percentage and mmol/mol measurements of HbA1c in venous whole blood.

Siemens offers its Atellica CH Enzymatic Hemoglobin A1c Assay to assist clinicians in diagnosing and monitoring diabetes.

Lab Automation

The Atellica automation solution can be used as a stand-alone system or scaled to support larger laboratory environments, with flexible configurations that can be adapted to a wide range of laboratory layouts, including linear, L-shaped, and U-shaped designs. The system is designed to accommodate diverse workflow requirements and can be integrated with Aptio Automation to support comprehensive, multidisciplinary laboratory operations. It is compatible with a broad range of sample container types, including pediatric and specialty tubes, supporting high levels of workflow flexibility.

Siemens Healthineers supports these automation platforms with Atellica Process Manager software, a configurable solution that enables laboratories to monitor and manage workflow, instrumentation, and system performance across connected devices. The software provides centralized visibility into laboratory operations, allowing staff to oversee processes, track system status, and manage daily tasks more efficiently. Features include real-time monitoring of reagent and consumable levels, helping laboratories maintain continuity of operations and reduce manual intervention.

The Atellica Diagnostics IT portfolio extends these capabilities by enabling laboratories to leverage operational data to optimize workflow performance and resource utilization. This includes user interface enhancements designed to streamline operator interaction, such as simplified dashboards and workflow-based task organization that reduce system complexity and improve usability.

Immunoassays

Siemens became a top player in immunoassays through its 2006 acquisition of DPC. Since its introduction in 1992 by DPC, the IMMULITE family of systems has grown to be a premier brand in immunoassay testing. The tests complement Siemens' ADVIA Centaur systems. Together, they have a large global installed base in hospital clinical laboratories.

Siemens offers an FDA-cleared menu of Atellica infectious disease immunoassays, including HIV Ag/Ab Combo (CHIV), HBsAg II, HCV, and Syphilis. The HBsAg II SMART algorithm and the hot zone help reduce repeat testing and decrease turnaround time.

Siemens Healthineers sells its automated immunoturbidimetric assay for the quantitative determination of the von Willebrand antigen in plasma and an anti-Mullerian hormone sandwich immunoassay.

Additionally, the Atellica CH Diazo Direct Bilirubin assay for bilirubin detection is provided for use on the Atellica CH Analyzer.

Siemens Healthineers markets the Atellica CI Analyzer for immunoassay and clinical chemistry testing.

Siemens Healthineers provides its NfL assay for use on its Atellica IM Analyzer and the ADVIA Centaur XP/XPT systems. The test will be used to help predict the risk of MS disease activity in patients with RMS.

Hematology

Siemens Healthineers' hematology portfolio is led by its ADVIA systems, which support a broad menu of diagnostic assays and incorporate established flow cytometry methodologies for high-precision cell analysis. The company has advanced its digital hematology workflow through continued integration with the CellaVision DM1200 and next-generation morphology platforms, enabling automated slide review, AI-assisted classification, and remote hematopathology capabilities that reduce manual microscopy workload and improve standardization across laboratory networks.

The long-standing collaboration between Siemens Healthineers and HORIBA Medical remains active in 2026, supporting co-development and distribution of complementary hematology solutions. HORIBA Medical continues to expand its Yumizen platform portfolio with enhancements in automation, connectivity, and compact systems targeting decentralized and mid-volume laboratories, while leveraging Siemens' broader diagnostic ecosystem. The partnership focuses on integrated workflow solutions spanning hematology, chemistry, and hemostasis, with no indication of termination.

In hemostasis, Sysmex Corporation and Siemens Healthineers maintain their strategic alliance, with ongoing menu expansion on the CN-series analyzers. Systems such as the CN-3000 and CN-6000 continue to support advanced assays, including anti-Xa testing for both heparin and direct oral anticoagulants, while benefiting from improved throughput, automation, and standardized reagent integration. Siemens Healthineers continues to

commercialize these platforms under its brand, alongside the CS-2500, CS-5100, and CA-600 series, providing a full spectrum of solutions for laboratories ranging from low to high volume.

The Atellica HEMA 570 and Atellica HEMA 580 analyzers offered by Siemens Healthineers are part of the high-volume hematology strategy in 2026, offering scalable automation, intelligent sample routing, and integrated data management. Recent updates to the Atellica HEMA line include enhanced middleware connectivity, expanded digital morphology integration, and workflow-optimization features that enable continuous loading, reduce turnaround times, and improve flagging algorithms for abnormal cells. These systems are increasingly used as part of unified core lab automation tracks, aligning hematology with chemistry and immunoassay testing within a single operational framework.

Urinalysis

Siemens Healthineers has expanded its digital urinalysis strategy through its collaboration with Healthy.io, integrating Siemens' urinalysis chemistry and reagent expertise with Healthy.io's smartphone-based testing platform. The Dip.io system remains a key component of this partnership, combining a dipstick kit with a mobile application that uses image capture and AI-driven analysis to interpret results. The platform detects multiple parameters associated with kidney disease, urinary tract infections, and metabolic conditions, while enabling secure cloud-based data sharing with healthcare providers. Since its initial regulatory clearances, the system has been deployed more widely in home testing programs and remote patient monitoring initiatives, particularly in chronic kidney disease screening pathways and decentralized care models.

Healthy.io's digital urinalysis platform is utilized in established programs in Israel and the United Kingdom, where it has been incorporated into virtual renal care pathways and population health screening efforts. The platform has expanded its role in large-scale home testing programs, providing earlier detection of kidney disease and improving patient compliance through convenient at-home sample collection and analysis. Integration with healthcare systems and electronic medical records has also improved, allowing providers to track longitudinal patient data and intervene earlier in disease progression.

Within its core laboratory portfolio, Siemens Healthineers has advanced its urinalysis workflow with the Atellica UAS 60 analyzer, which supports high-resolution digital urine microscopy. The system combines automated sample processing with detailed imaging and

particle classification, reducing reliance on manual microscopy while improving consistency and throughput. Ongoing enhancements include improved image-analysis algorithms, expanded particle-recognition capabilities, and tighter integration with Atellica automation and informatics solutions.

Siemens Healthineers has expanded its urinalysis portfolio beyond the Atellica UAS 60 with a fully integrated solution that includes the Atellica UAC 800 urine chemistry analyzer, designed for high-throughput dipstick analysis with automated strip handling and standardized reading. The company also maintains its CLINITEK line, including the CLINITEK Novus automated urine chemistry analyzer and CLINITEK Status+ system, which remain widely used in decentralized and physician office settings. Recent updates across these platforms focus on improved connectivity, operator-independent workflows, and integration with laboratory information systems to support both centralized labs and near-patient environments. In addition, Siemens Healthineers has enhanced its urinalysis automation capabilities through track-based integration with Atellica Automation, enabling seamless movement of urine samples between chemistry and sediment analysis systems. Digital innovations include expanded use of AI-assisted image analysis in sediment microscopy and remote review capabilities, supporting workforce efficiency and standardization. Together, these additions strengthen Siemens Healthineers' position with a comprehensive urinalysis system spanning handheld, mid-volume, and high-throughput laboratory solutions, as well as emerging digital and home-based testing models.

Molecular

Siemens Healthineers continues to expand its molecular IVD portfolio with a strategic shift toward rapid, decentralized testing and streamlined workflows. While legacy platforms such as the VERSANT and TRUGENE systems established the company's presence in viral load testing and genotyping, the company offers the Atellica VTLi molecular platform. This cartridge-based PCR system delivers fast, sample-to-result testing with minimal hands-on time and is being expanded with an evolving menu of infectious disease assays, including respiratory and sexually transmitted infection panels designed for near-patient and urgent care settings. Enhancements to the VTLi system include improved assay turnaround times, expanded multiplex capabilities, and tighter integration with digital informatics for real-time result reporting and clinical decision support. Siemens Healthineers offers the VERSANT kPCR Molecular System for established applications such as HIV, HBV, and HCV viral load testing, while positioning newer molecular workflows around automation, connectivity, and

decentralized access. These developments reflect a broader transition toward flexible, distributed molecular diagnostics that complement centralized laboratory testing and enable faster, clinically actionable results.

Sequencing with Artificial Intelligence

Siemens Healthineers offers sequencing and AI-enabled molecular diagnostics through the continued integration of its NEO New Oncology acquisition, which provides advanced next-generation sequencing capabilities for tumor profiling and precision medicine. The Neo platform focuses on targeted sequencing of clinically relevant regions of tumor DNA, enabling high-resolution genomic analysis for oncology applications. Siemens Healthineers has also enhanced its offering with improved bioinformatics pipelines, enabling faster turnaround times and more standardized interpretation of complex genomic data. AI-driven analytics are increasingly embedded in workflows, supporting variant classification, quality control, and clinical reporting, and enabling laboratories to scale NGS testing with greater consistency and efficiency.

Additionally, Siemens Healthineers has expanded its molecular workflow solutions with the Fast-Track cycler, a compact and flexible thermocycler designed to support a wide range of PCR-based applications across laboratories of varying sizes. The FTC system is an accessible entry point for molecular testing, offering simplified operation, rapid cycling performance, and compatibility with multiplex assay formats.

A key innovation within the company's molecular portfolio is the FastFinder software, developed in collaboration with UgenTec, which introduces AI-powered automation into real-time PCR analysis. FastFinder enables fully automated interpretation of amplification data, using machine learning algorithms to evaluate curve kinetics, apply assay-specific decision logic, and generate standardized results without manual review. The platform is compatible with widely used PCR systems, including Applied Biosystems and LightCycler instruments, and supports multiplex workflows by consolidating multiple assay outputs into a single, clinically actionable report.

Acute Care – POC

Siemens Healthineers expanded its point-of-care portfolio through the acquisition of Epocal Inc., which provides the epoc Blood Analysis System, a handheld, wireless solution for near-

patient blood testing. The system utilizes single-use, room-temperature-stable BGEM test cards that incorporate a broad panel of analytes on a single card, enabling rapid assessment of blood gases, electrolytes, and key metabolic parameters. The epoc system delivers results for pH, oxygen and carbon dioxide levels, sodium, potassium, ionized calcium, hematocrit, glucose, lactate, creatinine, chloride, BUN, and total carbon dioxide in less than a minute, supporting fast clinical decision-making in emergency and critical care settings.

Updates to the epoc platform focus on enhanced connectivity, including support for newer host systems and improved data management capabilities, enabling seamless integration with hospital and laboratory information systems. These enhancements support real-time data transmission, centralized oversight of decentralized testing, and improved workflow efficiency across acute care environments.

Siemens Healthineers offers point-of-care assays for kidney function and metabolic assessment on the epoc system, with ongoing menu enhancements and usability improvements. In addition, the company maintains its CLINITEST rapid testing portfolio, including combination COVID-19 and influenza antigen assays that provide results in approximately 15 minutes and support decentralized respiratory testing in clinical and near-patient settings.

POC Connectivity

Siemens Healthineers has expanded its point-of-care connectivity capabilities through an integrated informatics strategy that supports centralized oversight of decentralized testing. The RAPIDComm Data Management System remains a core component, enabling healthcare organizations to manage point-of-care testing programs through a single, configurable interface that supports device connectivity, operator management, quality-control tracking, and real-time result reporting.

Building on its acquisition of Conworx Technology, Siemens Healthineers has also developed an open point-of-care informatics system that enables connectivity across a broad range of POC devices and healthcare IT systems. These solutions allow test results from multiple instruments to be automatically transmitted to electronic medical records, reducing manual data entry and improving accuracy and workflow efficiency. The system also provides centralized management of devices, reagents, and compliance processes, helping institutions standardize operations across distributed testing environments.

Siemens Healthineers has enhanced its ability to aggregate data from point-of-care instruments, including blood gas, urinalysis, and near-patient testing systems, enabling real-time visibility into testing performance and patient results across healthcare networks.

Business Expansion

Siemens Healthineers has expanded its role in managed laboratory services through long-term partnerships with healthcare systems, including large-scale public-private initiatives such as those established in Turkey. Under these models, Siemens Healthineers provides end-to-end laboratory solutions, including infrastructure design, instrumentation, consumables, maintenance, and operational support across multiple disciplines, including biochemistry, microbiology, hematology, immunology, pathology, genetics, and point-of-care testing. These agreements reflect the company's broader strategy to deliver integrated, high-efficiency laboratory services while supporting standardization and scalability across healthcare networks.

Siemens Healthineers has also advanced its digital health strategy through an integrated system that combines data from in vitro diagnostics, imaging, and clinical information systems. These platforms enable the aggregation and analysis of large volumes of healthcare data, support collaboration across institutions, and provide tools for predictive analytics, workflow optimization, and clinical decision support. The company continues to enhance these capabilities with cloud-based infrastructure and interoperability across enterprise systems.

The divestment of its microtiter-based ELISA immunodiagnostics business to Diasorin has enabled Siemens Healthineers to further streamline its portfolio and focus on higher-growth areas, including automation, molecular diagnostics, and advanced immunoassay technologies.

In addition, Siemens Healthineers maintains strategic collaborations with leading laboratory service providers such as Unilabs, supporting the modernization of laboratory infrastructure, improved workflow efficiency, and standardization across large diagnostic networks.

The company's partnership with Sysmex Corporation in hemostasis testing is a key component of its diagnostics strategy. Through this collaboration, both companies distribute

a combined portfolio of hemostasis instruments and reagents under their respective brands, expanding global reach and strengthening their offerings in coagulation testing, anticoagulation monitoring, and bleeding risk assessment. This integrated portfolio continues to be marketed across major regions, including the United States and Europe.

Sysmex Corporation

Kobe, Japan

www.sysmex.co.jp/

Table 14-21: Sysmex Revenue History, 2023-2025 (billions of Yen) FYE March 31

	FY2023	FY2024	FY2025
Total Revenues	¥411	¥462	¥503

Source: company reports, Kalorama Information

Sysmex's year-end is March 31, so the company reported 2025 IVD revenues of 503 billion yen.

EMEA - sales grew as a result of higher sales in the hematology and hemostasis

China - sales grew as instrument sales recovered to previous year levels and reagent sales increased

Asia Pacific – sales grew by double digits for both instruments and reagents due to increased activity in India and other countries

Japan – sales increased by double digits due to an increase in hematology and hemostasis segments and an increase in medical robotics

Sysmex is an integrated manufacturer of laboratory software and diagnostic systems involved in the development, production, marketing, and servicing of clinical laboratory testing devices and reagents. Sysmex's products are used by medical institutions in more than 190 countries, with a significant portion of sales concentrated in Europe, the Americas, Japan, and China.

Since its establishment in 1968, Sysmex has concentrated on hematology and urinalysis. Sysmex has expanded its portfolio and offers clinical laboratory systemization and solutions, including clinical diagnostics, automation, and information systems. The company is

innovating across all of its diagnostic practices, including flow cytometry, urinalysis and hematology.

Hematology

Sysmex strengthened its position in hematology by combining established high-throughput systems with newer analyzers designed for decentralized and mid-volume laboratories. The XN-Series remains the flagship of the company's hematology portfolio, with modular configurations that combine analyzers, slide preparation systems, and digital morphology solutions for laboratories ranging from major hospital networks to smaller routine testing sites. Systems such as the XN-9100, XN-3100, and XN-1500 continue to support automated, high-volume workflows with strong standardization and scalability.

A newer product is the XR-Series Automated Hematology Analyzer, which expands Sysmex's next-generation hematology offering with improved automation, workflow efficiency, and advanced clinical parameters. The system is designed to support highly automated laboratories seeking greater productivity, enhanced data management, and stronger integration across health system networks. Sysmex has also expanded its lower-volume hematology line with the XQ-320, a compact three-part differential analyzer intended for physician office laboratories, stat labs, and smaller hospital settings. This platform emphasizes fast turnaround, ease of use, and dependable performance in space-constrained environments.

Sysmex offers decentralized testing needs with the XN-L series, which brings many capabilities of the broader XN family into a smaller footprint for lower-volume laboratories. These systems, along with the XQ line, are designed offered by the BeyondCare Quality Monitor, a web-based quality management approach that helps laboratories identify shifts and trends earlier, reduce manual quality control burden, and standardize performance across distributed testing sites.

The company also offers differentiated products such as the XN-31, which provides automated detection and quantification of malaria-infected red blood cells in addition to routine CBC parameters, extending hematology into infectious disease applications. Sysmex has further advanced digital hematology through its collaborations in automated cell morphology and slide review, helping laboratories reduce manual microscopy demands and improve workflow consistency.

Coagulation

Sysmex Corporation and Siemens Healthineers continue to expand their collaboration in hemostasis through a global OEM partnership that enables both companies to distribute a combined portfolio of coagulation analyzers and reagents under their respective brands. This collaboration offers testing for blood clotting disorders, anticoagulant therapy monitoring, and perioperative risk assessment, and has been fully commercialized across major markets, including the United States and Europe.

While established systems such as the CS-2500 and CS-5100 remain widely used in high-volume laboratories, recent product development has focused on newer generation platforms within the CN-Series. A key advancement is the CN-6000 Automated Blood Coagulation Analyzer, which received U.S. regulatory clearance in 2025. This system is designed for high-throughput laboratories and incorporates enhanced automation, continuous sample loading, and improved workflow efficiency. The platform is supported by a comprehensive reagent menu, including assays for prothrombin time (PT/INR), activated partial thromboplastin time (APTT), fibrinogen, antithrombin, and D-dimer using established INNOVANCE reagents.

The CN-3000 system complements the CN-6000 by addressing the needs of mid- to high-volume laboratories, offering similar automation capabilities in a more compact configuration. Together, the CN-Series platforms provide scalable solutions for laboratories of all sizes while supporting integration with automated track systems and broader laboratory workflows.

Urinalysis

Sysmex Corporation expanded its urinalysis portfolio through advanced automation, digital imaging, and rapid microbiology solutions. The company's UN-Series systems represent the core of its automated urinalysis offering, combining fluorescence flow cytometry and digital imaging to deliver standardized and high-throughput urine sediment analysis. Platforms such as the UN-2000 integrate particle counting with imaging capabilities, enabling laboratories to reduce manual microscopy while improving consistency and workflow efficiency.

Sysmex also provides dedicated urine particle analyzers such as the UF-1500, which offers automated sediment analysis using flow cytometry and enables walk-away operation for routine laboratory workflows. Digital imaging capabilities are further supported by systems such as the UD-130, which capture and store high-resolution images of urine particles, enabling automated classification and remote review. Together, these systems create a fully integrated urinalysis workflow that enhances accuracy and reduces operator variability.

A key area of innovation for Sysmex is rapid testing for urinary tract infections, driven by its investment in Astrego Diagnostic AB. Sysmex is advancing point-of-care and near-patient systems capable of detecting bacterial presence in urine within minutes and determining antimicrobial susceptibility in approximately 30 minutes. These systems combine compact instrumentation with cartridge-based testing to support faster clinical decision-making and improved antimicrobial stewardship.

Immunoassays

Sysmex offers its HISCL Series, which utilizes chemiluminescence enzyme immunoassay technology to deliver high-sensitivity testing across a broad range of clinical applications. Current systems such as the HISCL-5000 and HISCL-800 form the foundation of Sysmex's immunochemistry offering, supporting both routine and specialized assays in areas including infectious disease, oncology, metabolic disorders, and inflammatory conditions.

Sysmex has focused on expanding its assay menu, introducing new parameters that enhance the clinical value of the HISCL platform. Notable developments include assays targeting amyloid beta biomarkers for Alzheimer's disease, enabling blood-based assessment of Aβ accumulation to support earlier diagnosis and treatment planning. Additional assay expansions include panels for gynecologic and gonadal hormones, as well as targeted tests such as the HISCL HIT IgG assay for heparin-induced thrombocytopenia and the HISCL C-peptide assay for diabetes management.

The company's established specialty markers, such as M2BPGi for liver fibrosis, TARC for atopic dermatitis, and presepsin for sepsis, are reinforcing the HISCL platform's role in both routine and advanced clinical testing. These assays are designed to deliver rapid turnaround times with small sample volumes while improving laboratory efficiency and standardization.

Additionally, Sysmex is advancing next-generation immunoassay technologies through systems such as the HI-1000, an ultra-high sensitivity platform intended for research and

emerging clinical applications. This system provides detection of extremely low-abundance biomarkers, particularly in liquid biopsy and precision medicine, and reflects Sysmex's long-term strategy to expand into high-sensitivity protein analysis.

Lab Information System

Sysmex's digital diagnostics is offered through its Caresphere platform, a networked system that connects laboratory instruments, information systems, and operational data in real time. Caresphere enables laboratories to standardize workflows across locations, improve operational visibility, and support data-driven decision-making through centralized monitoring and analytics.

The Caresphere laboratory workflow system serves as a core component, integrating pre-analytical, analytical, and post-analytical processes into a unified platform. The system provides real-time insight into laboratory operations, including sample tracking, turnaround times, and instrument utilization, allowing laboratories to optimize workflow efficiency and resource allocation. By linking multiple instruments and systems,

Sysmex has enhanced the Caresphere system with expanded cloud-based capabilities and interoperability, enabling remote access to operational data and improved coordination across healthcare networks. Additional modules such as Caresphere QM support quality management by providing continuous monitoring of quality control data, trend analysis, and compliance support, helping laboratories maintain standardized performance and regulatory adherence.

Sysmex has also introduced new diagnostic assays that integrate with its informatics infrastructure. These include immunoassay-based tests for neurological and metabolic conditions, such as blood-based amyloid beta assays used to support the evaluation of Alzheimer's disease. More recent additions to the HISCL assay menu include hormone panels, HIT antibody testing, and C-peptide assays, reflecting ongoing expansion of clinical parameters across its immunoassay systems.

Flow Cytometry

In flow cytometry, Sysmex offers its clinical flow cytometry portfolio with integrated systems designed to improve workflow standardization, automation, and analytical

performance. The company provides flow cytometry platforms supported by dedicated sample-preparation systems, such as the PS-10, along with a broad menu of antibody reagents for clinical and research applications. These solutions are designed to streamline sample handling, reduce manual preparation steps, and improve reproducibility across laboratories.

Sysmex offers a flow cytometry system configuration that emphasizes automated sample preparation, standardized reagent panels, and enhanced data analysis capabilities. The company's platforms offer a wide range of clinical applications, including hematologic malignancy assessment, immune profiling, and monitoring of therapeutic response.

Recent developments focus on improving integration between flow cytometry systems and laboratory information environments, enabling more efficient data management and workflow coordination. Sysmex is also expanding its reagent portfolio and panel design to support multiparameter analysis and more precise characterization of cell populations.

Precision Medicine / Companion Test Diagnostics

In Japan, Sysmex markets the PrismGuide APOE Genotyping Kit, an in vitro diagnostic assay that determines APOE genotype from genomic DNA extracted from whole blood and identifies six genotype combinations. The test is designed to support clinical decision-making by assessing a patient's risk of developing amyloid-related imaging abnormalities associated with anti-amyloid β antibody therapies used in Alzheimer's disease. While not a traditional oncology-style companion diagnostic, the assay serves as a therapy-guiding test, helping physicians evaluate treatment suitability and risk before initiating anti-amyloid therapies.

Sysmex's companion diagnostic activity remains focused on oncology through its OncoGuide NCC Oncopanel System, which continues to be expanded and used to identify actionable mutations and guide targeted therapies, including with FGFR inhibitors such as futibatinib. In 2025–2026, Sysmex has focused more on expanding the clinical utility of its genomic profiling and biomarker platforms rather than launching entirely new standalone companion diagnostics, with ongoing development of additional gene panel content, biomarker-driven assays, and collaborations to link diagnostics with targeted and precision therapies across oncology and neurodegenerative diseases.

Liquid Biopsy

Sysmex, through its subsidiary RIKEN GENESIS Co., Ltd., established the RIKEN GENESIS Innovation Genome Center at the Life Innovation Center within the Kawasaki Innovation Gateway at SKYFRONT to support large-scale genomic analysis. The facility integrates next-generation sequencing and liquid biopsy technologies to provide high-throughput gene analysis services and clinical sequencing with quality systems aligned to international standards, supporting both research and clinical applications in oncology and precision medicine.

Sysmex markets its blood-based RAS mutation testing in Japan through the OncoBEAM RAS CRC Kit, which detects circulating tumor DNA to identify mutations relevant to colorectal cancer treatment selection. The assay is used in clinical practice to guide targeted therapy decisions and represents one of Sysmex's key liquid biopsy offerings.

Sysmex's collaboration with QIAGEN is paramount to its companion diagnostics strategy, combining Sysmex's expertise in plasma-based testing with QIAGEN's assay development and global commercialization capabilities. The partnership, which has been expanded in recent years, continues to support the development and deployment of liquid biopsy-based companion diagnostics and therapy-guiding assays, with ongoing efforts focused on broadening biomarker coverage, improving sensitivity, and extending applications across additional cancer types.

Sysmex Inostics

Sysmex acquired Inostics GmbH from Indivumed and renamed the business Sysmex Inostics, establishing a foothold in liquid biopsy and molecular oncology. The company maintains its headquarters in Hamburg, Germany, and a CLIA-certified laboratory in Baltimore, Maryland, which supports clinical testing services and pharmaceutical collaborations. Sysmex Inostics specializes in highly sensitive mutation-detection technologies, including BEAMing and plasma-based sequencing approaches for analyzing circulating tumor DNA in blood samples.

Sysmex Inostics' OncoBEAM platform provides quantitative detection of tumor-specific somatic mutations for routine testing. These assays are widely used in oncology clinical trials, translational research, and therapy selection, particularly where tissue samples are limited or unavailable. Sysmex continues to position BEAMing as a core technology for liquid biopsy

applications and for integration into companion diagnostic development programs with pharmaceutical partners.

Sysmex Inostics operates globally across Europe, the United States, and Japan, providing assay services and supporting precision medicine initiatives through collaborations with academic institutions, research organizations, and biopharmaceutical companies. The company's core focus remains on oncology, specifically the detection of actionable genetic alterations in cell-free DNA, rather than broad infectious disease testing as previously emphasized.

The Sysmex Inostics OncoBEAM RAS CRC assay is the flagship product, enabling detection of RAS mutations in circulating tumor DNA to guide treatment decisions in metastatic colorectal cancer. The test supports the identification of patients unlikely to benefit from anti-EGFR therapies and provides a non-invasive alternative to tissue-based testing, particularly when rapid results are required or tumor samples are unavailable.

In addition to RAS testing, Sysmex Inostics offers a sequencing-based assay menu that includes targeted panels for solid tumors and hematologic malignancies, such as assays for head and neck cancer and acute myeloid leukemia. The company has also continued to refine its liquid biopsy portfolio by enhancing sensitivity, broadening biomarker coverage, and integrating with next-generation sequencing workflows.

Forging New Markets

Sysmex is investing heavily in artificial intelligence, data analytics, and digital health technologies to strengthen its position in personalized medicine, with a particular focus on integrating genomic testing, molecular diagnostics, and data-driven clinical decision support. The company has expanded its Cytocell operations by moving to a larger facility at Cambridge Science Park in the United Kingdom to accommodate increasing demand for fluorescence in situ hybridization (FISH) probes and support continued growth in cytogenetics and cancer diagnostics. Sysmex has also expanded into rapid antimicrobial susceptibility testing through its acquisition of Astrego Diagnostics AB, aiming to accelerate the clinical adoption of fast phenotypic AST solutions for urinary tract infections and to address the growing global challenge of antimicrobial resistance.

In Japan, Sysmex introduced the PrismGuide IRD Panel System, a diagnostic solution combining reagents and analysis software to perform comprehensive genomic profiling for

inherited retinal diseases, enabling the detection of mutations across a broad panel of disease-associated genes and supporting earlier and more precise diagnosis. The company has also collaborated with Hitachi High-Tech to advance genetic testing systems based on capillary electrophoresis sequencing technologies, reinforcing its capabilities in clinical genomics.

Geographically, Sysmex continues to expand its global infrastructure by strengthening direct sales and service operations in Italy across hematology, urinalysis, and hemostasis; establishing Sysmex East Africa in Kenya to support growth in multiple emerging markets; and expanding its diagnostic reagent production capacity in Brazil to improve regional supply and responsiveness. In addition, Sysmex has announced plans to relocate its headquarters functions within Kobe by 2028 to enhance operational integration and support long-term growth.

Thermo Fisher Scientific Inc.

Waltham, MA

www.thermofisher.com

Table 14-22: Thermo Fisher Revenue History, Clinical Diagnostics, 2023-2025 ($ million)

	2023	2024	2025
Specialty Diagnostics	$4,405	$4,512	$4,676

Source: company reports, Kalorama Information

Specialty diagnostics revenues grew in 2025 approximately 3.6% over 2024. The increase results from strong growth in sales of immunodiagnostics and transplant diagnostics.

Thermo Fisher Scientific was formed through the $10.6 billion merger of Thermo Electron and Fisher Scientific in 2006 and has since evolved into one of the largest global providers of scientific instrumentation, specialty diagnostics, and laboratory services. The company offers a broad portfolio spanning analytical instruments, including advanced mass spectrometry systems, as well as reagents, chemicals, antibodies, and consumables used across biotechnology, pharmaceutical, and clinical laboratory settings. Thermo Fisher serves a diverse customer base, including healthcare providers, pharmaceutical and biotech companies, academic institutions, and government laboratories, with a strategy focused on integrating research, diagnostics, and applied markets.

Its core brands, including Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, and Unity Lab Services, collectively support end-to-end laboratory workflows from discovery through clinical application. The company has transformed from a traditional laboratory supply and distribution model into a highly diversified life sciences and diagnostics leader through sustained acquisitions and product development. In the in vitro diagnostics sector, Thermo Fisher operates primarily through its Thermo Scientific platform, with strong capabilities in specialty diagnostics, including immunodiagnostics, clinical chemistry, microbiology, and molecular testing, while Fisher Scientific continues to function as a global distribution and services channel. The company has emphasized expanding

translational capabilities, aiming to bridge genomic and proteomic research into clinical diagnostics and precision medicine applications.

Thermo Fisher has further strengthened its position in specialty diagnostics and proteomics through targeted acquisitions, including The Binding Site Group, which expanded its presence in plasma protein testing and hematology diagnostics, particularly in multiple myeloma and related disorders, and Olink, which enhances its leadership in high-throughput proteomics and biomarker discovery.

Additionally, the company continues to invest in molecular diagnostics, next-generation sequencing workflows, and companion diagnostics, supporting the growing demand for personalized medicine and integrated diagnostic solutions. Thermo Fisher has expanded beyond its traditional focus on tools and diagnostics into a more comprehensive role across clinical research, data, and pharmaceutical services. The acquisition of Clario strengthens its capabilities in clinical trial data capture and endpoint analytics, while collaborations in real-world data integration enhance its ability to support evidence generation and regulatory decision-making. The company is also increasing its presence in contract development and manufacturing, including investments in sterile drug manufacturing capacity and biologics production, aligning with demand for outsourced pharmaceutical development and domestic manufacturing. Additional expansion in bioprocessing and filtration technologies further supports cell and gene therapy and biologics workflows.

Immunoassays

Thermo Fisher Scientific has one of the broadest specialty immunodiagnostic and drugs-of-abuse testing menus in the market. In toxicology, the company offers assays such as the DRI Hydrocodone assay and the CEDIA Buprenorphine II assay, offering urine drug testing with sensitivity suited to modern opioid-monitoring requirements. Its drugs-of-abuse portfolio also includes the Thermo Scientific CEDIA Mitragynine assay for kratom detection, marketed for forensic and criminal justice use, and Thermo Fisher continues to maintain a broad menu of assays for prescription drug, opioid, and substance-use monitoring on routine clinical chemistry analyzers. In allergy and autoimmunity, Thermo Fisher is a major contributor through its ImmunoCAP and EliA product lines and Phadia laboratory systems. The company offers EliA anti-thyroglobulin and anti-thyroid peroxidase tests for autoimmune thyroid disease, while the Phadia 200 supports a broad menu of ImmunoCAP and EliA assays used in the diagnosis of allergic and autoimmune conditions. Its

ImmunoCAP specific IgE menu, including peanut component testing such as Ara h 6, remains an important part of component-resolved allergy diagnostics and continues to see broader clinical adoption.

Thermo Fisher also has a strong position in maternal-fetal and specialty protein testing through its B·R·A·H·M·S and Binding Site businesses. The B·R·A·H·M·S KRYPTOR GOLD system supports assays for prenatal screening and preeclampsia risk assessment, including sFlt-1 and PlGF biomarkers, while the company has also expanded its oncology-supportive immunoassay offerings with products such as the B·R·A·H·M·S CgA II KRYPTOR assay. In plasma cell disorder testing, Thermo Fisher strengthened its portfolio through the Optilite Freelite assays, which received expanded U.S. clearance in 2024 for evaluation of monoclonal gammopathy of undetermined significance. The company further advanced this area in 2025 with U.S. clearance for the EXENT system, an automated mass spectrometry platform designed to aid in the diagnosis of multiple myeloma and related monoclonal gammopathies. These additions broaden Thermo Fisher's role beyond traditional immunoassay testing and reinforce its position in specialty diagnostics across toxicology, allergy, autoimmunity, women's health, oncology-related testing, and hematologic disease assessment.

Microbiology

Thermo Fisher Scientific offers one of the most comprehensive antimicrobial susceptibility testing portfolios in the clinical microbiology market. The company offers its Thermo Scientific Sensititre platform. Sensititre systems provide both manual and automated broth microdilution testing, delivering standardized minimum inhibitory concentration results that remain the gold standard for antimicrobial susceptibility assessment. The platform includes a range of workflow solutions, including the Sensititre ARIS 2X automated reading and incubation system, the Sensititre Vizion digital MIC viewing system, and supporting informatics and barcoding tools designed to streamline laboratory operations. Thermo Fisher continues to expand its panel offerings to include clinically relevant antimicrobials, particularly those targeting multidrug-resistant Gram-negative organisms, reinforcing its role in addressing antimicrobial resistance challenges.

The Sensititre microbroth dilution plate portfolio includes panels designed for both Gram-negative and Gram-positive organisms, incorporating newer antimicrobial combinations such as beta-lactam/beta-lactamase inhibitor therapies. These plates enable laboratories to

generate precise MIC values across a broad range of antibiotics, supporting optimized therapeutic decision-making, antimicrobial stewardship initiatives, and resistance surveillance. While individual plate configurations evolve over time to reflect emerging therapies and resistance patterns, the overall Sensititre system remains a cornerstone technology for standardized AST in clinical laboratories worldwide.

In addition to AST, Thermo Fisher supports microbiology workflows through its Oxoid culture media and chromogenic media portfolio, which are used for organism isolation and preliminary identification. Earlier integrations with digital colony counting and chromogenic media interpretation systems helped automate portions of the microbiology workflow, and more recent efforts have focused on improving laboratory efficiency through enhanced workflow connectivity, data management, and compatibility with laboratory information systems. The company continues to align its microbiology solutions with broader trends toward automation, digital microbiology, and faster turnaround times.

Thermo Fisher's AST solutions are also used to support antimicrobial development and clinical decision-making, including applications for newer antibiotics targeting resistant infections.

Molecular Test Business

Thermo Fisher Scientific's molecular diagnostics business offers a portfolio of PCR, next-generation sequencing, and genetic analysis platforms that support both research and clinical applications. Core systems include the Ion Torrent sequencing platforms, the Applied Biosystems 3500 Dx Series genetic analyzers for capillary electrophoresis, and the Applied Biosystems QuantStudio Dx family of real-time PCR instruments, which are used in clinical and public health laboratories. The company has expanded the clinical utility of these platforms through assay menu development, automation, and integration with laboratory workflows, with a particular focus on infectious disease, oncology, and genetic testing. While Affymetrix microarray technologies historically played a major role in multiplex genomic analysis, their importance has declined relative to PCR and NGS-based approaches, although they continue to be used in selected research and specialty applications.

Thermo Fisher's PCR assay portfolio includes a broad menu of syndromic and targeted panels. Products such as the TaqPath enteric testing panels and the TrueMark STI Select Panel support multiplex detection of gastrointestinal pathogens and sexually transmitted infections, respectively, using streamlined workflows on QuantStudio systems. The company

has also expanded its presence in decentralized molecular testing through the Accula platform, which delivers rapid PCR-based results for respiratory infections such as influenza at or near the point of care. In infectious disease response, Thermo Fisher provides public health testing through assays targeting emerging pathogens, building on earlier test development for orthopoxviruses and other high-priority infectious threats.

In addition to PCR, Thermo Fisher is increasingly positioning its Ion Torrent sequencing platforms for clinical applications, including oncology and genetic disease testing, with ongoing efforts to simplify workflows and improve turnaround time for clinical laboratories. The company is also enhancing its molecular portfolio through automation, sample-preparation solutions, and data-analysis tools to support higher throughput and more standardized testing environments. While earlier collaborations, such as integration efforts involving third-party molecular systems, helped expand workflow flexibility, Thermo Fisher's current strategy is more focused on delivering integrated, end-to-end molecular solutions across PCR and sequencing.

In recent years, Thermo Fisher has expanded its molecular diagnostics portfolio beyond traditional PCR systems into fully integrated and automated clinical testing solutions. An example is the Ion Torrent Genexus Dx system, an automated next-generation sequencing platform designed to deliver sample-to-report results with minimal hands-on time. The system, paired with the Oncomine Dx Express test, supports oncology applications including companion diagnostics, reflecting Thermo Fisher's growing presence in clinical NGS. Additionally, the company has enhanced its PCR system through workflow-integration tools, such as Diomni software and automated sample-preparation systems, enabling more efficient and standardized molecular testing. These developments highlight Thermo Fisher's strategic shift toward fully integrated molecular diagnostics solutions that combine PCR, sequencing, automation, and data management to support precision medicine and decentralized testing environments.

Next-Generation Sequencing

Thermo Fisher Scientific's next-generation sequencing portfolio includes Ion Torrent semiconductor technology and a strategic shift toward fully integrated, automated, and clinically focused solutions. While earlier workflows relied on systems such as the Ion Chef and Ion GeneStudio S5 series, the company's current emphasis is on the Genexus platform, including the Genexus Dx system, which enables automated sample-to-report sequencing

with minimal hands-on time and rapid turnaround, suitable for decentralized clinical laboratories. Supporting this platform, the Oncomine Dx Express test and related oncology panels provide clinically actionable tumor profiling, including companion diagnostic applications, while the Oncomine Precision Assay enables comprehensive genomic profiling from both tissue and liquid biopsy samples. Thermo Fisher continues to expand its targeted sequencing capabilities through Ion AmpliSeq HD technology, which supports high-sensitivity detection of low-frequency variants in applications such as liquid biopsy and heterogeneous tumor analysis. In parallel, the company is strengthening its integrated NGS ecosystem through automation, software, and workflow standardization, aligning its sequencing portfolio with the growing demand for precision medicine, decentralized testing, and rapid clinical decision-making in oncology and genetic disease.

Thermo Fisher provides its Oncomine Dx Target test as a companion diagnostic to identify patients eligible for treatment with Hernexeos, a tyrosine kinase inhibitor offered by Boehringer Ingelheim. The company also provides its Oncomine Dx Express NGS Assay as a companion diagnostic for Zegfrovy and for tumor profiling.

qPCR

Thermo Fisher Scientific offers the Applied Biosystems QuantStudio 6 and 7 Pro Real-Time PCR Systems, advanced connected qPCR platforms designed to improve laboratory workflow efficiency, data integrity, and user interaction. These systems incorporate features such as user authentication, voice-enabled operation, and RFID-enabled plate recognition to streamline assay setup and reduce manual input errors. The instruments support the use of TaqMan Array Plates with embedded assay information, enabling automatic upload of plate layouts and minimizing setup variability. QuantStudio Pro systems are also integrated with cloud-based connectivity through Instrument Connect software, allowing users to monitor runs, access data, and perform remote analysis from desktop or mobile devices. In current use, these platforms are positioned as part of Thermo Fisher's broader connected laboratory system, offering applications in research, clinical diagnostics, and high-throughput testing environments.

Oncology Companion Diagnostics

Thermo Fisher offers its Oncomine family of next-generation sequencing assays, with a clear transition from earlier platforms such as the Ion PGM Dx system to fully automated,

integrated sequencing solutions. The Oncomine Dx Target Test, originally developed using Ion AmpliSeq technology, established Thermo Fisher as an early leader in NGS-based companion diagnostics by enabling multiplex detection of clinically relevant genomic alterations from limited tissue samples. While this assay remains in use and continues to receive expanded indications, the company's current strategy is focused on more advanced platforms.

The Oncomine Dx Express Test, designed for use on the Genexus Dx system, represents Thermo Fisher's most recent and important advancement in molecular oncology diagnostics. This fully automated, sample-to-report sequencing solution enables rapid tumor profiling and companion diagnostic testing with turnaround times of approximately one day, supporting decentralized clinical laboratories and faster treatment decisions. The assay can detect a broad range of genomic alterations, including mutations, insertions and deletions, gene fusions, and copy number changes across multiple cancer-related genes, and has received expanded regulatory approvals for both tumor profiling and targeted therapy selection in oncology.

Thermo Fisher has expanded its companion diagnostic portfolio through collaborations with pharmaceutical companies to support targeted therapies across multiple tumor types, including lung cancer and other solid tumors. The company is also advancing multi-biomarker companion diagnostic systems designed to support a broader range of genomic targets within a single assay, reflecting the shift toward comprehensive genomic profiling in precision medicine. In addition, Thermo Fisher offers specialized sequencing solutions, such as the SeCore HLA system, for immunotherapy applications.

Transplant Medicine

Thermo Fisher Scientific offers its transplant line through the One Lambda brand acquired in 2012, and provides a comprehensive portfolio of HLA typing and antibody detection assays used to assess donor–recipient compatibility and monitor transplant patients for signs of rejection. The company offers testing solutions based on serological, molecular, ELISA, flow cytometry, and bead-based multiplex technologies, supporting both pre-transplant matching and post-transplant surveillance. One Lambda is a global leader in transplant immunology, serving transplant centers worldwide with assays designed to improve graft survival and clinical outcomes. Thermo Fisher has expanded its transplant diagnostics

capabilities beyond traditional HLA typing into advanced molecular and genomic approaches.

The company offers next-generation sequencing that is based HLA typing through its Ion Torrent platforms and associated workflows, while continuing to provide PCR-based and multiplexed assay solutions for comprehensive genetic profiling, including HLA, KIR, and platelet antigen testing. In recent years, Thermo Fisher has strengthened its position in transplant monitoring by introducing novel molecular assays and services that enable earlier, less invasive detection of rejection. These include the CXCL10 testing service, which uses urine samples to detect inflammatory signals associated with early kidney transplant rejection, and the One Lambda Pre-Transplant Risk Assessment assay, which uses a multi-gene expression signature to generate a risk score for early acute rejection.

Thermo Fisher is also advancing its transplant diagnostics portfolio through sequencing and PCR approaches for donor-derived cell-free DNA analysis, supporting non-invasive monitoring of graft health and expanding its role in next-generation transplant surveillance alongside traditional immunological testing.

Mass Spectrometry

Thermo Fisher Scientific is one of the leaders in mass spectrometry, with a strong presence across research, pharmaceutical development, and applied markets. While mass spectrometry has historically been used primarily in research settings, the company continues to advance its technologies for use in clinical and translational diagnostics. Thermo Fisher's current strategy focuses on enabling clinical laboratories to adopt liquid chromatography–tandem mass spectrometry through improved automation, standardized workflows, and integrated software solutions that reduce the need for highly specialized expertise. Earlier efforts to introduce fully automated clinical mass spectrometry systems, such as the Cascadion platform, demonstrated the potential for broader adoption of MS-based testing in hospital laboratories, particularly for small-molecule analysis. However, more recent developments have shifted toward high-performance, flexible mass spectrometry systems capable of supporting both research and clinical applications. In 2025, Thermo Fisher expanded its portfolio with the introduction of advanced Orbitrap-based systems, including the Orbitrap Astral Zoom and Orbitrap Excedion Pro mass spectrometers. These systems are designed to deliver higher sensitivity, speed, and analytical resolution, supporting applications in proteomics, biomarker discovery, and translational research, as well as emerging clinical use

cases. Thermo Fisher also provides integrated mass spectrometry workflows that combine high-resolution instrumentation with standardized sample preparation, software, and data analysis tools to support clinical research and emerging diagnostic applications.

Werfen

Barcelona, Spain

http://www.werfen.com/en

Table 14-23: Werfen Recent Revenue History, 2023-2025 (€ billion)

	2023	2024	2025 est
Total IVD Revenues	2.1	2.2	2.1

Source: company reports, Kalorama Information

Werfen is a family-owned diagnostics company focused on specialized testing segments, with core operations built around several key business units including Instrumentation Laboratory (hemostasis and acute care), Biokit (immunodiagnostics), and Inova Diagnostics (autoimmunity). Instrumentation Laboratory, headquartered in Bedford, Massachusetts, serves as the primary R&D, manufacturing, and commercial engine for hemostasis and blood gas testing, while Biokit, based in Spain, develops and supplies reagents, and Inova Diagnostics, based in San Diego, focuses on autoimmune disease diagnostics. The company operates globally with a direct presence in approximately 30 countries and distribution in more than 100 territories, employing close to 7,000 people, with manufacturing and research activities concentrated in the United States and Europe.

Werfen generated approximately €2.13 billion in revenue in 2025, down from €2.2 billion in 2024, reflecting continued underlying growth despite some regional market pressures. Revenues are driven by its core segments: hemostasis, acute care diagnostics, and autoimmunity, with strength in North America and other key markets. There is a slower demand in certain parts of Asia. Across its installed base, Werfen systems and reagents continue to process well over a million patient samples per day globally.

Hemostasis remains the company's largest business line, supported by its ACL TOP family of coagulation analyzers, which continues to expand through ongoing menu development and system enhancements. The segment generated roughly €699 million in 2025, driven by reagent utilization and analyzer placements. Werfen maintains a strong position in specialized coagulation diagnostics, particularly in hospital-based and high-throughput

settings, while expanding its assay menu in areas such as thrombosis risk and anticoagulant monitoring.

In acute care diagnostics, Werfen has strengthened its position in blood gas testing with the rollout of the GEM Premier 7000 platform featuring iQM3 intelligent quality management. This system represents an advancement in point-of-care blood gas testing, incorporating real-time quality control and improved detection of pre-analytical issues such as hemolysis. The GEM Premier 7000 was launched in the United States in 2024 and expanded into Europe in 2025, with continued rollout underway. The acute care segment generated approximately €649 million in 2025 and continues to grow across all regions outside China. The company is placing increasing emphasis on connectivity and data integration, with iQM3 positioned as a key differentiator in improving workflow efficiency and reducing errors at the point of care.

In autoimmunity, Inova Diagnostics offers its BIO-FLASH chemiluminescent platform and the Aptiva system, which utilizes particle-based multi-analyte technology for autoimmune testing. The segment generated approximately €192 million in 2025, achieving 8% growth as laboratories shift toward fully automated, random-access systems and multiplex testing approaches. Werfen continues to offer assays for conditions such as antiphospholipid syndrome, including IgG and IgM antibody testing, while benefiting from broader trends toward earlier and more precise diagnosis of autoimmune diseases.

Werfen has expanded beyond traditional immunoassay and coagulation testing with the acquisition of Omixon, strengthening its position in transplant diagnostics and next-generation sequencing-based HLA typing. This adds a molecular component to its portfolio and is expected to become more important as integration progresses. The company is focused on increasing product launches, expanding installed-base utilization, and advancing its capabilities in connectivity, automation, and molecular diagnostics.

Chapter 15: Company Profiles: The Second Tier

Scope

In this section, Kalorama has selected a group of companies that have demonstrated longevity, market penetration, and/or contributed important innovations in IVD. The profiles are not intended to be comprehensive reviews or histories of the companies included in this section, and are listed alphabetically.

ARKRAY

Kyoto, Japan

www.ARKRAY.co.jp/english

ARKRAY, Inc. was founded in 1960 and has established presence in the global diagnostic industry, particularly in diabetes care and clinical laboratory testing. The company develops and manufactures a broad range of diagnostic and monitoring solutions, including automated systems for urinalysis, HbA1c testing, and clinical chemistry, along with associated reagents and consumables. ARKRAY is recognized for early innovation in diabetes diagnostics, including the introduction of the EYETONE system in 1971, one of the first portable blood glucose analyzers, and the development of an HbA1c analyzer based on HPLC technology in the early 1980s. The company remains a significant global supplier of glucose monitoring systems, with a strong presence in both professional and self-testing markets.

ARKRAY has expanded its international footprint, with commercial operations across Europe, including offices in Italy, Spain, Portugal, the United Kingdom, and Belgium, and a manufacturing facility in Ireland that supports regional distribution and production. In clinical diagnostics, ARKRAY markets fully automated urine analyzers and sediment analysis systems, as well as dry-chemistry analyzers designed for small- to mid-sized laboratories and decentralized testing environments. The company has also strengthened its portfolio in HbA1c testing with both laboratory-based and point-of-care systems, supporting diabetes management across care settings.

Updates reflect ongoing operational and portfolio alignment rather than major product platform shifts. In 2025, ARKRAY America implemented a labeling update associated with the relocation of its U.S. operations office, representing an administrative change without impact on product performance or regulatory status

Dry Chemistry / Immunoassays

ARKRAY, Inc. has a presence in decentralized clinical chemistry, with its SPOTCHEM series of dry-chemistry analyzers supporting near-patient and small-laboratory testing since the late 1980s. The SPOTCHEM EZ remains a compact, portable, CLIA-waived benchtop chemistry analyzer designed for rapid testing in physician offices and clinics. Utilizing dry

chemistry technology, the system supports flexible testing with panels, single assays, or combinations, and accommodates whole blood, serum, or plasma samples. It features automated calibration via magnetic card, minimal operator intervention, and walk-away operation, eliminating the need for sample pre-treatment. The test menu continues to focus on routine chemistry and lipid testing, with a defined panel structure suited to point-of-care environments and has been incrementally expanded with additional multi-analyte reagent strips targeting liver, renal, and metabolic testing.

In the United States, ARKRAY's SPOTCHEM platform is available with CLIA-waived testing for lipid panels and general chemistry, while additional moderately complex assays extend its capabilities to diabetes-related markers, calcium, proteins, and enzymes, enabling broader use in physician office laboratories and decentralized settings. The company also offers the SPOTCHEM EL system, which applies similar dry-chemistry principles in specialized and veterinary settings, further broadening the platform's reach. Complementing its hardware, ARKRAY has continued to enhance connectivity and workflow integration, including compatibility with laboratory information systems and simplified data management, to support efficient operations in small- and mid-sized clinical environments.

ARKRAY has continued to refine its dry chemistry offering with updates such as the SPOTCHEM D-00 QR, an evolution of the SPOTCHEM D-Concept system. This platform integrates dry chemistry with immunoassay measurement capabilities and is configured as a modular system comprising a central operating unit and interchangeable measurement modules for immunology, biochemistry (including electrolytes), and centrifuge-based processing. The SPOTCHEM D-Concept platform remains differentiated by its modular design and ability to combine multiple testing modalities within a compact footprint, enabling primary screening for kidney function, liver function, metabolic conditions, and lifestyle-related diseases through flexible reagent configurations.

Urinalysis

ARKRAY, Inc. has a long history in urinalysis dating back to the early 1970s, when it introduced one of the first automated urine analyzers in urine chemistry and sediment analysis. Since that time, the company has steadily expanded its urinalysis portfolio to include fully automated urine chemistry analyzers, test strips, sediment analysis systems, and data management solutions. ARKRAY's development efforts focus on improving laboratory

efficiency, automation, and clinical utility, particularly for the early detection and monitoring of kidney disease and metabolic disorders.

The AUTION ELEVEN series is a main component of ARKRAY's urine chemistry offering, with systems such as the AE-4021 and AE-4022 providing compact, automated analysis for low- to mid-volume laboratories. These instruments offer a broad menu of urine dipstick tests, including advanced parameters enabled by test strips such as the Uriflet S 11UA, which allow measurement of albumin-to-creatinine and protein-to-creatinine ratios in addition to standard analytes. These capabilities enhance the clinical value of routine urinalysis by supporting early identification of chronic kidney disease and diabetic nephropathy and reflect continued expansion of multi-parameter strip offerings.

ARKRAY has also advanced automation in pre-analytical and analytical workflows with systems such as the AUTION DISPENSER UD-9440, which automates sample handling processes including barcode identification, mixing, aliquoting, and labeling. This system integrates with high-throughput analyzers such as the AUTION MAX AX-4060 and AX-4061, enabling seamless sample transport and continuous processing. The AUTION MAX series is central to ARKRAY's high-volume urinalysis strategy, offering fully automated measurement of routine chemistry parameters, as well as proteinuria and microalbuminuria, with flexible sample handling, including small-volume and direct-cup analysis.

In addition to chemistry-based urinalysis, ARKRAY has expanded its capabilities in automated urine sediment analysis through image-based systems such as the AUTION EYE AI-4510, which incorporates advanced digital imaging and AI-assisted particle recognition to improve standardization, reduce manual microscopy, and enhance workflow efficiency. This technology reflects the broader shift toward integrated urine chemistry and sediment analysis within a single automated workflow.

ARKRAY's collaboration with Beckman Coulter continues to support high-throughput laboratory solutions through the iQ Urinalysis Workcell, which combines ARKRAY's AUTION MAX AX-4030 urine chemistry analyzer with Beckman Coulter's digital flow morphology system. Offered in scalable configurations, the system enables automated particle classification and harmonized chemistry results across platforms. Together with standalone analyzers and integrated systems, ARKRAY now provides a comprehensive urinalysis ecosystem that spans pre-analytical automation, chemistry testing, and AI-enabled sediment analysis, with ongoing enhancements focused on workflow integration, expanded test parameters, and improved laboratory efficiency.

BGI Genomics (formerly Beijing Genome Institute)

Shenzhen, China

http://www.genomics.cn/en

BGI Group (formerly Beijing Genomics Institute), with its publicly listed subsidiary BGI Genomics, is a global genomics organization headquartered in Shenzhen, China. Founded in 1999 to participate in the Human Genome Project, the company has evolved into a major provider of sequencing services, clinical genomics, and bioinformatics solutions. BGI operates through a network of research, clinical, and service laboratories across China, Europe, Asia Pacific, and the United States, supporting applications in healthcare, population genomics, agriculture, and pharmaceutical research. Its mission focuses on advancing life sciences through large-scale genomics, technology development, and global scientific collaboration.

BGI offers high-throughput sequencing and integrated multi-omics capabilities, supported by its proprietary sequencing platforms and bioinformatics infrastructure. Rather than relying on older Illumina-based systems, BGI has developed its own sequencing technologies through its affiliated platform-development arm, enabling scalable, cost-efficient genomic analysis. The company's clinical diagnostics operations, often referred to as BGI Genomics or BGI Diagnostics, provide a broad range of testing services, including non-invasive prenatal testing, oncology testing, infectious disease detection, and genetic screening. These services are supported by centralized and regional laboratories, reflecting a global service model rather than reliance on a single high-capacity sequencing site.

In recent years, BGI has expanded its focus to include clinical and public health applications, such as population-scale screening programs, oncology genomics, and infectious disease surveillance. The company continues to integrate sequencing, mass spectrometry, and data analytics to support precision medicine initiatives, while also maintaining activity in research and industrial applications, including agriculture and synthetic biology. While BGI has explored consumer-facing genomics services, its primary strategic direction is concentrated on clinical diagnostics, large-scale genomic projects, and partnerships with healthcare systems and governments.

MGI Tech Co., Limited, China

MGI Tech Co., a subsidiary of BGI Group, develops and manufactures sequencing instruments, consumables, and reagents designed to support life science research, clinical diagnostics, and population genomics. The company's technology platform provides its proprietary DNBSEQ sequencing technology, which enables high-throughput, cost-efficient genomic analysis. As the instrumentation arm of BGI, MGI focuses on providing integrated sequencing solutions, including automated sample-preparation systems, sequencing platforms, and associated reagents, to support applications across healthcare, agriculture, and environmental research. MGI's current product portfolio offers its DNBSEQ and CycloneSEQ platforms, which have largely superseded earlier BGISEQ systems. Key instruments include mid- to high-throughput sequencers, such as the MGISEQ-2000 series, and high-output systems, such as the DNBSEQ-T7, designed for large-scale genomic projects and clinical sequencing applications. More recently, MGI introduced the DNBSEQ-T1+ sequencer, a flexible platform featuring multiple flow cell formats and lane configurations to support a wide range of throughput requirements. These systems are supported by advances in sequencing chemistry, including HotMPS and CoolMPS technologies, which are designed to improve accuracy, reduce duplication rates, and enable PCR-free workflows.

In addition to instrumentation, MGI has expanded its portfolio of targeted sequencing solutions and workflow packages. Additional offerings include ATOPlex-based assays for infectious disease applications, such as dengue virus and multipathogen panels, as well as whole-genome sequencing solutions for microbial isolates that are compatible with newer sequencing platforms. The company also offers clinical applications such as circulating tumor DNA and minimal residual disease analysis in oncology, reflecting the growing importance of liquid biopsy and precision medicine

Prenatal Testing

Founded in 2007, BGI Diagnostics focuses on applying genomic technologies to clinical practice, with an emphasis on reproductive health, disease prevention, and precision medicine. The company is widely recognized for its leadership in non-invasive prenatal testing (NIPT), particularly through its NIFTY test, which uses cell-free DNA sequencing to screen for common fetal chromosomal abnormalities such as trisomies 21, 18, and 13 from early pregnancy. Over time, the NIFTY test has evolved into a broadly adopted screening

solution with expanded capabilities, including detection of sex chromosome aneuploidies, selected microdeletions and microduplications, and, in some markets, more comprehensive genome-wide screening options. In addition to its core NIPT offering, BGI Diagnostics has expanded its reproductive genomics portfolio to include carrier screening, preimplantation genetic testing, and other prenatal and neonatal genetic services, reflecting a more integrated approach to reproductive health.

Test Services

The following are representative examples of the test services offered by BGI Group. The company has processed large volumes of clinical samples globally across a range of applications, including noninvasive prenatal testing, human papillomavirus screening, newborn screening, hearing impairment testing, and rare disease analysis. BGI has established itself as a high-throughput service provider, leveraging large-scale sequencing infrastructure to deliver cost-efficient genomic testing across diverse clinical and public health programs.

BGI provides its proprietary sequencing platforms and a global laboratory network, enabling the company to offer whole-genome sequencing, targeted sequencing, and population-scale genomic analysis. The company continues to pursue cost reduction strategies and high-volume sequencing capabilities, with long-term goals of making genomic sequencing more accessible and affordable for routine clinical use. Rather than focusing on earlier-generation platforms, BGI emphasizes its DNBSEQ-based technologies to support scalable sequencing services.

BGI Genomics has established multiple collaborations with healthcare providers, research institutions, and industry partners to expand the use of genomic testing in oncology, reproductive health, and precision medicine. These partnerships include efforts to apply whole genome sequencing and advanced analytics to improve cancer treatment selection, support immunotherapy response prediction, and enable personalized healthcare approaches. The company is also active in expanding reproductive health services and integrating genomic technologies into broader clinical workflows.

In addition to large-scale sequencing services, BGI has developed targeted testing panels such as hereditary cancer assays, which are designed to identify germline variants across multiple cancer-associated genes. These offerings are supported by high-throughput sequencing platforms and bioinformatics pipelines that enable comprehensive genomic

profiling. BGI continues to expand its presence in precision medicine and public health initiatives, including collaborations focused on population genomics and data-driven healthcare.

Whole Genome Sequencing (WGS)

BGI Genomics has expanded its capabilities in clinical whole-genome sequencing through collaborations with diagnostic and bioinformatics partners to improve the analysis, interpretation, and reporting of genomic data. These efforts combine BGI's proprietary DNBSEQ sequencing technology with advanced bioinformatics pipelines to support the diagnosis of genetic disorders and enable broader adoption of whole-genome sequencing in clinical settings. The company's strategy emphasizes integration of sequencing, artificial intelligence, and cloud-based computing to deliver scalable and clinically actionable genomic insights.

BGI has pursued long-term initiatives to reduce sequencing costs and turnaround times, focusing on high-throughput whole-genome sequencing supported by advanced computing infrastructure. These efforts have evolved into increasingly standardized clinical sequencing workflows that support both diagnostic applications and large-scale genomic programs. BGI Genomics has developed a range of clinical sequencing-based assays, including tests for hereditary conditions and oncology applications. These include homologous recombination deficiency detection assays used to support treatment decisions in cancer patients, as well as genetic testing panels for inherited disorders such as thalassemia. The company is also expanding its oncology portfolio into circulating tumor DNA and minimal residual disease applications, as well as targeted sequencing panels for infectious disease detection and public health surveillance.

NGS Sequencing

BGI Genomics offers its infectious disease and genetic testing portfolio through sequencing-based diagnostic solutions. The company has introduced metagenomic next-generation sequencing tools, such as GPMeta, designed to detect a broad range of pathogens directly from clinical samples by analyzing complex sequencing data. These solutions enable comprehensive identification of bacteria, viruses, fungi, and other microorganisms, supporting clinical microbiology, particularly in cases where conventional methods are inconclusive, and are increasingly applied in areas such as sepsis, respiratory infections, and

central nervous system infections. BGI has also expanded targeted sequencing approaches for multi-pathogen detection and public health surveillance, supporting rapid response to infectious disease outbreaks.

In addition to infectious disease diagnostics, BGI offers a range of reproductive and genetic screening services, including its VISTA Carrier Screening program, which uses next-generation sequencing to identify individuals or couples at risk of passing on inherited genetic conditions. The panel has been expanded to include a large number of genes associated with rare disorders and is increasingly positioned alongside broader reproductive genomics services.

BGI has also developed pathogen detection workflows, such as PMseq, designed for rapid, sensitive identification of infectious agents across a variety of clinical sample types. These tools are being increasingly used in clinical and public health settings, including outbreak surveillance and epidemiological monitoring, where rapid and unbiased pathogen detection is critical.

Biocartis

Mechelen, Belgium

www.biocartis.com

Biocartis' flagship Idylla platform is a fully automated, cartridge-based molecular diagnostics system designed to process a wide range of biological samples in decentralized laboratory settings. The platform integrates sample preparation, nucleic acid extraction, amplification, and detection into a single workflow, enabling results in approximately 35 to 150 minutes with minimal hands-on time. Idylla assays are compatible with formalin-fixed, paraffin-embedded (FFPE) tissue and other tumor sample types through onboard liquefaction and lysis, and support both DNA and RNA analysis. The system's compact footprint, ease of use, and rapid turnaround time make it well-suited for near-patient and routine pathology laboratory environments.

Biocartis offers a growing menu of molecular assays on the Idylla platform, primarily focused on oncology, with additional applications in infectious disease. The oncology portfolio includes assays for clinically actionable biomarkers such as EGFR, KRAS, NRAS, and BRAF, as well as microsatellite instability (MSI) testing. The Idylla MSI test has received regulatory clearance and provides a rapid assessment of MSI status directly from tumor tissue. The company has also expanded into liquid biopsy with assays targeting circulating tumor DNA, including EGFR mutation detection.

Recent product development has focused on expanding menu flexibility and oncology coverage. The Idylla FLEX technology enables separation of assay-specific reagents from core system components, supporting faster development and broader test menus. Using this approach, Biocartis offers assays such as the Idylla IDH1-2 Mutation Assay and is expanding into breast cancer testing with panels targeting biomarkers including PIK3CA and AKT1, as well as gene expression–based subtyping assays. The Idylla GeneFusion Panel supports the detection of key gene fusions relevant to non-small cell lung cancer, including ALK, ROS1, and MET alterations.

Biocartis continues to advance its companion diagnostics strategy through collaborations with pharmaceutical partners and the development of regulatory-cleared assays. In 2025, the company achieved CE marking for its EGFR Mutation Test as a Class C companion

diagnostic, supporting targeted therapy selection in non-small cell lung cancer. Additional partnerships and assay development efforts are focused on expanding biomarker testing across oncology indications and enabling rapid, decentralized access to molecular diagnostics.

Biocartis offers Idylla CDx MSI Test, which is designed to identify eligible microsatellite instability-high colorectal cancer patients who may benefit from treatment with Opdivo. The test is run on the Idylla platform and qualitatively detects a panel of seven monomorphic biomarkers to detect MSI in a CRC tissue sample. The test runs in a single-use cartridge and provides results in about 3 hours.

Diagnostica Stago S.A.S.

Asnières sur Seine, France

www.stago.com

Founded in 1945 and focused exclusively on hemostasis for decades, Diagnostica Stago has built a comprehensive portfolio of coagulation diagnostics spanning routine and specialized testing. The company offers a broad range of reagents, analyzers, and software solutions designed to support clinical laboratories of all sizes, from basic PT/INR testing to advanced hemostasis investigations. Stago operates globally through an extensive commercial network and affiliated entities, with capabilities that include coagulation testing, platelet function analysis, and thrombin generation assays.

Stago's product portfolio includes the STA series of hemostasis analyzers, with its latest Max Generation 3 systems, including the STA R Max 3 and STA Compact Max 3, representing the company's flagship platforms for high-throughput and mid-sized laboratories. These systems incorporate advanced automation, enhanced sample integrity checks such as detection of hemolysis, icterus, and lipemia, and full connectivity to laboratory automation systems, supporting efficient and standardized workflows. Stago also provides the ST hemO range of analyzers, including the ST hemO 301 for higher-throughput laboratories and the ST hemO 201 for smaller laboratories, expanding its offering across different laboratory segments.

Stago markets an extensive menu of reagents for coagulation and anticoagulant monitoring, including assays designed to support the management of direct oral anticoagulants and other newer therapeutics that are not adequately monitored by traditional PT/INR testing. The company continues to expand its specialty testing capabilities through innovations such as thrombin generation assays, supported by systems such as ST Genesia, and new reagent kits aimed at assessing thrombosis risk in specific patient populations. Stago is enhancing its offering with workflow optimization and laboratory support solutions designed to improve efficiency and standardization in hemostasis testing.

Through its acquisition of HemoSonics, Stago entered the point-of-care hemostasis market with viscoelastic testing technology, including the Quantra Hemostasis Analyzer, which is used for rapid assessment of coagulation status in critical care and surgical settings.

Diasorin S.p.A

Saluggia, Italy

www.Diasorin.com

Diasorin has established a long-standing position in the immunodiagnostics market, with over five decades of experience developing and commercializing specialty diagnostic tests for clinical laboratories. The company continues to expand beyond its traditional immunoassay base into molecular diagnostics and decentralized testing, reflecting broader industry trends toward integrated and near-patient solutions. In recent years, Diasorin has strengthened its menu through targeted partnerships and internal development, including the LIAISON MR-proADM chemiluminescent immunoassay, which assesses infection severity and sepsis risk, and a collaboration with Gilead Sciences to develop a fully automated hepatitis D assay for the LIAISON XL platform.

POC

A significant strategic shift has been Diasorin's entry into the molecular point-of-care market with the LIAISON NES platform, a next-generation system designed to deliver rapid, near-patient molecular testing with simplified workflow. By 2026, commercialization has expanded through distribution agreements, supporting broader access to the platform and its initial multiplex respiratory panel for detecting influenza A/B, RSV, and SARS-CoV-2. Diasorin continues to build out its molecular portfolio by expanding the LIAISON PLEX system, which enables flexible, multiplex syndromic testing. In addition to respiratory panels, the platform now includes blood culture assays targeting gram-negative bacteria and yeast pathogens, along with associated resistance markers, strengthening its role in sepsis and critical care diagnostics.

Immunoassays

Diasorin maintains a broad immunoassay portfolio with more than 100 assays spanning infectious disease, endocrinology, oncology, cardiovascular markers, and autoimmune conditions. The LIAISON analyzer family remains central to its business, offering fully automated chemiluminescent testing in a closed-system format. Recent menu additions,

including Streptococcus pneumoniae urinary antigen testing and ongoing Lyme disease assay development, further strengthen its infectious disease offering. Overall, Diasorin's strategy through 2026 reflects a transition toward a balanced portfolio that combines high-throughput immunoassays, advanced multiplex molecular diagnostics, and emerging point-of-care solutions, with a strong focus on infectious diseases, syndromic testing, and rapid diagnostics that support clinical decision-making in both centralized and decentralized care settings.

Diasorin offers the LIAISON QuantiFERRON-TB-Gold Plus II assay through its partnership with QIAGEN. The LIAISON QuantiFERRON-TB Gold Plus assay is a next-generation automated Interferon Gamma Release Assay designed to increase productivity and workflow efficiency, providing a 25% faster turnaround time than the previous-generation assay. The new assay enables labs to test up to 75% more patients per hour.

Molecular

The company has also expanded its direct molecular testing capabilities through the Simplexa platform, including the addition of the Simplexa C. auris Direct assay for rapid detection of this emerging multidrug-resistant fungal pathogen. This complements a broader menu of assays for respiratory infections, congenital CMV, and other infectious diseases, all designed to streamline workflow by eliminating the need for separate nucleic acid extraction. Diasorin also continues to advance host-response diagnostics through the LIAISON MeMed BV test, which helps differentiate bacterial from viral infections and supports more informed treatment decisions. The LIAISON PLEX Gram-Negative Blood Culture Assay detects 27 targets, including 19 gram-negative bacteria and 8 resistance gene targets.

Molecular Oncology

Diasorin offers CE-IVD molecular diagnostic assays for hematologic oncology, including tests designed to detect key genetic abnormalities associated with acute myeloid leukemia. These include assays targeting common translocations such as AML1-ETO, CBFB-MYH11, BCR-ABL, and PML-RARA, which are used to support rapid molecular characterization at diagnosis. These assays are designed to provide streamlined workflows and relatively fast turnaround times compared to traditional molecular methods, enabling earlier clinical decision-making in acute leukemia management

Eiken Chemical Co., Ltd

Tokyo, Japan

www.eiken.co.jp/en/

Eiken Chemical's goal is to establish itself as a leader in the clinical diagnostics market by developing molecular diagnostics. Its products are used primarily in the diagnosis and treatment of microbial infections. Eiken plans to expand into Europe, the U.S., Australia, and Latin America.

Eiken Chemical is a long-established diagnostics company with a portfolio spanning fecal testing, urinalysis, microbiology media, and molecular diagnostics. While the company offers a range of immunoassay and screening products, its most significant contribution to the in vitro diagnostics market has been the development and commercialization of loop-mediated isothermal amplification (LAMP) technology, which enables rapid, sensitive molecular testing without complex thermal cycling. Eiken markets a broad menu of LAMP-based assays under its Loopamp brand, targeting infectious diseases such as tuberculosis, gastrointestinal pathogens, sexually transmitted infections, and respiratory viruses. These assays are used in both centralized laboratories and decentralized settings, particularly in regions that require rapid, simplified molecular testing, and continue to expand through global health initiatives and infectious disease applications.

Eiken maintains a strong global presence in fecal testing through its OC-Sensor series of automated analyzers and OC-Auto reagents for fecal immunochemical testing. More recent systems, including the OC-SENSOR Ceres and higher-throughput platforms such as OC-SENSOR PLEDIA, support multi-parameter stool analysis, including hemoglobin and inflammatory markers such as calprotectin, enabling broader use in colorectal cancer screening and gastrointestinal disease management. These systems are widely used in population screening programs and continue to improve workflow efficiency and test integration.

Fujirebio Diagnostics, Inc.

Malvern, PA

www.fdi.com

Fujirebio Diagnostics, a subsidiary of H.U. Group Holdings, is a global provider of in vitro diagnostics with a strong focus on immunoassays, molecular diagnostics, and biomarker development. The company has built a broad portfolio through internal development and strategic acquisitions, with particular strength in specialty diagnostics areas such as oncology, infectious disease, fertility, and neurodegenerative disorders. Its flagship LUMIPULSE platform, based on chemiluminescent enzyme immunoassay technology, supports a wide range of automated immunoassay testing in clinical laboratories worldwide.

Fujirebio is widely recognized for its leadership in biomarker development, particularly in neurodegenerative disease diagnostics. A major recent advancement is the marketing of the LUMIPULSE G pTau 217/β-Amyloid 1-42 Plasma Ratio test, the first FDA-cleared blood-based in vitro diagnostic test to aid in the identification of amyloid pathology associated with Alzheimer's disease. This test enables less invasive assessment using a simple blood draw and represents a significant step forward in early diagnosis and patient management. The company has further expanded its neuro portfolio with additional assays targeting pTau217 in both plasma and cerebrospinal fluid, supporting earlier and more accurate detection of Alzheimer's disease and differentiation from other dementias.

The LUMIPULSE system has expanded the company's assay menu across disease areas. Developments include assays targeting cardiac markers, infectious diseases, fertility hormones, and metabolic disorders, as well as an expanding range of neurological biomarkers such as β-amyloid, tau proteins, and neurofilament light. The company continues to strengthen its capabilities through collaborations focused on biomarker discovery and assay development.

The LUMIPULSE G NfL blood assay is a relatively recent addition to the company's automated immunoassay menu for neurological biomarkers. The assay was first introduced around 2023 in a research and early-evaluation setting as part of the growing use of blood-based markers for neurodegenerative disease and brain injury.

Its transition into the clinical diagnostics market occurred in 2026, when the test became available in Europe as a CE-marked assay on the LUMIPULSE G platform. This marked an important step, moving the test from research use into routine laboratory settings, particularly in regions adopting blood-based neurology testing.

The assay measures neurofilament light chain (NfL) in blood, which reflects neuroaxonal damage and is being used to support evaluation and monitoring of conditions such as Alzheimer's disease, multiple sclerosis, and other neurological disorders. Its main advantage is that it allows testing from a simple blood sample rather than cerebrospinal fluid, making it easier to integrate into routine clinical workflows.

As of 2026, the LUMIPULSE G NfL blood assay is considered a new clinical product, with growing adoption in Europe and ongoing expansion of Fujirebio's broader neurology menu, which includes additional blood-based biomarkers for neurodegenerative disease.

Fulgent Genetics, Inc

El Monte, CA

www.fulgentgenetics.com

Fulgent was founded in 2011 and has developed an impressive line of tests and services. The company developed a proprietary technology platform that allows it to offer a flexible test menu that can be expanded. The company combines NGS with its technology platform to perform full-gene sequencing and deletion analysis in a single test.

Fulgent Genetics offers molecular diagnostic testing services across infectious disease, reproductive health, and oncology. The company introduced testing solutions for emerging infectious diseases, including orthopoxvirus detection, supporting public health response efforts. In reproductive genetics, Fulgent launched its Beacon expanded carrier screening panel, which analyzes hundreds of genes associated with autosomal recessive and X-linked conditions, reflecting growing demand for comprehensive carrier screening.

Fulgent has also strengthened its position in oncology and hereditary disease testing through strategic partnerships and contract awards. The company secured agreements to provide hereditary cancer and genetic testing services to large healthcare networks, including government-related programs, supporting broader access to genomic testing. In addition, Fulgent has partnered with pharmaceutical and diagnostics companies to support the commercialization of germline cancer testing panels, enabling analysis of clinically relevant genetic variants associated with hereditary cancer risk.

The company continues to advance its testing capabilities through its proprietary sequencing and bioinformatics platform, including exome-based testing and integrated data analysis solutions. These services support the detection of single-nucleotide variants, copy number variations, and other genomic alterations across a range of clinical applications.

GeneDx

www.genedx.com

GeneDx is a genomic diagnostics company focused on translating complex genetic data into clinically actionable insights, with a strong emphasis on rare and pediatric diseases. The company offers a broad portfolio spanning whole-genome sequencing, whole-exome sequencing, and targeted gene panels, supported by curated variant databases and advanced interpretation capabilities.

GeneDx has shifted its strategy toward exome and genome sequencing as first-line tests, particularly in neonatal and pediatric intensive care settings where rapid diagnosis can significantly impact clinical management. The company has built one of the largest rare-disease genomic datasets, which it uses to improve diagnostic yield, variant interpretation, and reanalysis over time. GeneDx has also expanded its collaborations with health systems and research networks, supporting earlier diagnosis and more precise treatment pathways, while increasingly positioning itself as both a diagnostics provider and a data-driven precision medicine company.

Grifols S.A.

Barcelona, Spain

www.grifols.com

Grifols operates as a global healthcare company with core business areas focused on Biopharma, Diagnostic, Bio Supplies, and contract manufacturing and services, marketing its products in more than 100 countries. The company is a leading producer of plasma-derived therapeutics and maintains a strong position in transfusion medicine and in vitro diagnostics. Grifols' Diagnostic division provides a broad portfolio of products for laboratory analysis, including blood typing, antibody detection, coagulation testing, and automated immunoassay systems, as well as reagents and instrumentation for hospital blood banks and transfusion centers.

Grifols is particularly well established in transfusion medicine, where its product portfolio includes nucleic acid amplification testing (NAT) systems for detecting infectious agents in blood and plasma donations, as well as solutions for immunohematology and molecular blood group typing. These technologies support blood safety by enabling sensitive detection of viral pathogens and accurate donor–recipient matching. The company continues to expand its molecular testing capabilities in transfusion diagnostics, reinforcing its leadership in blood screening and compatibility testing.

In clinical diagnostics, Grifols offers assays for infectious diseases, autoimmune conditions, and specialized therapeutic monitoring, including immunoassay-based and molecular testing solutions. The company is also expanding its presence in select areas of personalized medicine, particularly in monitoring patients receiving biologic therapies. Additionally, Grifols provides specialized clinical laboratory services that integrate molecular and proteomic diagnostics to support disease diagnosis, prognosis, and treatment monitoring.

Blood Transfusion Business

Grifols expanded its position in molecular blood screening through its longstanding partnership with Hologic, ultimately assuming full control of the Procleix diagnostic business, including customer service, manufacturing, and product development activities. This acquisition strengthened Grifols' capabilities in nucleic acid amplification testing for

transfusion and transplantation screening and included manufacturing facilities, intellectual property rights, and access to key technologies. As a result, Grifols has established a leading position in molecular blood screening, with Procleix systems widely used by blood centers globally to test donations for major transfusion-transmissible infections.

The Procleix platform, based on the fully automated PANTHER system, supports high-throughput, sensitive detection of viral pathogens, including HIV, hepatitis B and C, and other emerging infectious agents. The system is widely used in large-scale blood screening programs and continues to expand its test menu to address evolving transfusion safety needs. Grifols has introduced a range of NAT assays on this platform, including tests for West Nile virus, Zika virus, Babesia, and malaria, enabling the detection of pathogens that may not be identified through traditional serological screening.

Grifols has expanded its molecular screening portfolio with multiplex assays, such as the Procleix ArboPlex test, which simultaneously detects multiple arboviruses in a single run, improving efficiency and throughput in blood screening laboratories. These developments reflect a broader shift toward multiplex NAT testing and enhanced preparedness for emerging infectious diseases.

ABO Blood Typing

The ABO blood group system classifies human blood based on the presence or absence of A and B antigens on the surface of red blood cells. Individuals are categorized as type A, B, AB, or O depending on these antigenic properties. First described by Karl Landsteiner in 1901, the ABO system remains the foundation of transfusion medicine, as it is critical for determining compatibility between donor and recipient blood. ABO typing, along with antibody screening, forms the basis of pre-transfusion testing and has traditionally been performed using manual serological methods, although automation has become increasingly common in modern laboratories.

Grifols offers an immunohematology portfolio through the development and commercialization of reagents and automated systems designed for both routine and complex blood typing. The company offers a range of antisera reagents and gel card–based technologies that support accurate blood grouping and antibody detection in clinical laboratories. These products are widely used in transfusion services and blood banks to ensure safe and compatible blood transfusions, with ongoing expansion of reagent menus to support the detection of rare blood group antibodies and complex cases.

Grifols has also advanced automation in immunohematology with systems such as the Erytra Eflexis and Wadiana analyzers, which are designed for pre-transfusion compatibility testing using DG Gel technology. These automated platforms improve workflow efficiency, standardization, and throughput in blood bank laboratories by integrating sample processing, testing, and result interpretation. Recent developments emphasize enhanced connectivity with laboratory information systems, improved traceability, and scalability for high-volume blood centers and centralized testing environments. The company continues to expand the global availability of these systems, including growth in Asia and other emerging markets.

Molecular ABO Blood Typing

Serological blood grouping involves testing a blood sample to detect the presence or absence of clinically significant blood group antigens on red blood cells. This approach is the standard method for routine blood typing and compatibility testing. However, serological results can be difficult to interpret in certain patients due to the presence of alloantibodies or autoantibodies arising from prior transfusions, pregnancies, or underlying medical conditions, complicating antibody identification in complex cases.

Molecular blood grouping, or genotyping, augments serological testing by analyzing DNA to predict blood group antigen profiles. This approach enables more precise identification of both common and rare blood group variants and supports improved donor–recipient matching, particularly in patients requiring chronic transfusion support, such as those with sickle cell disease, thalassemia, or oncology-related anemia. Molecular typing is increasingly used in both patient care and donor screening programs to enable extended antigen matching and identification of rare donors.

Grifols has expanded its molecular immunohematology portfolio with assays such as the ID Core XT and ID RHD XT, which genotype multiple blood group antigens beyond the ABO system. These assays support extended antigen profiling across clinically significant blood group systems, improving transfusion compatibility and reducing the risk of alloimmunization. The tests are used in both donor screening and patient testing and are integrated into laboratory workflows and reference laboratory services, including Grifols' Immunohematology Center.

Immunoassays

Revenues in specialty diagnostics have remained stable, with growth expected as Grifols continues to expand its clinical diagnostics portfolio. The company's PROMONITOR ELISA assays provide important information on drug levels and immunogenicity in patients receiving biologic therapies, particularly for chronic inflammatory diseases. These assays support therapeutic drug monitoring by helping clinicians assess treatment response, optimize dosing, and detect anti-drug antibodies. The PROMONITOR portfolio continues to expand to cover a broader range of biologic therapies, particularly in gastroenterology and autoimmune diseases, reflecting the increasing role of personalized medicine and targeted therapies in clinical practice.

Through its subsidiary, Araclon Biotech, Grifols has also developed diagnostic assays targeting neurodegenerative diseases, including tests that quantify amyloid-beta biomarkers associated with Alzheimer's disease. These assays measure Aβ40 and Aβ42 proteins using both immunoassay and mass spectrometry–based approaches and are intended to support early detection and research applications in Alzheimer's disease. While these tests represent innovative developments in blood-based biomarker detection, their use remains primarily in specialized and emerging diagnostic settings.

Guardant Health, Inc.

Redwood City, CA

www.guardanthealth.com

Guardant Health, founded in 2013, is a leading developer of liquid biopsy diagnostics based on proprietary digital sequencing technology. This approach uses molecular barcoding and advanced error-correction methods to enable highly sensitive detection of tumor-derived cell-free DNA in blood samples. The technology offers comprehensive genomic profiling by identifying multiple classes of genomic alterations, including point mutations, insertions and deletions, fusions, and copy number changes, allowing for non-invasive tumor characterization and disease monitoring.

The company's flagship product, Guardant360, is a blood-based comprehensive genomic profiling test used to guide treatment selection and monitor disease progression in patients with advanced solid tumors. The test has evolved with expanded biomarker identification and cancer subtyping capabilities, improving clinical decision-making. Guardant360 is complemented by tissue-based profiling solutions, including Guardant360 Tissue and TissueNext, with multiomic approaches integrating DNA, RNA, methylation, and protein expression data to provide more comprehensive tumor characterization.

Guardant Health offers Guardant360 CDx as a companion diagnostic to identify advanced breast cancer patients with ESR1 mutation who may benefit from Eli Lilly's Inluriyo. Guardant's CDx was approved in conjunction with Inluriyo for the treatment of patients with estrogen receptor-positive ESR1-mutated advanced or metastatic breast cancer.

Guardant Health markets cancer screening and early detection with its Shield blood test for colorectal cancer, which has received regulatory approval as a primary screening option and achieved reimbursement milestones. The company also offers Guardant Reveal for minimal residual disease detection and recurrence monitoring, extending its portfolio across the cancer care continuum.

More recently, Guardant has expanded into germline testing with the introduction of the Guardant Hereditary Cancer Test, a blood-based panel designed to identify inherited cancer risk. In addition, the company continues to enhance its platform capabilities through

integration of artificial intelligence and large-scale genomic datasets, supporting more advanced biomarker discovery and precision oncology applications.

Haemonetics

Boston, Mass

www.haemonetics.com

Haemonetics, founded in 1971, is an established provider of blood and plasma collection technologies and hospital-based solutions that support transfusion medicine and critical care. The company operates across three primary segments, plasma, blood center, and hospital, reflecting its broad reach from donor collection through to patient care. Its portfolio includes systems designed to optimize plasma collection efficiency and quality, including the NexSys PCS Plasma Collection System with Persona technology, which enables more personalized donation protocols and helps increase average plasma yield while maintaining donor safety and consistency.

In 2024, Haemonetics streamlined its portfolio by divesting its whole-blood product line to GVS S.p.A., allowing the company to focus more heavily on higher-growth, higher-margin areas such as plasma collection and hospital-based technologies. This shift aligns with ongoing global demand for plasma-derived therapies and the need for more efficient collection infrastructure. The company continues to invest in software, automation, and data-driven collection tools that improve operational efficiency for plasma centers and enhance traceability and compliance.

Haemonetics reported revenues of approximately $1.36 billion in 2025, representing moderate growth over 2024. Performance was largely driven by the hospital segment, supported by recent acquisitions and continued demand for technologies used in surgical blood management, cell salvage, and transfusion optimization. At the same time, the plasma segment remains a core growth engine, benefiting from sustained demand for immunoglobulins and other plasma-derived therapies, while blood center operations continue to provide stable, though more mature, revenue contributions.

Horiba

Kyoto, Japan

www.horiba.com

The Horiba Group provides a broad range of analytical and measurement systems across multiple industries, including automotive, environmental monitoring, semiconductor manufacturing, and in vitro diagnostics. Within healthcare, Horiba Medical focuses on hematology and clinical chemistry solutions, offering analyzers, reagents, and associated laboratory systems. Hematology remains the company's core business, accounting for the majority of its diagnostics revenue and supported by a global installed base of instruments and reagent contracts.

Horiba's diagnostic portfolio includes hematology analyzers, clinical chemistry systems, and supporting technologies for laboratory testing. The company has expanded its Yumizen product line, which serves laboratories of varying sizes with scalable and automated solutions. Recent additions include enhancements to the Yumizen H500 and H550 platforms, designed to deliver efficient workflows, continuous loading capabilities, and rapid turnaround times for routine hematology testing, as well as the integration of erythrocyte sedimentation rate estimation via VoRA technology.

In clinical chemistry, Horiba offers analyzers such as the Yumizen C230, C240, and C560, paired with dedicated reagent systems to support routine and specialty testing. In hematology, the company has advanced its high-throughput capabilities with the HELO 2.0 platform, a modular, automation-ready solution designed for mid- to high-volume laboratories that supports integration into core laboratory workflows and connectivity with laboratory information systems.

Horiba has also expanded its mid- to high-throughput hematology offering with systems such as the Yumizen H2500, as well as new variants within the Yumizen H500 series, including models with autoloading and open- and closed-tube configurations. These systems incorporate advanced parameters and workflow efficiencies to reduce manual intervention and improve turnaround time.

Menarini Diagnostics

Florence, Italy

www.menarinidiagnostics.com

The Menarini Group, founded in 1886 and headquartered in Florence, Italy, is a global healthcare company with operations spanning pharmaceuticals, diagnostics, and biomedical measurement technologies. The group operates through an extensive international network of subsidiaries and partners across Europe and other global markets. A. Menarini Diagnostics, established in 1976, represents the group's diagnostics division and focuses on laboratory and near-patient testing across multiple clinical areas, including diabetes, clinical chemistry, hematology, autoimmunity, and pathology.

Menarini Diagnostics offers a broad portfolio of products through a combination of in-house development and strategic partnerships. Its products include blood glucose monitoring systems, HbA1c testing, clinical chemistry analyzers, hematology systems, urinalysis, and immunoassays. The company maintains a strong presence in diabetes diagnostics, with its GlucoMen line of blood glucose meters and continuous glucose monitoring solutions supporting both self-testing and connected care. Menarini's strategy relies heavily on collaborations with diagnostic manufacturers to expand its product offering and geographic reach.

In molecular diagnostics, Menarini has expanded its PRIME MDx platform, a sample-to-result real-time PCR system that supports a growing menu of infectious disease assays, including respiratory panels. The platform is positioned for decentralized and routine laboratory use, enabling flexible processing of multiple sample types. The company has also entered into distribution and collaboration agreements to broaden its molecular testing portfolio, including point-of-care and syndromic testing solutions.

Menarini has expanded into specialty diagnostics through partnerships, including collaborations in liquid biopsy and oncology. A key example is its agreement to commercialize epigenetic-based cancer detection assays, such as bladder cancer tests, that support non-invasive diagnosis and recurrence monitoring.

Meridian Bioscience, Inc.

Cincinnati, OH

www.meridianbioscience.com

Meridian Bioscience is a life science company that develops, manufactures, and distributes diagnostic test kits, purified reagents, and biopharmaceutical components. The company has established strong positions in infectious disease diagnostics, particularly in gastrointestinal and respiratory infections, as well as in serology, parasitology, and fungal disease testing. Meridian's products are used by hospitals, reference laboratories, research institutions, diagnostics manufacturers, and biotechnology companies in more than 60 countries.

In addition to its diagnostics business, Meridian is a supplier of specialty biologicals and recombinant reagents used in drug discovery, vaccine development, and diagnostic assay production. The company's life science segment provides critical raw materials, including antigens, antibodies, and proteins, supporting both research and commercial applications.

Founded in 1977, Meridian has extensive experience in immunoassay-based diagnostics and offers a broad menu of assays for infectious diseases, including Clostridioides difficile, Escherichia coli Shiga toxin, and Helicobacter pylori. These tests are widely used in clinical laboratories to detect gastrointestinal pathogens and contribute to the company's strong presence in this segment.

Meridian expanded its diagnostics portfolio through the acquisition of Magellan Diagnostics, which develops and markets blood lead testing systems for use in point-of-care and laboratory settings. These systems support screening and monitoring of lead exposure in both pediatric and adult populations and are widely deployed in physician offices and clinical laboratories.

The acquisition of EUPROTEIN enhanced Meridian's capabilities in recombinant protein production, strengthening its position in life science reagents and enabling the development of advanced immunological components. Following its 2023 acquisition by SD Biosensor and its investment partners, Meridian has been integrated into a broader global diagnostics platform, supporting expanded geographic reach, manufacturing scale, and product development capabilities.

Meridian Bioscience has continued to expand its diagnostics portfolio, including immunoassays and molecular solutions. The company markets its Curian Shiga Toxin Assay, designed for use on the Curian analyzer platform. This assay is a rapid, qualitative fluorescent test that enables simultaneous detection and differentiation of Shiga toxins, thereby improving the diagnosis of gastrointestinal infections. Meridian also offers its Premier HpSA FLEX assay, a non-invasive enzyme immunoassay for the qualitative detection of Helicobacter pylori antigens in both preserved and unpreserved stool samples, further strengthening its position in gastrointestinal diagnostics.

Meridian has expanded its portfolio of PCR-based solutions designed to assist high-throughput and decentralized testing workflows. The company introduced its Lyo-Ready range of PCR master mixes, including one-step RT-qPCR formulations optimized for RNA virus detection and multiplex applications. These lyophilization-ready reagents are designed for stability, rapid rehydration, and compatibility with automated platforms, supporting scalable molecular testing.

Meridian has also developed inhibitor-tolerant qPCR reagents that enable reliable amplification from challenging sample types, including crude lysates and inhibitor-rich specimens such as blood, saliva, stool, and other clinical matrices. These reagents reduce the need for extensive sample preparation and improve workflow efficiency in both research and diagnostic settings.

Additionally, the company introduced a series of sample-specific qPCR master mixes tailored for different specimen types, including saliva, blood, and stool. These products are designed to enhance sensitivity and simplify molecular workflows, supporting applications such as infectious disease testing and liquid biopsy research.

Mindray - Shenzhen Mindray Bio-medical Electronics Co., Ltd.

Shenzhen, China

http://mindray.com

Founded in 1991, Mindray is a global provider of medical devices and diagnostic solutions, with a strong presence in in vitro diagnostics, patient monitoring, and medical imaging. Headquartered in Shenzhen, China, the company operates in more than 190 countries and maintains a global network of research, manufacturing, and service facilities. Mindray's in vitro diagnostics business includes hematology, clinical chemistry, immunoassay, coagulation, microbiology, urinalysis, and flow cytometry, supporting a wide range of laboratory needs.

Mindray offers a comprehensive hematology portfolio ranging from compact analyzers for small laboratories to high-throughput, fully automated cellular analysis lines. Systems such as the BC series analyzers and CAL family platforms provide scalable solutions with integrated slide-making and staining capabilities, supporting efficient workflow and high sample throughput. Developments include hematology systems that combine complete blood count testing with additional parameters such as erythrocyte sedimentation rate, reflecting increasing demand for multi-parameter testing in a single platform.

In immunoassay and clinical chemistry, Mindray provides a range of chemiluminescence and biochemistry analyzers, including integrated solutions that combine both technologies into unified platforms. These systems are designed to improve laboratory efficiency through automation, flexible configuration, and high-throughput processing. Recent product introductions include new standalone and integrated analyzers for mid-volume laboratories, as well as expanded assay menus in areas such as inflammation and infectious disease.

Mindray has also advanced its automation strategy by developing integrated laboratory solutions and collaborating with automation providers. These efforts support total laboratory automation by enabling connectivity across hematology, chemistry, and immunoassay systems, improving workflow efficiency and data management in high-volume laboratories.

Mindray has expanded into microbiology by introducing automated culture systems that support blood culture and pathogen detection workflows. These systems provide automated sample handling, detection, and data management capabilities, extending Mindray's reach into microbiology diagnostics and complementing its broader IVD portfolio.

Recent product developments have expanded Mindray's presence across multiple diagnostic segments. The company introduced the FA-N Series fully automated microbial culture system, marking its entry into microbiology diagnostics with automated blood culture detection capabilities. In immunoassay and clinical chemistry, Mindray launched analyzers such as the CL-2600i and BS-1000M, along with integrated solutions including the M680 and M980 systems, which combine immunoassay and chemistry testing in compact, high-efficiency platforms. These additions reflect Mindray's focus on integrated core laboratory solutions, automation, and expansion into new diagnostic areas.

Myriad Genetics, Inc.

Salt Lake City, UT

www.myriad.com

Myriad Genetics is a publicly traded personalized medicine company focused on the development and commercialization of molecular diagnostic tests across oncology, women's health, and mental health. The company's testing portfolio is based on advanced genomic and molecular technologies, including DNA sequencing, RNA expression profiling, and biomarker analysis, supporting risk assessment, diagnosis, treatment selection, and disease management.

Myriad's core oncology offering includes the myRisk Hereditary Cancer test, a comprehensive panel designed to assess inherited risk for multiple cancers, including breast, ovarian, colorectal, pancreatic, prostate, melanoma, gastric, and endometrial cancers. The company has expanded its hereditary testing portfolio to support broader risk assessment and preventive care, particularly in women's health. In addition, Myriad offers Prolaris, a gene expression test used to assess the aggressiveness of prostate cancer and guide treatment decisions.

Myriad provides the GeneSight Psychotropic test, which uses pharmacogenomic insights to help guide medication selection for patients with depression and other neuropsychiatric conditions. The company has demonstrated the test's clinical utility through studies showing improved treatment outcomes when gene–drug interactions are considered in therapy selection.

Myriad also plays a significant role in companion diagnostics and targeted therapy selection. Its BRCAAnalysis CDx test is an FDA-approved germline companion diagnostic that identifies patients with BRCA1 and BRCA2 mutations who may benefit from PARP inhibitor therapies across multiple cancer types, including ovarian, breast, pancreatic, and prostate cancers. The company has expanded its companion diagnostic partnerships with pharmaceutical companies to support precision oncology.

The company has further broadened its oncology portfolio with integrated testing solutions, including its prostate cancer risk and management offerings, which combine hereditary

testing, tumor profiling, and prognostic assessment. Myriad has also expanded its biomarker portfolio to include additional targets relevant to ovarian cancer and other malignancies, supporting more personalized treatment strategies.

In women's health and oncology, Myriad offers its myChoice CDx test to assess homologous recombination deficiency (HRD), which helps identify patients who may benefit from specific targeted therapies. Recent collaborations have focused on expanding access to HRD testing and improving identification of patients eligible for advanced treatments.

Myriad Genetics offers the MyChoice CDx Test as the companion diagnostic for Zejula, a PARP inhibitor from GSK, for patients with advanced ovarian cancer. The MyChoice CDx is the only FDA-approved companion diagnostic test in the United States that identifies patients with HRD-positive status who are eligible for treatment with Zejula.

OraSure Technologies, Inc.

Bethlehem, PA

www.orasure.com

OraSure Technologies is a developer and manufacturer of diagnostic solutions and sample-collection technologies, with a strong focus on infectious-disease testing and oral-fluid–based diagnostics. Formed through the merger of STC Technologies and Epitope, the company expanded its molecular capabilities by acquiring DNA Genotek, enabling entry into genomic sample collection for DNA and RNA analysis. OraSure's products are used globally across public health organizations, clinical laboratories, and decentralized testing environments.

The company's core diagnostic portfolio is its OraQuick platform, which includes rapid tests for HIV and hepatitis C. The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test remains a widely used point-of-care assay that utilizes oral fluid samples, while the OraQuick In-Home HIV Test and OraQuick HIV Self-Test support consumer-directed, decentralized testing. Recent updates have expanded the eligible age range for HIV self-testing, supporting broader adoption in screening and prevention programs. OraSure also offers rapid HCV testing and other infectious disease assays, reinforcing its presence in public health diagnostics.

OraSure maintains a strong position in oral fluid–based toxicology testing through products such as the Intercept Oral Fluid Drug Testing System and the Q.E.D. Saliva Alcohol Test. These solutions are widely used in workplace testing, clinical toxicology, and forensic applications, offering convenient, non-invasive sample collection and reliable laboratory-based analysis.

The company has significantly expanded its sample collection portfolio, including the Oragene and ORAcollect systems for DNA and RNA collection, as well as specialized devices for microbiome and women's health applications. This includes the Colli-Pee urine collection device, developed for non-invasive self-sampling in applications such as HPV testing, supporting increased adoption of at-home and decentralized screening approaches. These innovations reflect the growing demand for patient-friendly, non-invasive diagnostic solutions.

OraSure has also advanced its rapid testing capabilities with lateral flow platforms such as the InteliSwab rapid antigen test, while continuing to validate performance against emerging variants and explore broader infectious disease applications. In addition, the company has strengthened its molecular diagnostics pipeline through the acquisition of Sherlock Biosciences, adding CRISPR-based detection technologies that support the development of next-generation rapid molecular tests.

Randox Laboratories Ltd.

Crumlin, N. Ireland

www.randox.com

Randox Laboratories Ltd. is a privately held diagnostics company specializing in the development and manufacture of diagnostic reagents, instruments, and quality control solutions. Founded in 1982, Randox has established a global presence with distribution in more than 130 countries and offices across Europe, North America, Asia, Africa, and Australia. The company's core capabilities include its proprietary Biochip Array Technology, clinical chemistry analyzers, external quality assessment (EQA) programs, quality control materials, antibodies, recombinant proteins, and a broad range of clinical and environmental diagnostic reagents.

Randox has also expanded into laboratory testing services through its Randox Testing Services division, which provides drug and alcohol testing and forensic toxicology services. These services are widely used by law enforcement agencies and workplace testing programs, with capabilities including hair testing that enables long-term monitoring of substance use. This complements Randox's broader diagnostics portfolio by integrating laboratory services with its testing technologies.

The company has strengthened its manufacturing and research capabilities through investments in facilities such as Randox Teoranta in Ireland, which supports the production of clinical chemistry analyzers and Biochip-based diagnostic products.

Randox Biosciences represents the company's focus on advancing scientific discovery, drug development, and companion diagnostics. This division integrates capabilities across life sciences, pharmaceutical services, molecular diagnostics, and research technologies, supporting both internal innovation and external collaborations.

Strategic developments include the acquisition of Cellix Limited, a company specializing in microfluidic technologies and impedance-based flow cytometry. This acquisition enhances Randox's capabilities in cell analysis and supports expansion into advanced diagnostic and research applications.

Clinical Chemistries

Randox offers an extensive portfolio of clinical chemistry reagents, comprising thousands of assay procedures designed to support a wide range of automated analyzers. The company's reagent menu covers routine chemistry, specific proteins, lipids, therapeutic drugs, drugs of abuse, antioxidants, diabetes testing, autoimmune conditions, cardiac markers, electrolytes, anemia markers, liver function, inflammation and infection, neonatal screening, nutritional status, and renal function.

Randox markets the RX series of clinical chemistry analyzers, including the RX daytona+, RX imola, and RX modena. These systems are designed to deliver flexible, scalable testing solutions for laboratories with varying throughput requirements. The RX series utilizes technologies such as latex-enhanced immunoturbidimetry to support a broad range of assays, including specific protein testing.

The platforms offer an expanded test menu that includes assays such as direct HbA1c, apolipoproteins (including Apo C-II, Apo C-III, and Apo E), cystatin C, and microalbumin, enabling comprehensive evaluation of metabolic, cardiovascular, and renal health. The integration of advanced hardware with user-friendly software supports efficient workflow, high throughput, and consistent performance across diverse laboratory settings.

POC and Rapid

Randox has expanded its molecular diagnostics portfolio through its Vivalytic platform, developed in collaboration with Bosch Healthcare Solutions. The company introduced a rapid PCR-based MRSA/SA assay for detection and differentiation of methicillin-resistant and methicillin-sensitive Staphylococcus aureus, delivering results in under one hour and supporting rapid infection control and clinical decision-making.

The Vivalytic test menu has continued to expand and includes a growing range of multiplex panels targeting respiratory, genitourinary, and hospital-acquired infections. More recent developments include the introduction of assays for central nervous system infections, such as bacterial meningitis panels, which are being evaluated and implemented to support rapid diagnosis of severe infectious diseases. The platform combines both low-plex PCR and higher-plex multiplexing technologies, enabling flexible testing options depending on clinical needs.

Companion Diagnostics

In 2025, Randox received U.S. FDA De Novo authorization for its first companion diagnostic, the ConcizuTrace ELISA, developed to support treatment monitoring in patients receiving concizumab therapy for hemophilia A and B. The assay is designed for the quantitative measurement of concizumab concentrations in plasma samples and is used to guide dose adjustment decisions following initiation of therapy. The test represents a new class of diagnostic systems for monitoring non-factor replacement therapies and reflects the growing shift toward precision dosing in hemophilia management.

Developed in collaboration with Novo Nordisk, the ConcizuTrace ELISA supports the use of concizumab, a next-generation therapy targeting the tissue factor pathway inhibitor to reduce bleeding risk. The solution is offered as part of a comprehensive service model that includes standardized sample collection, transportation, and centralized laboratory analysis, with results delivered through an integrated reporting platform. This approach enables clinicians to incorporate drug level monitoring into individualized treatment strategies.

Controls

Randox's quality control products and external quality assessment program account for a significant share of the company's revenue. With more than 30 years of experience developing Laboratory Quality Control for the in vitro diagnostics market, Randox is one of the largest manufacturers of quality control products worldwide. The product portfolio includes Acusera true third-party quality controls, Acusera 24.7 interlaboratory data management software and the RIQAS EQA scheme.

Introduced in 1990, RIQAS (Randox International Quality Assessment Scheme) has developed into one of the world's largest global External Quality Assessment (EQA / Proficiency Testing (PT) schemes serving over 45,000 participants in more than 133 countries. Currently, 33 comprehensive EQA programs are available covering a wide range of clinical diagnostic testing.

The Acusera range of Quality Controls and Calibrators covers over 300 parameters for clinical chemistry, immunoassay, urine, immunology/proteins, lipids, cardiac, CSF, therapeutic drug monitoring, toxicology, urine chemistry, urinalysis, coagulation, blood gas, tumor markers, maternal screening, antioxidants, diabetes and a number of research-based areas.

A wide range of formats is available, including liquid/lyophilized, assayed/unassayed, and human/bovine. Customers can even choose between multi-analyte and single-analyte controls, depending on their laboratory needs. According to Randox, its assay controls are the most comprehensive on the world market to date, containing a unique combination of proteins, lipids, immunoassays, cardiac markers, blood markers, therapeutic drugs, and routine chemistry analytes. For example, the Acusera Chemistry Premium Plus control contains 100 analytes, while the Acusera Chemistry Premium control offers 91.

Randox also offers Acusera 24.7 Live Online, an interlaboratory peer-group reporting software package that extends the capabilities of Internal Quality Controls (IQC) by providing a tool to monitor and analyze daily control data and compare results with other laboratories using the same control lot. With Acusera 24.7 users benefit from online access anytime, peer group data generated from thousands of laboratories every 24 hours, fully interactive charts and reports and automatic import of QC data direct from the Laboratory Information Management Systems (LIMs) or instrument via Acusera 24.7 Connect.

Randox offers the Acusera Infectious Disease Controls. The Infectious Disease Serology Internal Quality Controls will include quality control material for Lyme Disease, ToRCH, Epstein-Barr virus, HIV, Hepatitis A virus, Human T-lymphotropic virus, Cytomegalovirus, and Varicella zoster virus (Chickenpox or Shingles).

In June 2023, Randox introduced the Acusera Ultra-low PSA Control, which is designed to assist in the quantification and monitoring of ultra-low levels of PSA in post-therapy prostate cancer patients.

Evidence Series - Multistat Biochip Analyzers

Randox developed its proprietary Biochip Array Technology (BAT) to enable multiplex detection of multiple analytes from a single patient sample. This technology underpins the company's Evidence series of immunoassay analyzers, including the Evidence, Evidence Evolution, Evidence Investigator, and Evidence MultiSTAT platforms. Unlike traditional single-analyte systems, BAT allows simultaneous measurement of multiple biomarkers, supporting efficient, high-throughput testing while reducing sample volume requirements. The systems support a wide range of sample types, including serum, plasma, whole blood, urine, and oral fluid.

Ongoing developments have expanded the Evidence series with the introduction of the Evidence Random Access Biochip Technology Analyzer, a next-generation platform that delivers higher throughput and greater workflow flexibility. The system incorporates random-access processing, enabling continuous loading and prioritization of samples, and supports rapid turnaround times while maintaining the ability to multiplex dozens of analytes from a single sample.

Randox continues to expand its menu of biochip-based assays across clinical and toxicology applications. New multiplex panels have been developed for the rapid detection of drugs of abuse and emerging synthetic opioids, supporting both clinical and forensic testing. These panels enable simultaneous detection of multiple compounds from a single sample, delivering rapid results to support timely decision-making.

The Evidence Investigator is a compact, semi-automated benchtop analyzer utilizing chemiluminescent detection with CCD imaging to quantify analyte concentrations. The platform supports a wide range of disease-specific panels, including applications in cardiovascular disease, neurology, toxicology, and metabolic disorders.

Molecular

Randox has licensed other companies' multiplex PCR technologies to expand its molecular diagnostics portfolio and develop high-throughput screening panels for detection of a wide range of pathogens and genetic markers. These technologies are integrated with Randox's Biochip Array Technology, enabling workflows that combine multiplex PCR amplification, array-based hybridization, and chemiluminescent detection on platforms such as the Evidence Investigator.

The workflow involves standard nucleic acid extraction followed by amplification using multiplex PCR on conventional thermal cyclers. Amplified products are then hybridized to biochip arrays, allowing simultaneous detection of multiple targets within a single sample. This approach supports efficient, cost-effective testing with turnaround times typically within a few hours after extraction.

Randox's molecular portfolio includes assays for diagnostic, prognostic, and predictive applications across a range of disease areas, including sexually transmitted infections, respiratory infections, cardiovascular disease, and inherited conditions. The technology supports multiple assay formats, including pathogen detection, single-nucleotide

polymorphism genotyping, and mutation analysis. The company expanded its multiplex infectious disease panels, enabling simultaneous detection of multiple bacterial, viral, and protozoan targets and supporting identification of co-infections.

Randox has developed biochip arrays for genetic and cardiovascular applications, including panels targeting mutations in genes such as KRAS, BRAF, and PIK3CA, as well as assays for familial hypercholesterolemia. These arrays enable simultaneous detection of multiple clinically relevant mutations, supporting precision medicine and treatment selection.

Randox also offers genetic risk assessment panels, including arrays designed to evaluate predisposition to cardiovascular disease through multiplex SNP analysis, as well as expanding capabilities in advanced cell analysis through integration of microfluidic technologies.

Seegene, Inc.

Seoul, Korea

www.seegene.com

Seegene, Inc. is a global molecular diagnostics company founded in 2000 and headquartered in South Korea, with additional operations in the United States and Europe. The company specializes in advanced multiplex PCR technologies that enable highly sensitive and specific detection of multiple targets in a single assay, supporting applications in infectious disease, pharmacogenetics, and oncology.

Seegene has developed a suite of proprietary PCR chemistries designed to enhance multiplexing capability, sensitivity, and specificity. These technologies enable simultaneous detection and quantification of multiple pathogens within a single reaction, supporting efficient and comprehensive molecular diagnostics. The company offers a broad portfolio of multiplex systems, including Allplex, Anyplex, Seeplex, and Magicplex platforms, which are widely used in syndromic testing for respiratory infections, gastrointestinal diseases, sexually transmitted infections, sepsis, and human papillomavirus.

Seegene's assay menu includes a wide range of multiplex panels targeting viral and bacterial infections, allowing clinicians to differentiate between pathogens with similar clinical presentations and support appropriate treatment decisions. The company has achieved strong adoption of its syndromic panels, particularly in international markets, driven by demand for rapid and accurate diagnostic solutions.

The company has also advanced automation and workflow integration by integrating nucleic acid extraction, amplification, and result interpretation into streamlined processes for high-throughput laboratory environments. These systems are designed to reduce manual labor, improve reproducibility, and support efficient laboratory operations.

Seegene has also expanded its capabilities with the availability of CURECA, a fully automated molecular diagnostics system that integrates the entire PCR workflow from sample preparation through result reporting. The system supports a variety of specimen types and is designed to improve laboratory efficiency while minimizing hands-on time. Additionally, the company offers STAgora, a digital platform that enables real-time

visualization and analysis of infectious disease data, supporting epidemiological surveillance and more informed clinical and public health decision-making.

Seegene continues to advance its OneSystem strategy, which focuses on expanding access to its multiplex PCR technologies through collaborations and platform-agnostic assay development. This approach enables broader global distribution and integration of its assays across different diagnostic platforms, including decentralized and near-patient testing environments.

The company has also continued to expand its assay portfolio with additional Novaplex tests and enhanced Allplex panels, including expanded detection of antimicrobial resistance markers and broader coverage of respiratory, gastrointestinal, and sexually transmitted infections. At the same time, Seegene has strengthened its software system to support data analysis, reporting, and integration with laboratory information systems, complementing its digital surveillance capabilities.

Sekisui Diagnostics LLC

Burlington, MA

www.sekisuidiagnostics.com

Formerly Genzyme Diagnostics, Sekisui Diagnostics became part of Sekisui Medical in 2011 and has since developed a diversified diagnostics portfolio spanning clinical chemistry, coagulation, and rapid testing solutions. The company offers a broad range of products, including clinical chemistry reagents and analyzers, coagulation systems, ELISA and LINE immunoassays, and rapid diagnostic tests for infectious diseases. Sekisui Diagnostics maintains a strong presence in coagulation testing and clinical chemistry, particularly in its home market and selected international regions.

The company has also expanded its capabilities in molecular and genetic testing, including the development of assays for newborn screening. These include tests designed to simultaneously detect conditions such as severe combined immunodeficiency and spinal muscular atrophy, enabling early diagnosis and intervention in neonatal populations.

Sekisui Diagnostics has strengthened its position in point-of-care and near-patient testing through strategic partnerships and product launches. The company partnered with Aptitude Medical Systems to commercialize molecular testing solutions based on the Metrix platform, enabling rapid PCR-based detection of infectious diseases in decentralized settings. Building on this collaboration, Sekisui offers molecular assays for respiratory infections, including combination COVID-19 and influenza tests designed for point-of-care and at-home use, delivering results in approximately 20 minutes.

In addition to molecular diagnostics, Sekisui expanded its rapid antigen testing portfolio. This includes combination assays for detecting influenza A, influenza B, and SARS-CoV-2, as well as rapid tests for respiratory syncytial virus. These immunochromatographic assays are designed for ease of use in clinical and decentralized settings, with rapid turnaround times that support timely clinical decision-making.

Veracyte, Inc.

South San Francisco, CA

www.veracyte.com

Veracyte's flagship products include the Afirma platform for thyroid nodule assessment, which uses genomic analysis to help resolve indeterminate cytology results and reduce unnecessary surgeries. The company has expanded this offering with the Afirma Genomic Sequencing Classifier and the Afirma Xpression Atlas, which provides insights into gene alterations associated with thyroid cancer and supports treatment selection.

The company also markets a portfolio of genomic classifiers across multiple disease areas, including the Percepta Genomic Sequencing Classifier for lung cancer risk assessment, the Envisia Genomic Classifier for interstitial lung disease, and the Decipher test portfolio for prostate cancer. These tests are primarily offered as laboratory-developed tests in the United States, with select international expansion underway.

Veracyte has continued to invest in expanding its platform capabilities. The acquisition of C2i Genomics has added whole-genome minimal residual disease (MRD) capabilities, strengthening the company's oncology portfolio and enabling more comprehensive cancer monitoring solutions. In addition, Veracyte has advanced its strategy to decentralize testing through collaboration with Illumina to develop in vitro diagnostic versions of its assays for use on next-generation sequencing platforms.

Recent product developments include the introduction of new genomic classifiers within the Decipher portfolio, including tests designed to support risk stratification and treatment decisions in advanced prostate cancer. These offerings expand Veracyte's presence in oncology and reinforce its focus on precision medicine.

Chapter 16: Company Profiles: Blood Bank Specialists

Scope

This section presents a selection of companies that specialize in blood banking and that have contributed to test innovation to this segment. This is not a comprehensive review or history of the companies selected to appear in the section, listed alphabetically.

AliveDx

Eysins, Switzerland

www.alivedx.com

Quotient, now operating as AliveDx, has more than 30 years of experience in transfusion diagnostics, developing and manufacturing products for blood grouping and immunohematology. The company expanded into the U.S. market in the early 2010s with FDA authorization to commercialize conventional liquid reagents and has since built a broad portfolio of licensed products for transfusion medicine. AliveDx continues to offer a comprehensive range of immunohematology reagents, including its ALBAcyte product line, serving blood banks and hospital laboratories worldwide.

The company's main product is the MosaiQ platform, a fully automated microarray-based system designed to consolidate and streamline diagnostic testing. The platform provides multiplex testing across immunohematology, infectious disease, and autoimmune applications. The MosaiQ Extended Immunohematology Microarray enables simultaneous antibody screening and antigen typing, including ABO forward and reverse grouping, improving workflow efficiency and reducing manual processing.

AliveDx has continued to expand the MosaiQ test menu through internal development and partnerships. Collaborations with external partners have supported the development of additional assays, particularly in infectious disease testing, broadening the platform's clinical utility. More recently, the company has extended MosaiQ into new application areas, including allergy and autoimmune disease testing, with multiplex microarray assays designed to deliver automated, sample-to-answer workflows.

The company offers autoimmune testing panels, including multiplex assays for connective tissue diseases and celiac disease, which are designed to simplify laboratory workflows through fully automated processing. These assays support detection of multiple biomarkers in a single run, improving efficiency and clinical insight.

Cerus Corporation

Concord, CA

www.cerus.com

Product revenue increased 14% during the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to the continued expansion of the company's platelet products.

Cerus Corporation is a biomedical company focused on improving blood transfusion safety through pathogen reduction technologies. Its core product, the INTERCEPT Blood System, is designed to reduce the risk of transfusion-transmitted infections by inactivating a broad spectrum of pathogens, including viruses, bacteria, and parasites that may be present in donated blood. The system targets nucleic acids with a proprietary photoactive compound that, when activated by ultraviolet A (UVA) light, binds to DNA and RNA, preventing replication and thereby rendering pathogens and donor white blood cells inactive.

Cerus markets the INTERCEPT Blood System for platelets and plasma across the United States, Europe, the Middle East, and other international markets. The system is widely used as a proactive safety measure to address both established transfusion-transmitted pathogens, such as hepatitis viruses and HIV, and emerging infectious threats. The company is also advancing its INTERCEPT red blood cell system, which is in late-stage development and represents a significant opportunity to extend pathogen reduction technology across the full range of transfusable blood components.

Cerus has strengthened its commercial position through strategic partnerships and supply agreements, including long-term collaborations with major blood collection organizations. The company has also expanded its manufacturing capabilities through partnerships to support global demand for INTERCEPT products.

Recent product developments include enhancements to the INTERCEPT platform and supporting technologies. These include regulatory approvals for the extended shelf life of platelet processing sets, improving inventory management, and operational efficiency for blood centers. In addition, Cerus has introduced next-generation illumination technology,

including the INT200 system, an LED-based device designed to improve workflow efficiency, throughput, and scalability in blood processing operations.

Chapter 17: Company Profiles: Core Lab and Other Companies

Scope

This section presents a selection of companies that have brought and continue to bring innovation to clinical chemistry and the core laboratory. This is not a comprehensive review or history of the companies selected to appear in the section and is listed alphabetically.

SCIEX Pte Ltd.

Framingham, MA

www.sciex.com

A Danaher Corporation company since 2013, SCIEX is a leading provider of mass spectrometry solutions serving basic research, drug discovery and development, food and environmental testing, forensics, and an expanding role in clinical and translational diagnostics. With more than three decades of innovation, SCIEX offers a broad and integrated portfolio spanning quadrupole time-of-flight (QTOF), triple quadrupole, hybrid QTRAP, capillary electrophoresis, and high-throughput acoustic mass spectrometry platforms. Its high-resolution QTOF portfolio includes the TripleTOF series for advanced qualitative and quantitative workflows and the X500 family designed for routine and biotherapeutic characterization. In quantitative mass spectrometry, SCIEX continues to build on its widely adopted triple-quadrupole systems, including the 6500+ and the newer 7500+ platforms, which deliver enhanced sensitivity, robustness, and performance for regulated and high-throughput laboratories. The QTRAP series extends these capabilities by integrating linear ion trap functionality, enabling simultaneous quantitation and confirmation within a single workflow, while legacy systems such as the TOF/TOF 5800 have transitioned to limited support as the company advances newer technologies.

SCIEX's portfolio is increasingly defined by workflow integration and end-to-end solutions. The company's ExionLC and ExionLC AE systems provide optimized front-end separations for LC-MS/MS applications, while its software system, including SCIEX OS and cloud-enabled data platforms, offers instrument control, data acquisition, advanced analytics, and multi-omics integration. Product introductions reflect a continued focus on sensitivity, throughput, and application breadth. Zeno SWATH DIA has enhanced proteomic depth and quantitative performance for biomarker discovery and translational research. The ZenoTOF 8600 system represents a next-generation high-resolution platform with expanded mass range, improved speed, and increased sensitivity. In quantitative analysis, the SCIEX 7500+ system enhances performance in demanding applications that require ultra-low detection limits. High-throughput innovation is demonstrated by the Echo MS+ system, which combines acoustic ejection with open port interface sampling for rapid, label-free analysis and is now integrated with high-resolution platforms to enable large-scale screening workflows.

With increasing demand for mass spectrometry in regulated and clinical laboratory environments, SCIEX continues to advance standardized workflows, automation, and service capabilities to support routine adoption of LC-MS/MS in areas such as toxicology, endocrinology, and therapeutic drug monitoring.

Diabetes

ARKRAY, Inc. is a provider of diabetes management solutions and maintains a strong presence in the U.S. long-term care market, which is supported by a broad portfolio of glucose monitoring systems and HbA1c analyzers. The company has a long history of innovation in diabetes diagnostics, including the early development of portable blood glucose testing technologies and HbA1c analyzers based on HPLC. Since introducing its early glucose testing systems in the 1970s, ARKRAY has continued to expand its diabetes care portfolio, with the GLUCOCARD product line serving as a core offering for both professional and self-monitoring applications.

ARKRAY's blood glucose monitoring systems have placed a strong emphasis on accuracy, usability, and connectivity. The GLUCOCARD Shine family, including Bluetooth-enabled and accessibility-focused models, supports data sharing, remote monitoring, and integration with digital health platforms, making these systems particularly well suited for long-term care and home health environments. These meters are designed to meet stringent accuracy requirements and incorporate features such as hematocrit correction to improve reliability across diverse patient populations. ARKRAY has also expanded its digital health system through mobile applications and connected care solutions that enable patients and providers to track glucose trends, manage lifestyle factors, and support clinical decision-making.

In HbA1c testing, ARKRAY maintains a strong position with its ADAMS A1c series, which offers a tiered portfolio addressing a range of laboratory needs. Systems such as the HA-8180V and HA-8180T support routine clinical laboratories, while the compact HA-8380V serves smaller facilities and decentralized settings. The HA-8190V platform represents the company's advanced HPLC-based solution, delivering high-precision HbA1c measurement with enhanced detection of hemoglobin variants, supporting accurate assessment across diverse patient populations. This tiered approach enables ARKRAY to address both high-throughput central laboratories and near-patient testing environments.

In addition, ARKRAY has introduced systems such as the ADAMS Glucose GA-1180, a laboratory-based analyzer designed to support accurate glucose measurement and integration

with HbA1c testing workflows in centralized laboratory settings. The company has also expanded into adjacent diagnostic areas with products such as combination antigen tests for respiratory infections, reflecting diversification beyond core diabetes care.

Molecular

ARKRAY, Inc. has expanded its presence in molecular diagnostics by improving accessibility to genetic testing, with a portfolio designed to support streamlined workflows from sample preparation through analysis and reporting. The company's approach emphasizes simplified, cartridge-based systems suitable for hospital laboratories and decentralized testing environments. Its offering includes nucleic acid extraction through compatible platforms such as the Maxwell RSC system, amplification and detection using the i-densy Gene Analyzer series, and data management through connected software solutions such as MEQNET iDia, enabling an integrated sample-to-answer workflow.

The i-densy IS-5320 remains the core platform within ARKRAY's molecular diagnostics portfolio, providing fully automated genetic analysis from sample preparation through amplification and detection, with results delivered in a relatively short turnaround time and without the need for highly specialized technical expertise. The system is positioned for applications in pharmacogenomics, oncology, and infectious disease testing, and reflects the broader industry trend toward near-patient molecular diagnostics. ARKRAY has expanded the i-densy reagent menu, including assays targeting cytochrome P450 genotypes such as CYP2C19 for drug metabolism, as well as multi-analyte cartridge-based reagents that enable simultaneous detection of multiple genetic targets from whole blood or purified nucleic acid samples.

ARKRAY's molecular strategy focuses on menu expansion and workflow integration rather than new instrument platforms. Enhancements include broader assay availability across pharmacogenomics and disease-specific applications, improved ease of use through cartridge-based testing, and compatibility with laboratory information systems to support routine clinical adoption. The company also maintains collaborations with Promega Corporation for nucleic acid purification workflows, particularly in applications such as circulating cell-free DNA analysis. In addition, ARKRAY offers microfluidics-based systems such as the μTAS Wako platform for specific applications, including tuberculosis testing, although this remains a more specialized offering.

EKF Diagnostics Holdings Plc

Cardiff, UK

www.ekfdiagnostics.com

EKF Diagnostics Holdings plc develops, manufactures, and distributes point-of-care analyzers used in the detection and management of diabetes, anemia, lactate, and renal-related conditions. The company's portfolio includes systems for measuring glucose, lactate, hemoglobin, hematocrit, and HbA1c across a wide range of settings including physician offices, pharmacies, blood banks, sports medicine clinics, hospitals, and laboratories. EKF Diagnostics operates internationally, with products distributed in more than 100 countries and research, development, and manufacturing capabilities spanning Germany, Ireland, the United States, and the United Kingdom.

Founded in Germany in 1990, EKF has expanded acquisitions, building a diversified near-patient testing portfolio. Key acquisitions include Quotient Diagnostics, which strengthened its HbA1c capabilities, Argutus Medical, which added expertise in kidney biomarkers, and Stanbio Laboratory, which expanded its clinical chemistry and distribution footprint. These acquisitions have supported EKF's strategy of combining point-of-care technologies with central laboratory capabilities and consumables.

EKF's product portfolio includes hemoglobin analyzers such as the Hemo Control and DiaSpect Tm systems, which are widely used in hospitals, blood banks, and screening programs where rapid and reliable results are essential. The DiaSpect platform has been enhanced with connectivity features that enable integration with EKF's data management solutions, supporting traceability and workflow efficiency across decentralized settings. In HbA1c testing, the Quo-Test and Quo-Lab analyzers remain central offerings, utilizing boronate fluorescence quenching technology to deliver accurate HbA1c measurements from small blood samples. These systems are designed for ease of use and affordability, particularly in decentralized and resource-limited environments, and can be equipped with connectivity solutions that support data transfer, quality control, and integration with laboratory information systems.

In metabolic testing, EKF continues to advance its Biosen line of glucose and lactate analyzers, with the Biosen C-Line representing the latest generation of benchtop systems

designed for rapid, precise measurement in clinical, laboratory, and sports medicine settings. The company has also expanded its connectivity ecosystem, including EKF Link and related middleware solutions, enabling improved data management, remote monitoring, and interoperability across its analyzer portfolio. In addition, EKF maintains a broad offering of Stanbio-branded reagents, enzymes, calibrators, and controls, supporting both point-of-care and central laboratory testing workflows.

Shimadzu Scientific Instruments

Columbia, MD

www.ssi.shimadzu.com/

Shimadzu Corporation is a multinational company headquartered in Kyoto, Japan, with a long history dating back to 1875. Its operations span analytical instruments, medical systems, and industrial technologies. Shimadzu Scientific Instruments serves as the company's U.S. arm, providing sales, service, and technical support through a broad national network. Shimadzu maintains a strong presence in analytical instrumentation and has expanded its role in clinical diagnostics, particularly through liquid chromatography and mass spectrometry platforms that support in vitro diagnostic applications.

Shimadzu established an important position in clinical microbiology through its collaboration with bioMérieux, which led to the development of MALDI-TOF–based identification systems used in routine microbiology laboratories. In clinical diagnostics, the company has increasingly focused on LC-MS/MS–based workflows to support applications such as therapeutic drug monitoring, toxicology, and endocrinology. This includes the development of integrated solutions that combine triple-quadrupole mass spectrometry systems with automated sample-preparation platforms such as the CLAM series, enabling streamlined, sample-to-answer workflows suitable for routine clinical laboratory use.

Shimadzu's mass spectrometry portfolio has continued to evolve with systems such as the LCMS RX series and high-sensitivity triple quadrupole platforms, which offer improved robustness, throughput, and analytical performance for clinical applications. The company has also expanded its menu of clinically oriented assay kits, including immunosuppressant testing solutions such as the DOSIMMUNE LC-MS/MS kit, which support therapeutic drug monitoring in regulated laboratory environments and align with evolving regulatory requirements in regions adopting IVDR standards.

In addition to LC-MS/MS, Shimadzu markets MALDI-TOF–based clinical microbiology and maintains a broad analytical portfolio that includes UHPLC systems such as the Nexera series, imaging mass spectrometry platforms, and compact analytical instruments designed for ease of use and workflow integration. The company also continues to innovate in gas

chromatography and spectrophotometry, with systems such as the Brevis GC platform emphasizing compact design and energy efficiency.

Snibe Co. Ltd. (Shenzhen New Industries Biomedical Engineering Co. Ltd.)

Shenzhen, Guangdong, China

https://www.snibe.com/

Snibe (Shenzhen New Industries Biomedical Engineering Co., Ltd.) is a global diagnostics company specializing in the development, manufacturing, and commercialization of clinical laboratory instruments and in vitro diagnostic reagents, with a primary focus on chemiluminescence immunoassay technology. Founded in 1995, the company has built its platform around magnetic microbead–based separation technology and proprietary chemiluminescent labeling systems, enabling high sensitivity and throughput in immunoassay testing. Snibe was among the first Chinese companies to obtain U.S. regulatory clearance for a CLIA-based immunoassay system and to expand into regulated international markets.

The company's MAGLUMI series of automated CLIA analyzers forms the core of its portfolio, with a large global installed base across hospitals and clinical laboratories in more than 140 countries. The portfolio spans a wide range of throughput levels, from compact systems such as the MAGLUMI X3 to mid- and high-throughput platforms, including the MAGLUMI X6 and X8, and extends to flagship ultra–high-throughput systems, such as the MAGLUMI X10, designed for large core laboratories and high-volume testing environments. These systems are continuously expanding their assay menus to cover infectious diseases, endocrinology, oncology, cardiovascular markers, and other clinical areas.

Snibe has expanded beyond standalone immunoassay analyzers into integrated core laboratory solutions. Through its Biolumi systems, the company combines immunoassay and clinical chemistry platforms into unified workflows, enabling laboratories to streamline operations and improve efficiency. In addition, Snibe has introduced total laboratory automation solutions such as the SATLARS-T8 system, which incorporates automated sample handling, analyzer integration, and workflow management, reflecting a strategic shift toward fully automated, high-throughput laboratory environments.

Snibe has broadened its diagnostic portfolio into molecular diagnostics and additional testing segments. The Molecision series supports nucleic acid testing applications with multiple

configurations to meet different throughput needs, while newer product lines also extend into coagulation testing, with systems such as the Hemolumi H6 analyzer. The company has also expanded its regulatory footprint, including IVDR-certified assays for key infectious disease markers in Europe and ongoing regulatory clearances in the United States for selected analyzers and assays.

Tosoh Bioscience

Tokyo, Japan

www.tosohbioscience.com

Tosoh Bioscience is a subsidiary of Tosoh Corporation, a global group with a strong presence in specialty chemicals, materials, and life sciences. Tosoh Bioscience develops and manufactures a comprehensive portfolio of chromatographic media, bioseparation systems, and in vitro diagnostic analyzers, with a high degree of integration between its diagnostics and separation technologies.

The company's AIA series represents its core automated immunoassay platform, utilizing fluorescent enzyme immunoassay (FEIA) technology and a proprietary AIA-PACK test cup format. The portfolio spans a wide range of throughput levels, from the compact AIA-360 designed for physician office laboratories and small hospital settings, to mid-range systems such as the AIA-600II, and higher-throughput analyzers, including the AIA-900 and flagship AIA-2000, which supports continuous random-access processing and advanced workflow capabilities for large laboratories. These systems provide a broad assay menu covering oncology, endocrinology, fertility, cardiac, infectious disease, and metabolic testing.

Tosoh has expanded its immunoassay technology with the addition of chemiluminescent enzyme immunoassay (CLEIA) systems, including the AIA-CL300, which offers enhanced analytical sensitivity and supports a broader range of clinical applications in compact, decentralized laboratory environments. This expansion reflects a strategic shift toward higher-sensitivity immunoassay technologies while maintaining the reliability and workflow efficiency of its established AIA platforms. Higher-throughput CLEIA systems further extend this capability into larger laboratory settings.

In hemoglobin testing, Tosoh remains a leader in HPLC-based HbA1c analysis with its HLC-723 series, including the G8 and G11 systems. These analyzers provide rapid, high-resolution separation of hemoglobin fractions, with variant-detection capabilities and scalable sample handling, supporting both routine diabetes monitoring and specialized hemoglobinopathy analysis. Continued enhancements emphasize faster turnaround times, improved automation, and seamless integration into core laboratory workflows.

Tosoh strengthens its position through incremental innovation, including expanded immunoassay sensitivity, enhanced HbA1c performance, and increased connectivity with laboratory automation systems. Strategic collaborations and workflow integration initiatives further support its role in modern core laboratory environments, positioning the company as a reliable provider of immunoassay and HbA1c diagnostic solutions.

Trinity Biotech Plc

Bray, County Wicklow, Ireland

www.trinitybiotech.com

Trinity Biotech plc is a developer and manufacturer of diagnostic test kits and instruments serving both clinical laboratory and point-of-care markets. Founded in 1992, the company has built a broad portfolio spanning infectious disease, autoimmune disorders, hemoglobinopathies, and diabetes monitoring. Trinity operates manufacturing facilities in Ireland, the United States, and Canada, and also runs Immco Diagnostics, which provides specialized testing services for autoimmune and immunological disorders, including advanced serology and immunogenetics testing.

The company offers a wide range of diagnostic technologies, including rapid point-of-care immunoassays under the Uni-Gold brand, enzyme immunoassays, Western blot systems, indirect fluorescent antibody platforms, and line immunoassays for detecting infectious and autoimmune diseases. Its clinical chemistry portfolio includes specialized reagents and assay kits for metabolic and enzymatic testing, along with HPLC-based solutions for hemoglobin and other analytes. Trinity also develops automated laboratory instruments, including ELISA processors, Western blot automation systems, and integrated platforms that combine multiple assay technologies to improve laboratory efficiency and workflow standardization.

Trinity has strengthened its position in hemoglobin testing with automated systems such as the Premier Resolution platform, which enables detailed analysis of hemoglobin variants and supports the diagnosis of hemoglobinopathies. In point-of-care diagnostics, systems such as the Meritas analyzer provide quantitative fluorescence-based testing in a compact, easy-to-use format designed for decentralized settings. The company maintains a strong presence in autoimmune diagnostics through its Immco-branded assays and instrumentation, supported by its reference laboratory services.

In recent years, Trinity has expanded into next-generation diabetes management and data-driven diagnostics. The company has developed a continuous glucose monitoring platform based on advanced biosensor technology, strengthened through acquisitions and further advanced with the introduction of its AI-native CGM+ system, a wearable device that integrates glucose sensing with additional physiological parameters such as heart activity,

body temperature, and physical activity. This platform reflects a strategic move into digital health and multi-parameter monitoring.

Trinity has also expanded its clinical diagnostics portfolio into women's health with the introduction of the PreClara Ratio test, a biomarker-based assay that assesses the risk of preeclampsia. This addition broadens the company's reach into pregnancy-related diagnostics and complements its existing laboratory-based testing capabilities. In parallel, recent acquisitions have strengthened Trinity's position in metabolomics and oncology diagnostics, including the development of non-invasive prostate cancer risk assessment technologies.

Chapter 18: Company Profiles: CTC & Liquid Biopsy Test Providers

Scope

In this section, Kalorama has selected a group of companies that provide molecular and proteomic tests and technologies that advance the potential of circulating tumor cell (CTC) testing and cell-free DNA as liquid biopsy tools to diagnose, monitor, and guide therapy for cancer patients. This is not a comprehensive review or history of the companies selected to appear in the section and is listed alphabetically.

Epic Sciences

San Diego, CA

www.epicsciences.com

Epic Sciences is a privately held biotechnology company based in San Diego, California, founded in 2008 to commercialize rare cell detection and characterization technology originally licensed from Scripps Research. The company has developed a proprietary platform centered on its "no cell left behind" approach, enabling the detection and analysis of circulating tumor cells (CTCs) using high-definition imaging, multi-parameter analysis, and advanced software algorithms.

Epic Sciences' technology focuses on its high-definition circulating tumor cell platform, which performs detailed characterization of tumor cells through a combination of immunofluorescent staining, digital microscopy, and image analysis. This approach evaluates a wide range of cellular and morphological parameters, allowing for highly sensitive detection of rare tumor cells, including clusters and cells present in early-stage disease. The platform supports downstream molecular analysis directly on identified cells, including genomic and fluorescence-based techniques, enabling comprehensive tumor profiling from a blood sample.

Epic Sciences has developed a portfolio of liquid biopsy assays for precision oncology. Its AR-V7 assay remains a clinically relevant test for metastatic prostate cancer, identifying nuclear localization of androgen receptor splice variants to guide treatment selection. The company's flagship offering, DefineMBC, represents a multi-omic liquid biopsy solution for metastatic breast cancer that integrates circulating tumor cell analysis, circulating tumor DNA genomic profiling, and protein biomarker assessment to provide a comprehensive view of tumor biology. This platform offers therapy selection, treatment response monitoring, and identification of resistance mechanisms.

Epic Sciences expanded its molecular profiling capabilities by broadening genomic panels and enhancing single-cell analysis, combining cell-based and cell-free approaches in a unified workflow. These developments are accomplished by increasing clinical adoption and payer coverage for select genomic assays in oncology. Additionally, the company maintains active collaborations with pharmaceutical partners to develop companion diagnostics and

support clinical trials across multiple cancer types, including prostate, breast, lung, pancreatic, and bladder cancers.

Epic Sciences is advancing a multi-omic, data-driven approach to liquid biopsy, integrating high-definition CTC analysis with genomic and proteomic insights to support precision oncology, treatment decision-making, and disease monitoring.

Foundation Medicine, Inc.

Cambridge, MA

www.foundationmedicine.com

Foundation Medicine, Inc. develops and commercializes molecular diagnostics based on comprehensive genomic profiling using next-generation sequencing. The company has built a proprietary platform that integrates optimized sample preparation, high-throughput sequencing, and advanced bioinformatics to analyze cancer-related genes across their full coding regions, enabling detection of multiple classes of genomic alterations that inform treatment selection in oncology.

Foundation Medicine's portfolio includes tissue- and blood-based genomic profiling assays. Its flagship tissue test, FoundationOne CDx, provides broad genomic profiling of solid tumors and continues to expand its role through additional companion diagnostic indications and broader biomarker coverage. The company also offers FoundationOne Liquid CDx, a blood-based assay that enables genomic profiling when tissue samples are unavailable and is increasingly used as a primary testing option in certain clinical scenarios. Additional offerings include FoundationOne Heme for hematologic malignancies and sarcomas, supporting precision oncology decision-making across a wide range of cancers.

The company has significantly expanded its portfolio with molecular and monitoring solutions that support longitudinal cancer care. FoundationOne Tracker is a personalized, tissue-informed circulating tumor DNA assay designed for ongoing monitoring of disease burden, treatment response, and recurrence, while FoundationOne Monitor provides a tissue-naïve approach to ctDNA-based disease tracking. FoundationOne RNA further extends the platform by enabling the detection of gene fusions and transcriptomic alterations across hundreds of genes, complementing DNA-based profiling and improving the identification of actionable biomarkers.

Foundation Medicine has also broadened its offering into a multimodal biomarker platform that integrates genomic, transcriptomic, and proteomic analyses. The company has expanded its immunohistochemistry menu to include assays such as MET, HER2, PD-L1, CLDN18, and FOLR1, enabling protein biomarker assessment alongside genomic testing. In addition, the company has entered the hereditary cancer testing space with next-generation sequencing

panels that assess multiple genes associated with inherited cancer risk, extending its reach into earlier-stage disease assessment and prevention.

Collaborations with pharmaceutical partners continue to drive the expansion of companion diagnostics tied to targeted therapies across multiple cancer types, including lung, breast, colorectal, and hematologic cancers. Through continued development of tissue profiling, liquid biopsy, RNA analysis, immunohistochemistry, germline testing, and longitudinal monitoring solutions, Foundation Medicine has evolved into a comprehensive provider of precision oncology diagnostics, supporting therapy selection, disease monitoring, and personalized treatment strategies across the continuum of cancer care.

NeoGenomics

Fort Myers, FL

www.neogenomics.com

NeoGenomics is a CLIA-certified clinical laboratory and pharmaceutical services company specializing in cancer genetics and precision oncology testing. The company offers a comprehensive menu of diagnostic services spanning cytogenetics, fluorescence in situ hybridization (FISH), flow cytometry, immunohistochemistry (IHC), anatomic pathology, and molecular genetics. In addition to clinical testing, NeoGenomics provides biomarker and laboratory services to pharmaceutical companies supporting oncology clinical trials and companion diagnostic development.

Headquartered in Fort Myers, Florida, NeoGenomics operates a network of laboratories across the United States, including facilities in California, Texas, Florida, and Tennessee, as well as international operations in Switzerland and Asia to support global clinical trials. The company continues to expand its laboratory infrastructure and service capabilities to improve turnaround time and support growing demand in oncology testing.

NeoGenomics offers a broad portfolio of molecular and genomic assays, including its NeoTYPE and Neo Comprehensive platforms, which provide next-generation sequencing–based profiling for solid tumors, hematologic malignancies, and myeloid disorders. The company has expanded these offerings with additional panels such as Neo Comprehensive Heme Cancers and early-stage cancer profiling assays, as well as rapid testing solutions like AML Express, designed to deliver fast genomic insights for acute myeloid leukemia to support time-sensitive treatment decisions.

The company's liquid biopsy capabilities are anchored by its RaDaR assay, a personalized circulating tumor DNA test that tracks tumor-specific variants to detect molecular residual disease, recurrence, and treatment response across multiple cancer types. RaDaR has emerged as a flagship product with expanding clinical adoption and payer coverage, reflecting increasing demand for longitudinal cancer monitoring.

NeoGenomics continues to expand its companion diagnostic and biomarker portfolio, including assays such as PD-L1, c-MET CDx for non-small cell lung cancer, Pan-TRK, and

FOLR1 testing, to support targeted therapy selection. Additional specialized programs, such as ovarian cancer biomarker testing initiatives, further extend its clinical utility. The company is also advancing into multi-omic approaches through proteomics partnerships, enhancing its ability to support biomarker discovery and translational research.

Chapter 19: Company Profiles: Specialists

Scope

This section presents a selection of companies that have specialized in diabetes testing and monitoring. They have brought and continue to bring innovation to the segment. This is not a comprehensive review or history of the companies selected to appear in this section and is listed alphabetically.

Ascensia Diabetes Care Holdings AG

Basel, Switzerland

www.ascensia.com

Ascensia Diabetes Care Holdings develops and markets blood glucose monitoring systems and related digital health solutions, primarily under the CONTOUR brand, for the management of diabetes. The company operates as part of PHC Holdings Corporation, formerly known as Panasonic Healthcare Holdings, and has a global presence in both self-monitoring blood glucose (SMBG) and continuous glucose monitoring markets.

Ascensia's SMBG portfolio includes a range of CONTOUR-branded glucose meters such as CONTOUR NEXT ONE, CONTOUR NEXT, CONTOUR NEXT LINK, CONTOUR NEXT EZ, CONTOUR PLUS, CONTOUR PLUS ONE, and CONTOUR TS, which are widely used in home and clinical settings. These systems emphasize accuracy, ease of use, and connectivity through integrated digital platforms such as the CONTOUR DIABETES app and cloud-based data management tools, enabling patients and healthcare providers to track and manage glucose levels more effectively.

In continuous glucose monitoring, Ascensia partners with Senseonics to commercialize the Eversense implantable CGM systems, representing a differentiated approach to long-term glucose monitoring. The Eversense E3 system, introduced in recent years, offers up to six months of continuous monitoring and is supported by mobile applications including the EversenseNOW remote monitoring platform, which enables caregivers and healthcare professionals to access patient data in real time. The system has expanded its reimbursement access, including broader Medicare coverage, and regulatory advancements such as integrated CGM designation, supporting its use within connected diabetes management systems.

The company has continued to advance this platform with the introduction of the Eversense 365 CGM system, which extends continuous monitoring to up to one year from a single implanted sensor, representing a significant advancement in long-duration CGM technology. This system reinforces Ascensia's focus on reducing the frequency of sensor replacements while improving patient convenience and long-term adherence.

In addition to hardware, Ascensia has expanded its digital health capabilities through platforms such as GlucoContro.Online, which integrates data from glucose meters and connected applications to support analytics, remote monitoring, and clinical decision-making. Ascensia continues to evolve its diabetes care portfolio by combining traditional SMBG systems, long-duration implantable CGM technologies, and integrated digital health solutions to improve outcomes and patient engagement.

Insulet Corporation

Billerica, MA

www.insulet.com

Insulet Corporation is a medical device company focused on the development, manufacture, and commercialization of the Omnipod Insulin Management System, a tubeless, wearable insulin delivery platform for people with insulin-dependent diabetes. The system consists of a lightweight, disposable Pod worn on the body for up to three days and a separate controller or mobile app that manages insulin delivery. The tubeless design differentiates Omnipod from traditional insulin pumps and supports ease of use and patient convenience.

The company's flagship platform, Omnipod 5, is a fully automated insulin-delivery system that integrates with continuous glucose monitoring to adjust insulin dosing in real time via an embedded algorithm. Initially cleared in 2022, the Omnipod 5 builds on the Omnipod DASH platform and has since been expanded to offer broader compatibility and functionality. The system now integrates with multiple CGM sensors, including Dexcom G7 and Abbott FreeStyle Libre 2 Plus, and offers control via smartphone applications, including iPhone-based operation. Recent enhancements include updates to the automated insulin delivery algorithm, which improve flexibility in glycemic control and overall system performance, as well as continued expansion of interoperability across connected diabetes devices.

Insulet has also expanded its product portfolio with Omnipod Go, a basal-only insulin delivery option designed for individuals with type 2 diabetes who require consistent basal insulin without the complexity of full pump therapy. This system provides fixed-rate insulin delivery over a multi-day wear period and represents an entry point for patients transitioning from injections to wearable insulin delivery.

In addition to hardware, Insulet has expanded its digital system with platforms such as Omnipod Discover, which provides data analytics, retrospective insights, and reporting tools for both patients and healthcare providers, providing improved diabetes management and clinical decision-making. The company is also advancing next-generation automated insulin delivery technologies, including development of fully closed-loop systems, and exploring broader applications of its Pod platform beyond insulin delivery.

Medtronic plc

Dublin, Ireland

www.medtronic.com

Medtronic plc is a leading medical technology company that develops and markets therapies for chronic diseases across multiple business segments, including Cardiovascular, Neuroscience, Medical Surgical, and Diabetes. The Diabetes segment focuses on advanced, integrated diabetes management solutions, including insulin pump systems, continuous glucose monitoring technologies, and digital therapy management tools.

Medtronic's diabetes portfolio has evolved significantly from earlier systems such as the MiniMed 530G, 630G, 670G, and 770G to its current flagship MiniMed 780G platform. The MiniMed 780G system incorporates automated insulin delivery with SmartGuard technology, enabling real-time insulin adjustments and automated correction dosing every few minutes. The system is paired with advanced CGM technologies, including the Guardian 4 sensor and newer sensor options such as Simplera Sync, a disposable, all-in-one CGM designed to simplify the user experience. The company continues to enhance its system through software and digital tools that provide personalized insights, trend analysis, and remote monitoring capabilities, supporting more proactive diabetes management. The MiniMed 780G system has also expanded indications, including use in individuals with type 2 diabetes, and has gained broader reimbursement access.

Medtronic has been advancing next-generation insulin delivery systems, including smaller, more connected pump platforms and additional CGM innovations, reflecting a shift toward simplified, smartphone-controlled, and fully integrated diabetes management solutions. A major strategic transition is underway following the company's 2025 announcement to spin off its Diabetes business as a standalone entity, MiniMed. As of 2026, this separation is in progress through an IPO that was completed in March 2026 and a staged spin-off, with the diabetes portfolio, including insulin pumps, CGM systems, automated insulin delivery technologies, and digital platforms, being transferred to the new company.

During the transition period, Medtronic continues to support and report its diabetes operations; however, once the separation is complete, MiniMed will operate as an

independent, pure-play diabetes technology company, while Medtronic will exit the diabetes market and focus on its remaining core medical technology segments.

In March 2026, Minimed started trading on the Nasdaq under the ticker “MMED”.

Verily Life Sciences LLC

Mountain View, CA

www.verily.com

Verily Life Sciences, a subsidiary of Alphabet Inc., is an active health technology company focused on data-driven healthcare, precision medicine, and digital health platforms. The company develops tools and infrastructure to collect, analyze, and apply health data to improve clinical decision-making, disease management, and population health outcomes. Its areas of focus include chronic disease management, clinical research, bioinformatics, and advanced analytics, reflecting a strategic shift away from hardware development toward integrated software and data solutions.

Verily has contributed to the development of next-generation continuous glucose monitoring technologies through its collaboration with Dexcom, Inc., emphasizing miniaturization, connectivity, and usability. While these efforts supported innovation in CGM design, commercialization has largely been driven through Dexcom's product portfolio, with Verily focusing on enabling technologies rather than launching standalone devices.

The company's product portfolio offers digital health and analytics platforms. Its flagship offering, Lightpath, is an AI-powered chronic care solution designed to support management of metabolic conditions such as diabetes, hypertension, obesity, and hyperlipidemia. Lightpath integrates clinical care, data from connected devices, and advanced analytics to provide personalized insights and treatment support. This platform is complemented by patient-facing applications that enable engagement, coaching, and remote care coordination.

Verily also offers a suite of platforms supporting clinical research and population health. These include Workbench, a scalable environment for multi-omic data analysis and large-scale research programs, and Viewpoint, a platform for clinical trial management and real-world evidence generation. In public health, Verily has developed solutions for disease surveillance and population monitoring, including tools for tracking infectious diseases through environmental and data-driven approaches.

The company is expanding its capabilities in artificial intelligence and data science, integrating predictive analytics and machine learning across its platforms to enhance disease detection, monitoring, and treatment optimization

Chapter 20: Company Profiles: Hematology (Cell Analysis) and Coagulation Specialists

Scope

This section presents a selection of companies that specialize in cell analysis. The profiles are not a comprehensive review or history of the companies selected to appear in the section and are listed alphabetically.

CellaVision AB

Lund, Sweden

www.cellavision.com

CellaVision AB develops and markets systems for digital cell morphology and automated analysis of blood and other body fluids in clinical laboratories. The company's technology combines advanced imaging, automated microscopy, and artificial intelligence to provide the identification, classification, and review of blood cells, improving workflow efficiency and diagnostic consistency in hematology.

CellaVision's portfolio includes digital morphology analyzers such as the DM-series, including systems designed for mid- to high-volume laboratories that automate the manual differential count of white blood cells and assessment of red blood cell morphology. These systems capture high-resolution images of blood smears, pre-classify cells using AI-based algorithms, and present results for verification by laboratory professionals. By digitizing traditionally manual microscopy workflows, the systems enhance standardization, enable remote review, and improve productivity. The portfolio has expanded to include compact systems such as the DC-1, which brings digital cell morphology capabilities to smaller laboratories and decentralized settings.

The company has also developed integrated workflow solutions that extend beyond analysis to include sample preparation. Through the integration of RAL Diagnostics products, CellaVision offers solutions for automated smearing and staining, improving pre-analytical quality and consistency. Systems such as the DIFF-Line combine smear preparation, staining, and digital analysis into a streamlined workflow tailored for smaller laboratories, enabling end-to-end automation of peripheral blood smear processing.

CellaVision has advanced its software capabilities, including tools for education, proficiency testing, and quality assurance, as well as enhanced connectivity that allows digital images and results to be shared across laboratory networks. Strategic collaborations, including its long-standing and expanded partnership with Sysmex Corporation, support integration of digital morphology with hematology analyzers and broader laboratory automation systems. This partnership was further strengthened by a renewed strategic alliance agreement that

extends collaboration through 2038, enabling deeper co-development, system integration, and workflow optimization across hematology platforms.

CellaVision is focused on expanding the adoption of digital morphology through scalable platforms, AI-driven image analysis, and integrated workflow solutions, supporting laboratories of varying sizes in transitioning from manual microscopy to standardized, automated hematology diagnostics.

Masimo Corporation

Irvine, CA

www.masimo.com

Masimo Corporation offers advanced noninvasive patient monitoring technologies centered on its Signal Extraction Technology (SET) platform. This technology enables accurate monitoring of physiological parameters under challenging clinical conditions and forms the basis of Masimo's rainbow pulse CO-oximetry, which allows continuous, noninvasive measurement of multiple blood constituents, including total hemoglobin, along with other key parameters.

Masimo's product portfolio includes the Radical-7 Pulse CO-Oximeter, a flagship monitor that tracks multiple parameters, including oxygen saturation, pulse rate, perfusion index, and total hemoglobin. The system is used across a wide range of care settings, including operating rooms, intensive care units, emergency departments, and neonatal care, to support continuous, noninvasive patient assessment.

The company has continued to expand its monitoring platform with portable and modular systems. Devices such as the Rad-G with Temperature provide handheld monitoring of pulse oximetry, respiration rate derived from the pleth waveform, and temperature, extending Masimo's capabilities into point-of-care and ambulatory environments. The Radium platform further advances this strategy as a modular, scalable patient monitoring system integrating multiple parameters, including pulse oximetry, blood pressure, ECG, temperature, and respiration, enabling flexible deployment across hospital settings.

Masimo has also expanded into new categories of monitoring and patient safety. The Opioid Halo system represents a wearable solution designed to detect and alert caregivers to opioid-induced respiratory depression, marking an entry into overdose prevention and remote monitoring. In addition, the company has broadened its portfolio into wearable and home-based monitoring with products such as the Masimo W1 medical watch, which enables continuous tracking of oxygen saturation and other physiological parameters in ambulatory and home settings. The company has also expanded its consumer and home-use offerings, including fingertip pulse oximeters and connected monitoring solutions that support remote patient monitoring and telehealth integration.

Nova Biomedical Corporation (Nova)

Waltham, MA

www.novabio.us.

Nova Biomedical is a developer, manufacturer, and marketer of advanced blood-testing analyzers and point-of-care testing systems for clinical and research applications. The company is one of the largest privately held in vitro diagnostics firms in the United States and maintains global operations, with manufacturing in the U.S., Taiwan, and Brazil, and subsidiaries across North America, Europe, and Asia.

Nova's analyzers use a broad range of measurement technologies, including potentiometric, amperometric, conductivity, immunochemical, spectrophotometric, photometric, and biosensor-based methods, that support testing in whole blood, plasma, and cell culture media. The company is particularly known for its STAT testing platforms, which provide rapid, multi-parameter results in critical care settings such as emergency departments, intensive care units, and operating rooms. Its product portfolio includes both central laboratory and point-of-care systems, as well as handheld meter-and-strip platforms for glucose, ketone, lactate, and creatinine testing.

Nova's StatStrip platform remains a cornerstone of its point-of-care offering, designed to improve glucose measurement accuracy by correcting for hematocrit and minimizing interferences that can impact critically ill patients. The company has expanded this platform with next-generation hospital glucose meter systems that enhance connectivity, interoperability with laboratory and hospital information systems, and usability in high-acuity environments. In addition, the Nova Max Pro system provides rapid creatinine and estimated glomerular filtration rate testing, with increasing adoption in decentralized care settings and screening programs for early detection of kidney disease.

In critical care diagnostics, Nova has expanded its analyzer portfolio with the Prime and Prime Plus systems, positioned as next-generation critical care analyzers that deliver comprehensive panels of blood gas, electrolyte, metabolite, and hematology parameters from small sample volumes with rapid turnaround times. These systems are designed to compete with leading critical care platforms by offering expanded menus, workflow efficiency, and ease of use. The company has also introduced the Nova Primary glucose reference analyzer,

which is gaining adoption as a replacement for legacy laboratory glucose analyzers and provides high-accuracy reference measurements in central laboratories.

Nova has expanded through industry consolidation. The acquisition of Nova Biomedical by Advanced Instruments was completed in 2025, resulting in a merged organization operating under the Nova Biomedical name. This combination brings together complementary strengths in clinical diagnostics and bioprocessing, further strengthening the company's position across healthcare and life sciences markets.

Chapter 21: Company Profiles: Histopathology Specialists

Scope

This section presents a selection of companies that specialize in tissue analysis using histopathology techniques for molecular analysis. They have brought and continue to bring innovation to the segment. This is not a comprehensive review or history of the companies selected to appear in the section and is listed alphabetically.

Amoy Diagnostics Co. Ltd.

Xiamen, China

www.amoydx.com

Amoy Diagnostics Co., Ltd. develops and commercializes molecular diagnostic assays for oncology, serving healthcare providers, academic institutions, and pharmaceutical partners. The company specializes in detecting gene mutations and measuring gene expression in formalin-fixed, paraffin-embedded tumor tissue, with technologies spanning real-time PCR and next-generation sequencing. Its proprietary ADx-ARMS PCR platform enables rapid, sensitive mutation detection and is widely used in clinical laboratories due to its ease of use and compatibility with standard PCR instrumentation.

AmoyDx has established a broad portfolio of oncology assays targeting key driver mutations, including EGFR, KRAS, NRAS, BRAF, PIK3CA, ALK, ROS1, RET, KIT, JAK2, BCR-ABL, and TP53, along with gene expression assays such as ERCC1, TYMP, STMN1, and RRM1 that support chemotherapy decision-making. The company's assays are widely used across solid tumors and hematologic malignancies and have achieved regulatory approvals across China, Europe, and Asia, reflecting strong global adoption of its PCR-based companion diagnostics.

AmoyDx's portfolio includes the Pan Lung Cancer PCR Panel, which enables simultaneous detection of multiple actionable driver mutations in non-small cell lung cancer. This panel continues to expand its clinical utility through additional companion diagnostic approvals for targeted therapies, including RET, MET, and ROS1 inhibitors, reinforcing its role as a rapid, front-line, multi-biomarker testing solution in lung cancer.

AmoyDx has also expanded into immuno-oncology and next-generation sequencing. The company has developed PD-L1 expression assays to guide immunotherapy selection and introduced broader genomic profiling solutions such as its Essential NGS Panel, which offers multi-gene mutation detection and is increasingly positioned as a primary companion diagnostic platform for targeted therapies, including detection of EGFR exon 20 insertion mutations. This reflects a strategic shift toward combining rapid PCR-based testing with more comprehensive NGS-based profiling.

The company's portfolio has further expanded through companion diagnostic development beyond lung cancer, including assays targeting BRCA and homologous recombination repair mutations for prostate and breast cancer, HER2 mutation testing associated with targeted therapies, and IDH1/2 mutation assays developed through pharmaceutical collaborations. These additions broaden AmoyDx's reach across multiple oncology indications.

AmoyDx maintains extensive and ongoing collaborations with global pharmaceutical partners, supporting companion diagnostic development, biomarker identification, and targeted therapy selection across multiple cancer types

Applied Spectral Imaging Inc. (ASI)

Carlsbad, CA

www.spectral-imaging.com

Applied Spectral Imaging (ASI) is a provider of automated microscopy imaging and digital analysis solutions for cytogenetics and pathology laboratories. Founded in 1993, the company has established a global presence with thousands of systems installed worldwide and a broad distributor network across North America, Europe, and Asia. ASI focuses on improving laboratory efficiency and diagnostic accuracy through automation, digital imaging, and advanced software for analysis of immunohistochemistry and fluorescence in situ hybridization assays.

ASI's portfolio is focused on its GenASIs platform, a modular software and imaging environment that supports a wide range of cytogenetic and pathology applications. Core solutions include BandView for karyotyping, FISHView for fluorescence in situ hybridization analysis, and SpotScan applications supporting assays such as CEP XY, UroVysion, ALK, and HER2. The company has expanded this platform with additional modules such as HiFISH, HiBand, and CytoPower, enabling comprehensive chromosome analysis and FISH workflows. In digital pathology, ASI offers solutions such as HiPath and HiPath Pro, which provide scanner-agnostic image analysis and quantitative interpretation for immunohistochemistry.

The GenASIs platform has evolved into an integrated, all-in-one workflow solution that combines cytogenetics, FISH, and digital pathology within a unified system. Enhancements in recent software releases, including versions 8.4 and 8.4.1, introduce improved AI-assisted chromosome classification, advanced karyotyping tools, mitotic index calculation, and enhanced automation capabilities. The platform also supports remote and distributed workflows through solutions such as GenASIs AnyWhere, enabling telepathology, remote case review, and collaboration across laboratory networks.

ASI continues to strengthen its system through strategic partnerships and integration initiatives. Collaborations with companies such as CytoCell, a division of Oxford Gene Technology within Sysmex Corporation, expand access to complementary probe technologies and global distribution channels. Partnerships with digital imaging providers,

including Barco and Motic, support integrated digital pathology solutions that combine imaging hardware, displays, and analysis software. In addition, ASI has expanded its capabilities through integration within the ZYTOMICS group, supporting the development of more comprehensive end-to-end diagnostic solutions that combine reagents, imaging, and analytics.

Visiopharm

Hørsholm, Denmark

www.visiopharm.com

Visiopharm provides quantitative digital pathology software solutions that enable pathologists and researchers to analyze tissue samples with high accuracy, reproducibility, and efficiency. Headquartered in Denmark with a North American presence in Colorado, the company focuses on image analysis, artificial intelligence, and workflow optimization for clinical diagnostics, life sciences research, and biopharmaceutical applications.

Visiopharm's platform focuses on modular software suites such as Oncotopix and Biotopix, which deliver advanced image analysis algorithms for tissue-based diagnostics and research. These platforms automate histological assessment and are used across cancer diagnostics, translational research, and drug development. Central components of the platform include the Engine module for processing digitized tissue sections and executing analysis applications, and the Viewer/Viewer+ modules, which support a wide range of whole-slide imaging formats and modalities, including brightfield, fluorescence, and multispectral imaging. The Author module enables users to develop and customize analysis applications without requiring programming expertise, supporting flexible deployment across laboratories.

The platform is further enhanced with specialized tools such as Tissuealign for alignment and analysis of serial sections, Tissuearray for high-throughput tissue microarray analysis, and Stereotopix for unbiased quantification of tissue morphology using stereological methods. These capabilities allow for detailed analysis of tumor microenvironments, biomarker expression, and tissue architecture. The company also offers integration with high-resolution slide scanners, including systems developed by Hamamatsu Photonics, enabling efficient digitization, storage, and sharing of pathology images across networks.

Visiopharm continues to expand its capabilities through artificial intelligence and multiplex imaging. Solutions such as Phenoplex provide integrated workflows for multiplex tissue analysis, enabling simultaneous evaluation of multiple biomarkers within a single tissue sample. The company also offers the advanced diagnostic algorithms, including Ki67 proliferation analysis tools, supporting clinical decision-making in oncology, and continued

enhancement of its platform through ongoing software updates that improve AI performance, workflow automation, and diagnostic application development.

Strategic collaborations remain a key component of Visiopharm's growth. The company has partnered with organizations such as Proscia, Deep Bio, Minerva Imaging, Grundium, Agilent, and PathAI to expand interoperability and integrate AI-driven pathology solutions. More recent collaborations include integration with Indica Labs' image management platform to enable seamless workflow connectivity, partnerships in spatial biology with Cell Signaling Technology, and collaborations with research organizations such as Glint Lab to enhance biomarker discovery and tissue analysis workflows.

Chapter 22: Company Profiles: Immunoassay Specialists

Scope

This section presents a selection of companies that specialize in immunoassays and have brought and continue to bring innovation to this segment in 2025. It is not a comprehensive review or history of the companies selected to appear in the section and is listed alphabetically.

Biohit Healthcare

Helsinki, Finland

www.biohithealthcare.com

Biohit Oyj, founded in 1988, develops and markets diagnostic tests and laboratory solutions focused on gastrointestinal diseases and associated conditions. The company operates internationally with subsidiaries in Europe and Asia and is listed on the Nasdaq Helsinki exchange. Biohit's strategy centers on noninvasive diagnostic testing, particularly for conditions related to digestive health and nutrient absorption.

Biohit's product portfolio includes the GastroPanel test, a blood-based diagnostic panel used to assess Helicobacter pylori infection and atrophic gastritis. The test measures key biomarkers, including pepsinogen I, pepsinogen II, gastrin-17, and H. pylori antibodies, providing a noninvasive method to evaluate gastric mucosal status. GastroPanel is also used to identify patients at increased risk of gastric cancer, peptic ulcer disease, gastroesophageal reflux disease, and deficiencies in vitamin B12, calcium, and iron, and continues to be positioned as a key tool for risk stratification, early detection, and population-level screening of gastric diseases.

Additionally, Biohit offers a range of rapid and laboratory-based tests targeting gastrointestinal and metabolic conditions. These include assays for active vitamin B12 (holotranscobalamin), celiac disease testing based on transglutaminase antibodies, and rapid tests for Helicobacter pylori and lactose intolerance. The company's Celiac Quick Test enables point-of-care detection from a fingerstick blood sample, supporting faster diagnosis in decentralized settings.

Biohit also provides stool-based diagnostics, including calprotectin testing to differentiate inflammatory bowel disease from irritable bowel syndrome, as well as fecal immunochemical tests such as ColonView for colorectal cancer screening. ColonView continues to gain adoption as a noninvasive screening tool with improved sensitivity compared to traditional methods, supporting broader use in colorectal cancer screening programs.

Recent product developments include the introduction of the FAEX Sample System, designed to improve stool sample collection, handling, and workflow efficiency in fecal testing applications. This addition complements Biohit's existing gastrointestinal testing portfolio by addressing pre-analytical challenges and supporting more reliable diagnostic results. Biohit continues to enhance its gastrointestinal diagnostic portfolio through incremental improvements to its core assays and sample-handling solutions, with an ongoing focus on noninvasive screening and early disease detection.

Biomerica Inc.

Irvine, CA

www.biomerica.com

Biomerica, Inc. develops, manufactures, and markets diagnostic products for use in the home, physician offices, and clinical laboratories, with a focus on early detection and monitoring of disease. The company's portfolio spans gastrointestinal health, diabetes, women's health, allergy and food sensitivity, and selected infectious disease applications, with a strong emphasis on point-of-care and over-the-counter testing.

Biomerica's consumer product line includes widely distributed over-the-counter tests such as EZ Detect for fecal occult blood, Fortel pregnancy tests, and the Aware Breast Self-Examination Pad. EZ Detect remains a flagship product, offering a noninvasive approach to colorectal screening that does not require direct stool handling or dietary restrictions, supporting ease of use in home settings. The company also offers Fortel Microalbumin Screening tests for early detection of kidney dysfunction, particularly in diabetic patients, and continues to expand its portfolio of rapid and home-use diagnostics.

In laboratory diagnostics, Biomerica provides ELISA-based assays including Transglutaminase IgA and Antigliadin IgA/IgG tests for celiac disease, as well as food sensitivity panels such as the Food Intolerance 14G test. The company has also expanded its gastrointestinal testing portfolio with products targeting Helicobacter pylori infection, including hp+detect and Fortel Ulcer tests, supporting both clinical and point-of-care applications.

Biomerica markets diagnostic offerings such as the InFoods IBS test, a laboratory-developed test designed to identify patient-specific food triggers associated with irritable bowel syndrome, enabling more targeted dietary management. The company has expanded this platform with the introduction of an AI-enabled dietary management tool that provides personalized guidance, meal planning, and food substitution recommendations to improve patient adherence and outcomes. Clinical validation studies and real-world data continue to support the effectiveness of the InFoods approach, and recent reimbursement developments are expected to support broader clinical adoption. The company continues to advance this

platform with additional InFoods-based applications focused on personalized nutrition and gastrointestinal health.

Geographically, Biomerica has expanded its distribution footprint through international partnerships. Agreements in regions such as China and the Middle East support broader access to its colorectal cancer screening and breast self-examination products, while recent commercialization collaborations, including partnerships to expand physician adoption in the United States, are expected to further drive uptake of its diagnostic solutions.

Bio-Techne Corporation

Minneapolis, MN

www.bio-techne.com

Bio-Techne is a developer and manufacturer of bioactive tools and diagnostic solutions for research, clinical, and biopharmaceutical applications. With more than four decades of experience, the company is a leading supplier of proteins, including cytokines and growth factors, antibodies, immunoassays, and small molecules used by biomedical researchers and clinical laboratories worldwide.

Bio-Techne has expanded its capabilities in cell and gene therapy by offering a comprehensive portfolio that includes GMP-grade cytokines, growth factors, media, and small molecules, as well as antibodies for cell characterization. The company has also provided enabling technologies such as Cloudz cell activation kits and automated immunoassay platforms like Ella, designed to streamline workflows, improve reproducibility, and support quality control in advanced therapy manufacturing. Recent additions include innovations in cell culture systems such as synthetic extracellular matrices designed to improve consistency and scalability in organoid and stem cell workflows, as well as GMP-ready cytokine packaging formats that support closed-system manufacturing environments.

The ProteinSimple-branded portfolio offered by Bio-Techne includes platforms such as Maurice and MauriceFlex, which support protein characterization through charge variant analysis and electrophoretic separation. Enhancements such as the CE-SDS PLUS system improve data consistency and analysis of complex biologics, while newer systems expand automation and increase throughput for protein analysis. The Ella platform continues to evolve with customizable cartridge options, enabling flexible, high-throughput immunoassays for research and bioprocessing applications.

Bio-Techne has also strengthened its position in molecular and spatial biology through its Advanced Cell Diagnostics RNAscope technology, which enables highly sensitive in situ hybridization for RNA detection. New assay formats and expanded probe menus support applications in oncology, gene therapy, and translational research. The company further expanded its spatial biology capabilities through the acquisition of Lunaphore, adding

automated multiplex tissue analysis and microfluidics-based imaging platforms and enabling integrated RNA and protein analysis workflows.

Strategic partnerships and collaborations play a key role in Bio-Techne's growth. The company has established relationships with organizations such as Thermo Fisher Scientific, Akoya Biosciences, and Spear Bio to expand distribution, enhance spatial biology workflows, and advance ultrasensitive immunoassay technologies. More recent collaborations include partnerships in AI-enabled protein engineering, expanded agreements in genetic sequencing technologies, and collaborations supporting biopharmaceutical standards and advanced therapeutic development.

Recent developments also include biomarker assay initiatives designed for point-of-care applications on existing immunoassay platforms, as well as the continued expansion of distribution agreements to broaden global reach. The company has also streamlined its portfolio through selective divestitures while retaining access to underlying technologies for future development.

Eurobio Scientific

Paris, France

www.eurobio-scientific.com

Eurobio Scientific is a Paris-based diagnostics group formed through the combination of Exonhit, InGen BioSciences, and Eurobio, creating a diversified provider of proprietary and distributed in vitro diagnostic products. The company operates across Europe, with an additional international presence, and has expanded through a series of acquisitions to build a broad portfolio spanning transplantation, infectious diseases, oncology, and specialty diagnostics.

Eurobio Scientific markets a mix of proprietary assays and distributed products. Its proprietary portfolio includes tests such as Tetanus Quick Stick for assessing tetanus immunity and BJI Inoplex for diagnosing bone and joint prosthetic infections. The company has also commercialized molecular diagnostics such as AlloMap in Europe under license for heart transplant monitoring, along with internally developed assays including thyroid cancer diagnostics designed to support clinical decision-making when cytology results are inconclusive.

The company has significantly expanded its molecular diagnostics capabilities, including mobile and decentralized testing solutions through agreements such as the commercialization of compact PCR-based systems designed for point-of-care and emergency use. Eurobio has also developed multiplex PCR assays under its Eurobioplex brand, including tests for respiratory viruses and emerging infectious diseases, supporting routine screening and variant detection. Additional developments include specialized assays such as fertility-related PCR tests targeting genetic markers associated with male infertility, as well as newer IVDR-compliant molecular assays that strengthen its regulatory and product positioning in Europe.

Eurobio Scientific has pursued an active acquisition strategy to strengthen its product portfolio and geographic reach. Key acquisitions include GenDx, which enhanced its HLA typing capabilities for transplantation compatibility, and multiple European distributors that expanded its commercial footprint across regions such as Benelux and Southern Europe.

More recent acquisitions, including companies and assets focused on molecular biology and oncology diagnostics, continue to broaden its capabilities and distribution network.

The company has also expanded its oncology diagnostics portfolio through agreements to distribute advanced biomarker tests, including genomic assays such as EndoPredict and Prolaris, as well as blood-based biomarkers for monitoring treatment response in cancer patients. These additions complement its growing presence in precision medicine and companion diagnostics. Eurobio Scientific has further strengthened this strategy by advancing companion diagnostic development through collaborations in immuno-oncology and precision medicine, including initiatives leveraging HLA-based technologies.

EUROIMMUN AG (Revvity)

Lübeck, Germany

www.euroimmun.com

A Revvity company, EUROIMMUN, founded in 1987, is a global developer and manufacturer of diagnostic reagents and systems, with subsidiaries across Europe, North America, Asia, and other regions. The company continues to operate under its established brand while benefiting from integration within Revvity's broader life sciences and diagnostics portfolio.

EUROIMMUN focuses on laboratory diagnostics for autoimmune diseases, infectious diseases, and allergy testing. Its technologies include indirect immunofluorescence, ELISA, chemiluminescence immunoassays, blot-based assays such as EUROLINE and EUROASSAY, and molecular diagnostic methods including PCR-based testing. The company is particularly known for its BIOCHIP technology, which enables miniaturized, standardized multiplex immunofluorescence testing by combining multiple substrates on a single slide. BIOCHIP mosaics enable the simultaneous detection of multiple antibodies, supporting efficient and comprehensive diagnostics for autoimmune and infectious diseases.

EUROIMMUN offers a broad menu of ELISA and immunoassay tests, as well as advanced blot systems that improve specificity and differentiation of antibodies that may be difficult to interpret using traditional immunofluorescence. Its platforms support both manual and automated workflows, including integration with digital microscopy systems such as EUROPattern for automated image acquisition and interpretation.

The company has continued to expand its product portfolio with molecular and specialty diagnostics. These include multiplex PCR assays such as EUROArray panels for infectious disease detection, as well as applications in oncology and women's health, including tests used alongside HPV screening to assess cancer risk. EUROIMMUN has also expanded into therapeutic drug monitoring with both ELISA- and chemiluminescence-based assays, and into genetic testing, including APOE genotyping.

EUROIMMUN has strengthened its automation strategy with the introduction of the IDS i20, a fully automated random-access immunoassay platform designed to support high-

throughput chemiluminescence testing across multiple diagnostic areas, including autoimmune, infectious disease, allergy, and endocrinology. In addition, the company continues to expand assay menus on platforms such as UNIQO, enabling broader autoimmune and specialty testing panels.

Recent developments also include continued additions to infectious disease testing, such as measles antibody detection assays, and expansion of molecular diagnostics through partnerships that increase access to PCR-based test kits across European markets.

EUROIMMUN remains an active and growing diagnostics provider within Revvity, continuing to develop and commercialize its own branded products while expanding its capabilities across immunology, molecular diagnostics, and automation-driven laboratory workflows.

INOVA Diagnostics, Inc.

San Diego, CA

www.inovadiagnostics.com

INOVA Diagnostics, part of Werfen, is a long-established provider of autoimmune diagnostic reagents and systems with nearly three decades of experience supporting clinical laboratories. The company focuses on assays for autoimmune diseases including anti-phospholipid syndrome, celiac disease, connective tissue disorders, gastrointestinal and liver diseases, rheumatoid arthritis, thyroid disorders, and vasculitis, and remains a key player in the global autoimmunity diagnostics market. Its portfolio includes QUANTA Lite ELISA assays, NOVA Lite IFA kits, NOVAGel systems, QUANTA Chek reference panels, and QUANTA Plex multiplexing reagents, which are run on BIO-FLASH chemiluminescent analyzers, NOVA View automated fluorescence microscopes, and QUANTA-Lyser processing systems. These platforms are integrated through QUANTA Link software, enabling automated workflow management across IFA, ELISA, and chemiluminescence testing and supporting improved standardization and laboratory efficiency.

The company expanded its chemiluminescent QUANTA Flash menu on BIO-FLASH, particularly in rheumatoid arthritis and connective tissue disease testing, including assays for CCP antibodies and rheumatoid factor isotypes, as well as additional markers supporting earlier and more comprehensive autoimmune disease detection. Its NOVA Lite DAPI ANA and dsDNA Crithidia luciliae assays are used for systemic lupus erythematosus testing, with ongoing emphasis on automation and digital image interpretation through NOVA View.

INOVA has been focusing on consolidation of autoimmune testing onto fewer platforms, broader adoption of random-access chemiluminescence, and improved connectivity across laboratory networks. As part of Werfen, the business is also benefiting from greater global reach and alignment with Werfen's broader specialty diagnostics strategy, with continued investment in menu expansion, workflow automation, and integrated data management solutions.

VolitionRx Limited

Namur, Belgium

www.volitionrx.com

VolitionRx Limited, founded in 2010 and operating as Volition, is a diagnostics company focused on developing blood-based tests for cancer and other diseases using epigenetic biomarkers. The company's research and development activities are centered in Belgium, with additional international operations supporting its global commercialization strategy.

Volition's core technology platform, Nu.Q, is based on nucleosomics, which enables the detection and characterization of circulating nucleosomes in blood. These nucleosomes carry disease-specific signatures, including patterns of histone modifications, DNA methylation, and other structural changes, enabling differentiation between cancerous and non-cancerous conditions, as well as between different cancer types. The company's goal is to develop simple, noninvasive blood tests that can be used routinely for early detection, prognosis, and disease monitoring.

The Nu.Q platform has expanded into a range of applications, including oncology, inflammatory diseases, and veterinary diagnostics. In cancer diagnostics, Volition has advanced its Nu.Q cancer assays toward commercialization, with initial clinical adoption and use in specialized laboratories to support prognosis and treatment decision-making. The company continues to generate clinical data across multiple cancer types, including lung, colorectal, and ovarian cancers.

Volition has broadened the application of its Nu.Q NETs assays, which are designed to detect neutrophil extracellular trap formation associated with inflammation and immune response. These assays are being evaluated and implemented in additional clinical settings, including sepsis and chronic inflammatory conditions, reflecting expansion into non-oncology indications.

Strategic collaborations remain central to Volition's growth, including partnerships to support market entry in Asia, expansion of veterinary diagnostics, and use of Nu.Q assays in pharmaceutical clinical trials. The company is also participating in large-scale clinical and

real-world evaluation programs to demonstrate the clinical utility of its biomarkers for early disease detection.

Volition is transitioning from a development-stage company to early commercialization, expanding its nucleosomics platform across oncology, inflammation, and veterinary diagnostics while building partnerships to support global adoption and clinical integration.

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Chapter 23: Company Profiles: Microbiology Specialists

Scope

This section presents a selection of companies that have specialized in molecular and immunoassay-based pathogen detection (microbiology) tests and technologies. They have brought and continue to bring innovation to the segment. The profiles include events that have occurred in the past several years; they are not a comprehensive review or history of the companies selected to appear in the section and are listed alphabetically.

Advanced Biological Laboratories, S.A. (ABL)

Luxembourg

www.ablsa.com

Advanced Biological Laboratories (ABL) is a biotechnology company founded in 2000 as a spin-off from CRP-Santé in Luxembourg. The company was further shaped through the merger with TherapyEdge, a clinical decision-support software company originally spun out of Triangle Pharmaceuticals, creating a combined organization focused on molecular diagnostics and bioinformatics-driven healthcare solutions.

ABL specializes in infectious disease diagnostics and clinical decision support, particularly in virology. The company integrates molecular testing with advanced data analysis tools to support personalized treatment decisions for chronic viral infections such as HIV and hepatitis. Its solutions combine sequencing technologies, proprietary databases, and interpretation software to deliver clinically actionable insights.

A main component of ABL's portfolio is the ViroScore Suite, part of the TherapyEdge platform, which provides genotype interpretation, sequence analysis, and reporting tools for viruses including HIV. The platform leverages curated genetic databases and advanced algorithms to support viral subtyping, resistance interpretation, and treatment guidance.

ABL has expanded its capabilities with the DeepChek platform, a next-generation sequencing-based solution designed to manage, analyze, and interpret high-throughput sequencing data. DeepChek supports multiple viral applications, including HIV, HBV, HCV, CMV, HSV, and tuberculosis, enabling laboratories to generate clinically relevant genotyping and drug-resistance reports for personalized patient management. The platform continues to evolve, with expanded workflows and integration of advanced library preparation technologies to improve scalability and reduce turnaround time.

In addition to its sequencing-based solutions, ABL has introduced syndromic molecular diagnostics through its UltraGene portfolio of multiplex qPCR panels. These panels support the detection of a wide range of infectious diseases, including respiratory, neurological, gastrointestinal, and urogenital infections, enabling rapid and comprehensive pathogen identification in clinical settings.

ABL continues to expand globally through strategic collaborations and distribution agreements, including partnerships to support the commercialization of its molecular diagnostics platforms in Asia and the integration of new sequencing and bioinformatics technologies. The company has also extended its capabilities into oncology and viral genomics through licensing and research collaborations, further broadening its application areas.

altona Diagnostics

Hamburg, Germany

www.altona-diagnostics.com

altona Diagnostics GmbH is a Hamburg-based molecular diagnostics company founded in 2007 (originally as astra Diagnostics) and rebranded as altona Diagnostics in 2011. The company specializes in the development and commercialization of real-time PCR–based assays for the detection of infectious diseases, with a strong focus on emerging pathogens and rapid response to outbreak situations.

altona Diagnostics offers a broad portfolio of CE-marked real-time PCR assays under its RealStar, AltoStar, and FlexStar product lines. These assays cover a wide spectrum of infectious diseases, including respiratory pathogens, gastrointestinal infections, blood-borne viruses, tropical diseases, and opportunistic infections such as herpesviruses and polyomaviruses. The company is also known for its Fever, Tropical, and Emerging (FTE) panel, which includes assays for pathogens such as dengue, chikungunya, and Zika virus, supporting testing in regions affected by endemic and emerging infectious diseases.

The RealStar product line is a cornerstone of the portfolio, offering highly specific PCR kits for individual pathogens, including malaria, yellow fever, orthopoxviruses, and a wide range of viral and bacterial targets. The company has demonstrated agility in responding to emerging threats, developing assays for pathogens such as SARS-CoV-2, monkeypox virus, and other outbreak-related organisms.

altona has expanded its offerings with the FlexStar platform, which provides multiplex PCR detection mixes for simultaneous identification and differentiation of multiple pathogens, including respiratory viruses, gastrointestinal infections, and co-infections such as SARS-CoV-2 and influenza. The AltoStar platform offers automated, high-throughput molecular diagnostics workflows that integrate nucleic acid extraction and PCR testing for routine laboratory use, reflecting the company's strategic focus on laboratory automation.

In addition to assay development, altona provides workflow solutions, including nucleic acid extraction kits such as the ExtraStar Purification Kit, designed for automated systems and

optimized compatibility with its PCR assays. The company continues to expand its automation capabilities to support higher throughput and standardized laboratory workflows.

Recent product developments include expanded assay menus across the AltoStar and FlexStar platforms, including new IVDR-compliant assays targeting parvovirus B19, hepatitis D virus, and Treponema pallidum, as well as multiplex panels for gastrointestinal pathogens and tropical diseases, including triplex detection of chikungunya, dengue, and Zika viruses. These developments reflect an ongoing transition toward IVDR-compliant products, expansion of multiplex testing capabilities, and continued emphasis on automated molecular diagnostic workflows.

ArcDia International Oy Ltd.

Turku, Finland

www.arcdia.com

ArcDia International Ltd is a Finland-based diagnostics company focused on developing and commercializing rapid, multianalyte point-of-care testing solutions for infectious diseases. The company remains active and operating as of 2026, continuing to expand its mariPOC platform and proprietary ArcDia TPX detection technology.

ArcDia's core product is the mariPOC system, a fully automated point-of-care immunoassay platform designed for the rapid detection of respiratory and other infectious diseases. The system delivers results in approximately 20 minutes and is intended for near-patient settings such as clinics and emergency departments, enabling faster clinical decision-making and reducing the need for follow-up visits. The mariPOC test menu includes a broad panel of viral and bacterial pathogens associated with acute respiratory infections, as well as selected applications in gastrointestinal infections and tonsillitis.

The mariPOC platform is based on ArcDia's proprietary two-photon excitation fluorescence detection technology, which enables separation-free immunoassay analysis from small sample volumes. The system utilizes microparticle-based immunocomplex formation and optical detection to differentiate bound and unbound components, supporting high sensitivity and specificity without the need for traditional washing steps. This approach enables automated, walk-away testing with multiplexing capabilities.

ArcDia has expanded the mariPOC system beyond the core analyzer to include integrated solutions such as syndromic respiratory panels, real-time epidemiological data platforms, and research-use tools for antimicrobial susceptibility testing. These additions offer broader clinical utility, including surveillance and infection management, and reflect a shift toward integrated diagnostic ecosystems.

Since its initial launch, the mariPOC platform has expanded its geographic reach across Europe, the Middle East, and Asia through a network of distributors and partnerships. The company continues to strengthen its commercial footprint through healthcare collaborations, including recent agreements supporting the deployment of mariPOC systems in clinical

networks. ArcDia has also pursued international expansion strategies, including licensing and localization agreements to support production and commercialization in key markets such as China.

Recent developments include continued enhancement of the mariPOC test menu and performance, particularly in respiratory diagnostics, as well as improvements in rapid antigen-based testing to better identify active infectious phases of disease. The company has also introduced advanced combination testing approaches for respiratory pathogens, including SARS-CoV-2, to support real-time clinical decision-making.

COPAN ITALIA S.p.A. and COPAN Diagnostics, Inc.

Brescia, Italy and Murrieta, CA

www.copangroup.com and www.copanusa.com

COPAN Italia S.p.A., founded in 1979, is a global leader in microbiology sample collection, transport, and laboratory automation. Originally established as a distributor of laboratory products, the company quickly transitioned into manufacturing and became a pioneer in pre-analytical solutions. COPAN operates worldwide through subsidiaries, including COPAN Diagnostics, Inc., which supports commercialization across the Americas.

COPAN is widely recognized for its innovations in specimen collection and transport, including the development of FLOQSwabs, ESwab liquid-based microbiology collection systems, and Universal Transport Medium. These products are designed to improve sample quality, recovery, and compatibility with both culture-based and molecular diagnostic methods. FLOQSwabs, based on patented flocking technology, enhance sample uptake and release, enabling improved detection sensitivity for infectious disease testing.

The company has expanded its portfolio beyond collection systems into laboratory automation, particularly in microbiology workflows. Key platforms include the WASP (Walk-Away Specimen Processor) and WASPLab, which automate specimen inoculation, incubation, imaging, and analysis. These systems are designed to streamline laboratory operations, improve standardization, and reduce manual workload. COPAN also offers a broad range of consumables, including microbial sampling devices, inoculation loops, and pipettes.

COPAN continues to innovate in pre-analytics and automation, with products such as FecalSwab, a Cary-Blair–based stool collection and preservation system optimized for molecular and culture-based testing. The company has also advanced automation capabilities with systems such as Colibri, an automated pre-analytic processor that prepares samples for identification and antimicrobial susceptibility testing workflows, including integration with MALDI-TOF mass spectrometry systems. Software solutions such as PhenoMATRIX further enhance automation by enabling intelligent colony selection and workflow optimization.

Recent developments include expanded automation solutions across the laboratory workflow. These include systems for automated handling and tracking of positive blood cultures, platforms for automated urine specimen processing, and AI-driven digital microbiology tools that support image analysis and colony classification. The company has also extended its automation capabilities into pharmaceutical microbiology applications and continues to invest in manufacturing expansion to support growing global demand.

Genetic Analysis AS

Oslo, Norway

www.genetic-analysis.com

Genetic Analysis AS is a privately held molecular diagnostics company focused on analyzing microbial imbalances in the gastrointestinal tract. The company develops DNA-based diagnostic solutions using its proprietary GA-map platform, which profiles gut microbiota composition and supports the identification of dysbiosis associated with gastrointestinal disorders, including irritable bowel syndrome and inflammatory bowel disease.

The GA-map Dysbiosis Test is the company's flagship product, offering CE-marked microbiome analysis for clinical use. The test is based on targeted DNA detection and provides a standardized profile of bacterial composition in stool samples, enabling clinicians to assess microbial imbalance and support diagnosis and treatment decisions. The platform is compatible with multiplex systems such as the Luminex MAGPIX instrument, allowing simultaneous detection of multiple bacterial targets in a single assay.

Genetic Analysis is expanding the clinical and commercial reach of its microbiome diagnostics through international regulatory approvals and distribution partnerships. The GA-map Dysbiosis Test has gained regulatory clearance in additional markets, including Asia, and is being commercialized through regional partnerships in areas such as Southeast Asia, India, and parts of Europe. These agreements support broader adoption of microbiome testing in both clinical and research settings.

The company has also pursued strategic collaborations to extend its technology into new applications. Partnerships with industry and research organizations are focused on developing microbiome-based diagnostics and potential therapeutic solutions, as well as integrating microbiome testing into digital health platforms. These initiatives reflect a growing emphasis on combining diagnostic data with digital tools to support personalized healthcare.

Recent product developments include expanding the GA-map platform with new solutions, such as AI-assisted interpretation tools that translate microbiome data into clinically actionable insights, and additional microbiome assays that provide standardized health

indices for gut microbiota assessment. The company is also advancing next-generation diagnostics for inflammatory bowel disease, designed to support prediction of disease progression and enable more personalized treatment strategies.

More recent developments include expansion into direct-to-consumer testing markets, with adapted versions of the GA-map Dysbiosis Test introduced through regional partners to increase accessibility of microbiome analysis. These offerings are tailored to local markets while maintaining the underlying GA-map technology platform.

Q-linea AB

Uppsala, Sweden

https://qlinea.com

Q-linea AB is a Sweden-based diagnostics company founded in 2008 that develops rapid antimicrobial susceptibility testing (AST) solutions to improve the management of infectious diseases, particularly sepsis. The company focuses on accelerating the identification of effective antibiotic treatments by providing phenotypic AST results faster than conventional laboratory methods.

Q-linea's primary platform is the ASTar system, a fully automated instrument that performs antibiotic susceptibility testing directly from positive blood cultures. The system delivers minimum inhibitory concentration (MIC) results within approximately six hours, significantly reducing the time required compared to traditional culture-based workflows. ASTar supports random access loading and utilizes comprehensive antibiotic panels covering a broad range of clinically relevant pathogens, including expanded panels for gram-negative bacteria with a large number of antibiotic-pathogen combinations. Following regulatory clearance, the company has begun commercialization of ASTar in key markets, including the United States, with early clinical adoption in hospital laboratories.

The company is also developing the ASTrID platform, which is designed to combine rapid pathogen identification and susceptibility testing directly from whole blood samples. ASTrID utilizes padlock probe technology and circle-to-circle amplification to enable highly multiplexed detection of pathogens and resistance markers. While ASTrID remains in development, the company has shifted its strategic focus toward commercialization of the ASTar platform, with ASTrID positioned as a longer-term innovation.

Q-linea has streamlined its operations to facilitate this commercial transition, focusing resources on expanding ASTar adoption, enhancing test menus, and improving operational efficiency. The company continues to update and expand its antibiotic panels to increase clinical utility, including broader pathogen coverage and resistance profiling.

The company has expanded its international footprint through distribution agreements in Europe and partnerships supporting market entry in regions such as the Middle East, while continuing to build its presence in the U.S. diagnostics market.

Chapter 24: Company Profiles: Molecular Test Specialists

Scope

In this section, Kalorama has selected a group of companies that have demonstrated longevity, market penetration, and/or contributed important innovation in molecular IVD. The profiles include events that have occurred in the past several years; they are not a comprehensive review or history of the companies selected to appear in the section and are listed alphabetically.

Pacific Biosciences of California, Inc. (PacBio)

Menlo Park, CA

www.pacb.com

Pacific Biosciences of California, Inc. (PacBio) is a leading developer of advanced DNA sequencing technologies, with a focus on long-read sequencing. The company's core platform is based on Single Molecule, Real-Time (SMRT) sequencing, which enables highly accurate, long-read analysis of complex genomes, structural variants, and epigenetic modifications. PacBio's technology is widely used in applications such as de novo genome assembly, rare disease research, oncology, and population genomics.

PacBio's product portfolio has evolved significantly beyond earlier systems such as the RS II. The company now focuses its offerings on high-throughput, high-accuracy sequencing platforms, including the Sequel II and Sequel IIe systems, which utilize SMRT Cell 8M technology to deliver substantially higher data output and improved cost efficiency. These systems offer HiFi sequencing, which combines long read lengths with high accuracy, enabling more comprehensive genomic analysis.

The company has expanded its platform lineup with the introduction of the Revio system, a high-throughput long-read sequencing platform designed for large-scale genomic studies, and the Vega system, a benchtop long-read sequencer that extends SMRT sequencing to smaller laboratories and decentralized settings. These platforms have been further enhanced with advanced sequencing chemistries that significantly reduce the cost of whole genome sequencing while improving throughput and performance.

PacBio has also advanced its technology with new sequencing chemistries and workflows that enable integrated multiomic analysis, allowing simultaneous assessment of genomic variation and epigenetic features such as DNA modifications and chromatin structure. These developments strengthen the utility of SMRT sequencing in both research and emerging clinical applications.

The company has increasingly focused its strategy on long-read sequencing, streamlining its portfolio to prioritize HiFi sequencing technologies while continuing to expand its applications in clinical genomics, rare disease research, and population-scale sequencing

projects. Enhancements to platforms such as Revio and Vega have improved scalability, speed, and cost efficiency, supporting broader adoption across research and clinical environments.

PacBio continues to expand its global presence through strategic collaborations and partnerships, including initiatives that support rare disease research, large-scale genomic data generation, and AI-driven metagenomics, as well as collaborations aimed at enhancing sequencing workflows and enabling advanced multi-omic analysis. These partnerships strengthen its role in both research and clinical genomics systems.

Standard BioTools

S. San Francisco, CA

www.standardbio.com

Standard BioTools Inc. develops, manufactures, and markets analytical and preparatory systems for applications in single-cell biology, genomics, and proteomics. The company's platforms are based on proprietary microfluidics and mass cytometry technologies, designed to simplify workflows, increase throughput, and deliver high-quality, high-dimensional biological data.

Standard BioTools' technology includes integrated fluidic circuits (IFCs), which precisely control nanoliter-scale fluid movement and enable highly multiplexed reactions. A foundational product is the BioMark real-time PCR system, which supports high-throughput genetic analysis using dynamic array technology, enabling thousands of reactions to be performed simultaneously with reduced reagent consumption and improved efficiency. The system is widely used for gene expression analysis, genotyping, and the detection of rare mutations.

The company's portfolio also includes advanced solutions for single-cell and multiomic analysis. Platforms such as the C1 system support detailed cellular characterization, including applications that combine RNA and protein analysis within individual cells. Additional technologies enable highly multiplexed targeted sequencing and genomic profiling for research applications, including oncology.

Standard BioTools is a leader in mass cytometry through its CyTOF and Imaging Mass Cytometry platforms, which allow high-dimensional analysis of proteins at the single-cell level. Systems such as Hyperion enable visualization and quantification of dozens of biomarkers simultaneously, supporting research in immunology, oncology, and drug development. The company has expanded these capabilities with next-generation imaging systems that improve speed, throughput, and reproducibility for large-scale and multi-site studies. The company offers next-generation mass cytometry systems with enhanced throughput and automation, further strengthening its position in high-dimensional single-cell and spatial biology research.

The company continues to enhance its product portfolio with high-throughput PCR systems, including advanced instruments capable of performing thousands of nanoliter-scale reactions per run, as well as expanded software and reagent solutions to support data analysis and workflow integration. It also offers comprehensive immune profiling solutions that enable standardized, reproducible analysis of immune cell populations across different sample types. Increasingly, the company is incorporating advanced data analytics and artificial intelligence approaches to support biomarker discovery and interpretation of complex multiomic datasets.

Recent strategic developments include a shift in business focus, with the company divesting its SomaLogic proteomics business, including the SomaScan platform, to Illumina, Inc. in 2025. This move reflects a strategic decision to concentrate on its core strengths in genomics, single-cell analysis, and mass cytometry, while streamlining operations and improving focus on high-growth research markets.

Chapter 25: Company Profiles: Point of Care Test Specialists

Scope

This section presents a selection of companies that specialize in point-of-care (POC) testing. This is not a comprehensive review or history of the companies selected to appear in the section and is listed alphabetically.

Abingdon Health Ltd.

York, England, UK

www.abingdonhealth.com

Abingdon Health plc is a medical diagnostics company focused on the development, manufacture, and commercialization of point-of-care lateral flow immunoassays. The company specializes in rapid diagnostic technologies for a range of applications, including infectious diseases, women's health, and other conditions requiring decentralized testing. While earlier efforts included work in areas such as hematology and oncology, the company's primary focus has evolved toward infectious disease, consumer diagnostics, and contract development and manufacturing services.

Abingdon Health offers proprietary lateral flow technologies, including nucleic acid lateral flow immunoassays such as PCRD and PCRD FLEX. These products provide a rapid and user-friendly alternative to traditional molecular detection methods, enabling visualization of amplified DNA products without the need for gel electrophoresis. The company's platforms are designed for ease of use in both laboratory and near-patient settings.

The company has established multiple collaborations to expand its test development and manufacturing capabilities. Partnerships with organizations such as Vatic Health and other developers have supported the creation of rapid tests for infectious diseases, including influenza and other viral pathogens. Abingdon has also positioned itself as a contract development and manufacturing organization providing lateral flow assay development, manufacturing, and regulatory support services to third-party partners.

Abingdon Health has expanded its commercial activities in consumer diagnostics through distribution agreements, including the launch of saliva-based pregnancy testing products in European markets. These products reflect the company's growing presence in over-the-counter and home-testing segments.

Recent developments include the expansion of manufacturing capacity with a new facility in the United States, strengthening its ability to serve international customers and scale production. The company has also entered into agreements to support regulatory submissions

for multiple self-tests targeting infectious diseases such as HIV, hepatitis B, hepatitis C, and syphilis, reflecting a continued push into regulated consumer and clinical markets.

In addition, Abingdon Health has expanded its capabilities with digital tools for test interpretation, including smartphone-based reader applications, and has initiated development of more sustainable lateral flow devices using alternative materials. The company is also advancing a broader pipeline of multiplex and duplex lateral flow assays across infectious disease, pharmaceutical, and veterinary applications. These developments, combined with strong growth in CDMO contracts and expanding U.S. operations, highlight a strategic shift toward integrated diagnostic services and scalable manufacturing.

binx Health

Trowbridge, UK

www.mybinxhealth.com

binx health, formerly Atlas Genetics, is a molecular diagnostics company focused on expanding access to rapid, point-of-care testing for sexually transmitted infections, particularly chlamydia and gonorrhea. The company's main platform, the binx io, is an FDA-cleared and CLIA-waived molecular system designed to deliver laboratory-quality PCR results in approximately 30 minutes, enabling true "test-and-treat" care in a single patient visit. The system offers both male urine and female vaginal swab samples and is positioned for use across decentralized healthcare settings including urgent care centers, public health clinics, and retail-based care environments.

The binx io platform utilizes a proprietary electrochemical detection method and a cartridge-based design capable of multiplex testing, supporting future menu expansion to include additional infectious disease targets such as HSV, HPV, Group A and Group B Streptococcus, and other high-impact conditions. While these expanded assays remain in development, the platform's architecture supports broader applications, including infectious disease panels and potential companion diagnostics aligned with personalized medicine strategies.

Recent developments highlight the company's continued commercial and clinical momentum. binx Health has expanded national distribution through partnerships such as Cardinal Health and additional regional distributors, supporting wider adoption of its CLIA-waived platform across the United States. The company also secured significant growth financing to accelerate commercialization and instrument placement. Clinical data released in 2025 demonstrated that the use of binx io significantly improves antibiotic stewardship, reducing inappropriate treatment rates by more than half and reinforcing its value in addressing antimicrobial resistance and improving patient outcomes.

Strategically, binx health has streamlined its operations to focus on its core diagnostics platform following the divestiture of its consumer testing business. The company continues to advance decentralized care models through programs that combine on-site rapid testing with at-home sample-collection initiatives, improving access to screening and treatment for

underserved populations. As of 2026, binx health remains focused on expanding its installed base, advancing its test menu pipeline, and strengthening its position in the growing market for rapid molecular point-of-care diagnostics in sexual health and beyond.

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Chembio Diagnostic Systems, Inc.

Medford, NY

www.chembio.com

Chembio Diagnostics, now part of Biosynex, develops and commercializes rapid diagnostic tests for infectious diseases, with a strong emphasis on point-of-care and decentralized testing markets. The company has established a strong presence in global HIV screening, with its rapid tests incorporated into national testing programs across Africa, Asia, and Latin America, supporting large-scale public health initiatives focused on early detection and treatment. These efforts remain aligned with ongoing international programs addressing HIV/AIDS and other infectious diseases in resource-limited settings.

Chembio's proprietary Dual Path Platform (DPP) technology continues to lead its product portfolio, offering a dual-membrane design that separates sample and reagent flow to improve assay performance, sensitivity, and specificity compared to traditional lateral flow tests. The platform also offers multiplexing capabilities, enabling the detection of multiple analytes from a single sample and supporting a development pipeline spanning HIV, syphilis, hepatitis C, and a range of tropical and neglected diseases affecting both human and animal health.

Since its acquisition by Biosynex in 2023, Chembio has been integrated into a broader global diagnostics network, enabling expanded commercialization and distribution, particularly in Europe and emerging markets. The company's strategy has shifted toward scaling its existing product portfolio while leveraging Biosynex's manufacturing and market access capabilities to increase penetration in decentralized and public health testing environments.

Recent developments highlight a growing emphasis on self-testing and consumer-access diagnostics. The SureCheck HIV Self-Test, a rapid immunochromatographic assay designed to detect antibodies to HIV-1 and HIV-2, has received Breakthrough Device designation and is being positioned for expanded use in at-home and community-based screening programs. This reflects a broader industry trend toward empowering patients through accessible diagnostic solutions and supporting earlier detection outside of traditional clinical settings.

As of 2026, Chembio's direction focuses on expanding access to rapid infectious disease diagnostics through decentralized care models, advancing its multiplex DPP pipeline, and strengthening its role in global health initiatives, with particular emphasis on HIV and sexually transmitted infection testing in underserved populations.

Co-Diagnostics, Inc.

Salt Lake City, UT

www.codiagnostics.com

Co-Diagnostics is a Utah-based molecular diagnostics company focused on the development, manufacture, and commercialization of PCR-based reagents and testing systems for decentralized, point-of-care, and at-home use. Following the sharp decline in COVID-19 testing demand, the company has shifted its strategy toward expanding its broader infectious disease menu and advancing its Co-Dx PCR platform. The Co-Dx PCR Pro instrument, along with a companion at-home system, remains under regulatory review and is not yet commercially available as of 2026. The company has made progress toward regulatory clearance by initiating clinical evaluations of a multiplex respiratory assay capable of detecting influenza A and B, COVID-19, and RSV from a single test, positioning the platform within the growing syndromic testing segment.

Beyond respiratory testing, Co-Diagnostics continues to expand its pipeline with assays targeting tuberculosis, HPV, and other infectious diseases, with development and validation efforts supported in part through its CoSara joint venture in India. CoSara plays an important role in advancing TB and HPV programs, reflecting India's high burden of infectious diseases and increasing emphasis on accessible molecular diagnostics. In addition, Co-Diagnostics is investing in workflow improvements, including the development of a proprietary sample preparation system designed to simplify point-of-care PCR testing. The company has also begun integrating artificial intelligence into its assay design and platform functionality to improve performance and reduce operator variability.

Internationally, Co-Diagnostics is expanding its footprint through partnerships and joint ventures, including efforts to localize manufacturing and distribution in regions such as the Middle East, while continuing to strengthen its intellectual property position with new patents covering its PCR platform.

Genedrive plc (formerly Epistem Holdings)

Manchester, UK

www.Genedrive.com

Founded in 2000 as Epistem Holdings, genedrive plc has evolved into a focused molecular diagnostics company centered on rapid, point-of-care genetic testing. While the company initially operated across contract research, pharmacogenomics services, and therapeutic development, its strategy has shifted toward commercialization of its proprietary Genedrive platform and a targeted menu of clinically actionable assays.

The Genedrive system is a portable, rapid molecular diagnostic platform designed to deliver PCR-based genetic results in decentralized and near-patient settings. The device is engineered for ease of use, low cost, and fast turnaround times, typically providing results in under an hour. It offers high-sensitivity DNA analysis for applications including infectious disease detection, antimicrobial resistance, and pharmacogenomics, with a particular emphasis on enabling immediate clinical decision-making in acute care environments.

A focus for the company is the MT-RNR1 ID Kit, a rapid point-of-care genetic test designed to identify neonates carrying a mitochondrial variant associated with aminoglycoside-induced hearing loss. This test enables clinicians to avoid administering certain antibiotics to at-risk infants, preventing irreversible hearing damage. The assay has gained significant regulatory and clinical momentum, including positive recommendations from UK health authorities and Breakthrough Device designation in the United States. More recently, the MT-RNR1 test has transitioned into real-world clinical use, with increasing adoption across UK hospitals and expansion into broader neonatal screening programs, reflecting a shift from early innovation to routine clinical implementation.

In addition, genedrive has expanded its presence in pharmacogenomics with the CYP2C19 ID Kit, which detects key genetic variants that influence patient response to clopidogrel. This test supports personalized treatment strategies in cardiovascular care and has received regulatory approval under the European IVDR. The company is actively supporting national rollout efforts, particularly within the UK healthcare system, while generating real-world evidence to demonstrate clinical utility and economic value. At the same time, genedrive

continues to pursue U.S. regulatory clearance for its MT-RNR1 test through the FDA De Novo pathway.

MedMira, Inc.

Halifax, Nova Scotia, Canada

www.medmira.com

Established in 1993, MedMira is a biotechnology company based in Nova Scotia, Canada, focused on developing and commercializing rapid diagnostic tests for infectious diseases. The company specializes in point-of-care and decentralized testing solutions using its proprietary Rapid Vertical Flow (RVF) technology platform, which delivers results in approximately three minutes and provides a fast, portable alternative to conventional laboratory-based diagnostics.

MedMira's product portfolio features rapid HIV and sexually transmitted infection testing, anchored by its Reveal family of assays, including the Reveal G4 Rapid HIV-1/2 Antibody Test, which has expanded regulatory clearances and supports use in decentralized clinical settings. The company has continued to strengthen its STI offering by adding rapid syphilis diagnostics, including the Reveal TP test, as well as multiplex assays under the Multiplo brand. The Multiplo TP/HIV test, which detects both HIV-1/2 and syphilis antibodies from a single sample, has been commercialized in Canada and other markets, reflecting growing demand for combined STI screening solutions. MedMira is also advancing next-generation multiplex assays, including tests designed to differentiate active from past syphilis infection, further enhancing clinical utility.

The company previously expanded its U.S. commercial presence through distribution relationships with major partners such as Cardinal Health and VWR; however, these arrangements have since been discontinued. MedMira has since shifted toward new distribution and market access strategies, including partnerships that expand reach across large healthcare provider networks and government channels, strengthening its presence in North America.

MedMira continues to advance its HIV testing franchise, with the Reveal G4 assay receiving additional regulatory recognition, including expanded claims and approval for point-of-care use in Canada. MedMira has regulatory clearance for its rapid HIV testing products in the United States; however, adoption remains limited due to the current classification of its assays as moderate-complexity tests. The company is pursuing CLIA-waived status, which

is expected to significantly expand access across decentralized care settings such as clinics, pharmacies, and community screening programs.

In addition to its current product line, MedMira is developing a next-generation quantitative rapid testing platform, MiRO Q, which is designed to extend the capabilities of RVF technology beyond qualitative results to include quantitative measurement and advanced data analysis. This platform is expected to support future applications in areas such as oncology and disease monitoring, incorporating digital and AI-enabled features to enhance clinical decision-making.

Chapter 26: Company Profiles: Prenatal Test Service Providers

Scope

In this section, Kalorama has selected a group of companies that provide prenatal tests. These companies represent a variety of molecular technologies and products used in prenatal and neonatal (newborn) testing. This is not a comprehensive review or history of the companies selected to appear in the section and is listed alphabetically.

Berry Genomics Co. ltd.

Beijing, China

www.berrygenomics

Founded in 2010, Berry Genomics is a China-based molecular diagnostics company focused on applying advanced sequencing technologies to clinical genetic testing and reproductive health. The company provides both clinical testing services and sequencing solutions and has established a broad network of hospital partnerships across China, supporting large-scale adoption of genomic testing in prenatal and clinical settings.

Berry Genomics is a leading provider of non-invasive prenatal testing (NIPT) in China, with its Bambni test serving as a core offering. The test analyzes circulating fetal DNA from maternal plasma to detect common chromosomal abnormalities, including trisomy 21, trisomy 18, and trisomy 13, and has been expanded to include additional chromosomal aneuploidies and microdeletions. The company also offers complementary reproductive health diagnostics, including Xromate for detecting chromosomal abnormalities, ChroSure for preimplantation genetic testing, and extended carrier screening panels tailored to population-specific genetic risks.

Berry Genomics has expanded into broader clinical genomics through the development of proprietary sequencing platforms and advanced diagnostic assays. The company has introduced sequencing systems, such as the NextSeq CN500, to support high-throughput clinical genetic testing and reduce reliance on imported technologies, enabling applications in prenatal screening and genetic disease diagnostics.

Berry Genomics has advanced into third-generation sequencing technologies by introducing long-read sequencing systems clinically, marking a significant expansion beyond traditional short-read NGS. This platform enables more comprehensive detection of complex genetic variations, including structural variants, repeat expansions, and copy number variations, and supports new clinical applications in rare and inherited diseases. Initial assay offerings include thalassemia testing, with planned expansion into additional conditions such as Fragile X syndrome, spinal muscular atrophy, Duchenne muscular dystrophy, and other single-gene disorders.

The company continues to strengthen its clinical portfolio with regulatory approvals for advanced genomic assays, including CNV-seq detection kits for identifying chromosomal abnormalities in high-risk pregnancies. At the same time, Berry Genomics is integrating bioinformatics and AI-driven analysis tools to support the interpretation of large-scale genomic data and improve clinical reporting workflows.

As of 2026, Berry Genomics is transitioning from a primarily NIPT-focused provider to a broader clinical genomics company, with expanding capabilities across reproductive health, rare disease diagnostics, oncology, and precision medicine.

INEX Innovate

Singapore

www.inex.sg

Innovations Exchange Pte Ltd (INEX), a spinoff from the National University of Singapore established in 2006, has evolved into a women's health-focused diagnostics company operating under INEX Innovate. The company is engaged in the research, development, commercialization, and licensing of technologies targeting maternal and fetal health, with a growing portfolio spanning reproductive health, oncology, and prenatal diagnostics.

INEX's prenatal offering is the iGene platform, a non-invasive prenatal testing solution that analyzes circulating fetal DNA using next-generation sequencing and proprietary bioinformatics. Initially developed to detect common chromosomal abnormalities, including trisomy 21, trisomy 18, and trisomy 13, the test has been expanded to include sex chromosome aneuploidies such as Turner syndrome, Klinefelter syndrome, Triple X, and XYY. The platform is supported by centralized laboratory testing infrastructure in Singapore and serves multiple markets across Asia Pacific, with continued efforts to improve workflow efficiency and broaden clinical adoption.

The company also offers FlashFISH, a rapid cytogenetic diagnostic solution based on modified fluorescence in situ hybridization technology that delivers results within hours following amniocentesis. FlashFISH enables the detection of major chromosomal abnormalities and provides a faster alternative to conventional karyotyping in high-risk pregnancies. The technology, originally developed at the National University of Singapore, is exclusively licensed to INEX and remains a differentiated offering in rapid prenatal diagnostics.

INEX has expanded its portfolio through licensing and technology partnerships, including collaborations focused on next-generation prenatal testing approaches such as circulating fetal cell analysis and semi-automated systems. The company's evolution accelerated following its merger with Nova Satra, which formed INEX Innovate and established a FemTech platform with a broad intellectual property base and a commercial presence across Asia Pacific markets.

Recent product development has significantly broadened the company's scope beyond prenatal screening into women's health and oncology diagnostics. The OvaCis Rapid Test is a point-of-care assay designed to differentiate between benign and malignant ovarian cysts, delivering rapid results to support intraoperative and clinical decision-making. Adoption of OvaCis has expanded across surgical and gynecologic workflows, with increasing use as a rapid triage tool for ovarian masses in Asia Pacific markets. INEX has also introduced epiHera for early detection of endometrial cancer, reflecting its growing focus on gynecologic oncology and early disease detection.

The company has further advanced its genomic testing capabilities with the introduction of FetalExome, a whole-exome sequencing solution for high-risk pregnancies that enables more comprehensive analysis of genetic abnormalities beyond standard NIPT. Utilization of advanced genomic testing is increasing in specialist maternal-fetal medicine settings, providing more detailed diagnostic insights in complex pregnancies. In addition, INEX has expanded into pregnancy-related conditions by developing a preeclampsia test, further broadening its women's health portfolio.

As of 2026, the company is positioned as an integrated FemTech diagnostics provider, combining prenatal screening, rapid cytogenetics, oncology diagnostics, and advanced genomic testing, with continued geographic expansion and increasing emphasis on clinically actionable, decentralized diagnostic solutions.

Oxford Gene Technology

Oxfordshire, UK

www.ogt.com

Oxford Gene Technology (OGT), founded in 1995, is a molecular genetics company focused on providing genomic research and clinical diagnostic solutions to academic, clinical, and research institutions. Now operating as part of Sysmex Corporation following its acquisition in 2017, OGT plays a key role in expanding Sysmex's capabilities in cytogenetics, molecular diagnostics, and genomic analysis.

OGT offers a broad portfolio spanning next-generation sequencing panels, microarray-based cytogenetics solutions, fluorescence in situ hybridization probes, and genomic services. Its CytoSure array platform supports detection of copy number variations across a wide range of genetic disorders and is available in genome-wide, targeted, and custom configurations, along with associated software and reagents. The company also provides specialized arrays for applications such as preimplantation genetic testing, enabling screening of embryos for chromosomal abnormalities.

In cytogenetics, OGT's CytoCell FISH probes are widely used for hematology and oncology applications, supporting identification of chromosomal abnormalities in cancer and genetic disease. The company has received regulatory recognition for a range of FISH probes in hematologic testing and continues to expand its cytogenetics offering through integration with imaging and analysis solutions, enabling more automated and digitally enabled laboratory workflows.

OGT has continued to expand its NGS portfolio through the SureSeq product line, with a strong focus on oncology and hematologic malignancies. Recent developments include enhanced panels for myeloid disorders and measurable residual disease (MRD) detection in acute myeloid leukemia, as well as updated panels for chronic lymphocytic leukemia with expanded gene content, improved probe density, and greater sensitivity for copy number variation detection. These assays are increasingly positioned to support longitudinal disease monitoring and treatment response assessment, aligning with the growing clinical importance of MRD testing in precision oncology.

As part of Sysmex, OGT is increasingly integrated into a broader diagnostics system that combines cytogenetics, molecular testing, and hematology platforms to support more comprehensive, end-to-end diagnostic solutions. This integration enables improved workflow efficiency and supports the adoption of advanced genomic tools in routine clinical practice.

OGT's growth is driven by continued enhancements to its existing platforms rather than by new standalone technologies, with an emphasis on expanding its oncology test menu, advancing MRD applications, and supporting automated, high-throughput cytogenetics and sequencing workflows in clinical and research settings.

Yourgene Health

Manchester, UK

www.yourgene-health.com

Yourgene Health is a molecular diagnostics company focused on non-invasive prenatal testing, reproductive health, and broader genomic applications including oncology and early disease detection. In 2023, the company was acquired by Novacyt, strengthening Novacyt's capabilities in molecular diagnostics and expanding its presence in reproductive health and sequencing-based testing.

Yourgene Health originated from the merger of Premaitha Health and Yourgene Bioscience, combining NGS-based prenatal testing expertise with advanced bioinformatics capabilities, including a strong footprint in Asia through operations in Taiwan. This integration enabled the company to expand access to high-growth NIPT markets while supporting global commercialization and cross-selling opportunities.

The company's flagship product is the IONA NIPT workflow, which uses next-generation sequencing and proprietary bioinformatics to analyze circulating fetal DNA for the detection of chromosomal abnormalities, including trisomy 21, trisomy 18, and trisomy 13. The platform has been expanded with additional capabilities such as microdeletion screening through modular software enhancements, allowing laboratories to broaden their clinical menu. Building on this foundation, Yourgene has introduced IONA Care+, a service-based prenatal screening offering that combines laboratory testing, reporting, and support services, and is being expanded across the UK and selected international markets as part of a shift toward integrated genomic service delivery.

Yourgene has continued to strengthen its technology portfolio with flexible bioinformatics solutions, including the Yourgene Flex analysis platform, which enables customizable NGS data processing and reporting for reproductive health, oncology, and other clinical applications. The company has also expanded its laboratory workflow solutions with automated sample-preparation technologies, such as the MagBench DNA extraction system, positioning itself as a provider of end-to-end genomic workflows spanning sample preparation, sequencing, and data analysis.

The company's product portfolio also includes rapid aneuploidy testing solutions such as the QST*R assay, which is gaining adoption as a complementary tool to NIPT by providing faster diagnostic results in prenatal settings. This reflects a broader strategy to support both screening and diagnostic workflows within reproductive health.

Yourgene is increasingly integrated into Novacyt's global diagnostics platform, leveraging expanded distribution channels and cross-selling opportunities to accelerate international growth. The company continues to expand its presence in emerging markets across Latin America, the Middle East, and Africa, while also exploring direct-to-consumer and retail-based testing channels to broaden access.

Chapter 27: Company Profiles: Quality Control & Sample Pretreatment Specialists

Scope

In this section, Kalorama presents a selection of companies that have been simplifying the process of molecular sample preparation. In recent years, molecular assays across all diagnostic test segments, along with liquid biopsy testing, have increasingly moved from research to routine diagnostics. As a result, advanced sample treatment is required to ensure testing quality, while quality control materials help assure test validity. The profiles include events that have occurred in the past several years; they are not a comprehensive review or history of the companies selected to appear in the section and are listed alphabetically.

Agena Bioscience, Inc.

San Diego, CA

www.agenabio.com

Agena Bioscience is a molecular diagnostics company focused on targeted genetic analysis using mass spectrometry-based technologies and operates as part of Mesa Laboratories. Its core platform, the MassARRAY system, enables rapid, highly multiplexed detection of genetic variants and is widely used in research, translational, and increasingly clinical laboratory settings.

The MassARRAY platform uses mass spectrometry to deliver precise, scalable genotyping, allowing simultaneous interrogation of tens to hundreds of genetic targets. It is particularly suited for targeted mutation analysis, orthogonal validation of next-generation sequencing results, and applications requiring cost-effective, medium-throughput workflows. The system offers flexible assay design, though robust performance requires appropriate analytical validation and optimization.

Agena Bioscience provides a comprehensive portfolio of instruments, reagents, and pre-designed panels, along with custom assay development services. Its product range spans oncology, pharmacogenomics, infectious disease research, identity testing, and sample quality control. UltraSEEK chemistry supports highly sensitive detection of low-frequency variants, particularly in liquid biopsy applications, while iPLEX chemistries enable multiplex genotyping in both somatic and germline testing. Oncology panels target key mutations in cancers such as colorectal and lung, while broader panels support profiling of multiple oncogenic mutations and gene fusions.

The introduction of MassARRAY Dx PLUS assays has expanded the company's presence in regulated diagnostic testing, enabling laboratories to adopt validated assays for targeted mutation analysis. In pharmacogenomics, updated panels, such as newer versions of the VeriDose portfolio, provide expanded coverage of clinically relevant variants and support guideline-aligned drug-response testing. These advancements strengthen Agena's position in precision medicine and clinical research.

The company has also expanded its role in liquid biopsy through collaborations that integrate upstream sample-preparation technologies with MassARRAY detection, thereby improving sensitivity for low-frequency circulating tumor DNA variants. In addition, emerging data highlight the platform's ability to complement next-generation sequencing, particularly in detecting actionable mutations in challenging samples such as degraded or low-input specimens.

Biotype Diagnostic GmbH

Dresden, Germany

http://www.biotype.de/en.html

Biotype Diagnostic GmbH develops and commercializes specialized molecular diagnostic solutions for clinical research and routine diagnostics, with a primary focus on hematology/oncology and dermatology. The company also offers integrated sample preparation technologies designed to support molecular workflows. Its diagnostic portfolio is marketed under the Mentype and MycoType product families, with an expanding presence in oncology-focused molecular profiling.

Biotype's Mentype product line includes a range of multiplex PCR- and qPCR-based assays for hematology and transplant monitoring. The Mentype AMLplex QS assay enables detailed subtype classification of acute myeloid leukemia through detection of multiple gene fusions and transcript variants. For post-transplant monitoring, the Mentype Chimera assay supports chimerism analysis using polymorphic STR markers, while the Mentype DIPscreen and DIPquant assays provide qualitative and quantitative chimerism assessment based on insertion/deletion polymorphisms, offering high sensitivity for detecting minimal residual disease and engraftment status. The company continues to refine its chimerism portfolio, including updates to improve analytical sensitivity and workflow efficiency.

In dermatological and infectious disease diagnostics, Biotype offers multiplex PCR assays such as Mentype MycoDermQS, designed to identify a broad range of dermatomycosis pathogens, alongside lateral flow-based detection formats and the MycoType Skin and MycoType Skin Med assays for fungal pathogen identification. These products provid rapid, targeted diagnosis in clinical microbiology and dermatology settings.

Biotype's Sampletype i-sep system provides a streamlined solution for DNA extraction and sample preparation across clinical and forensic applications. The i-sep SQ tubes enable combined lysis and DNA extraction in a single closed system, reducing handling steps and contamination risk, while the i-sep DL tubes incorporate a reversible membrane for differential extraction workflows. This design is particularly useful for complex sample types, including mixed forensic samples and FFPE tissues, enabling sequential processing and efficient separation of cellular components.

The company has expanded its oncology portfolio through its Modaplex platform, a benchtop molecular system designed for rapid, multiplex biomarker analysis. Available assays include mutation analysis kits for KRAS, NRAS, BRAF, POLE, and FGFR alterations, offering precision oncology applications, particularly in colorectal and urothelial cancers. Continued enhancements to the Modaplex platform have improved multi-gene testing capabilities, turnaround time, and workflow flexibility, positioning the system for decentralized molecular testing environments.

Biotype has also broadened its strategic collaborations to advance precision medicine. Partnerships focused on liquid biopsy development support early cancer detection and disease monitoring from blood-based samples, while collaborations in digital PCR technologies have expanded capabilities for highly sensitive mutation detection. Additional partnerships in molecular pathology aim to improve diagnostics and treatment stratification for cancers such as bladder cancer.

Product developments include updates to leukemia testing panels and chimerism assays, including enhancements to the Mentype DIPscreen and AMLplex QS assays to improve sensitivity and clinical utility. The company has further expanded its molecular profiling portfolio under the MODAPLEX brand, including assays targeting FGFR mutations and fusions, as well as expanded NRAS mutation panels designed to guide therapy selection in oncology.

Biotype Diagnostic has also accelerated its international expansion strategy, targeting growth in emerging and high-demand markets for precision diagnostics. The company is strengthening its distribution network through new regional partnerships and increasing its presence in Asia, where adoption of molecular oncology and transplant monitoring solutions is rising. At the same time, Biotype is aligning its product portfolio with evolving European regulatory requirements, including IVDR compliance, to support broader clinical adoption and global market access. The company is also increasing participation in collaborative life sciences networks to advance biomarker research and validation.

IncellDx

San Carlos, CA

www.incelldx.com

IncellDx, Inc. is a molecular diagnostics company focused on the detection and monitoring of complex diseases, including cervical cancer, infectious diseases such as HIV and hepatitis, and immune-related conditions, including transplant rejection and chronic inflammatory disorders. The company's core technology platform is based on proprietary methods for simultaneous, multiplex detection of protein, mRNA, and DNA biomarkers at the single-cell level using advanced flow cytometry and cell-based analysis. This approach enables detailed characterization of cellular function and disease progression with high specificity.

IncellDx's oncology portfolio provides its HPV OncoTect assay, which is designed to assess oncogenic activity associated with persistent human papillomavirus (HPV) infection. Unlike conventional HPV DNA testing, which detects viral DNA, HPV OncoTect assesses the expression of the E6/E7 mRNA oncogenes in individual cells. By quantifying both oncogene expression levels and the proportion of affected cells, the assay provides a more precise indication of whether an infection is progressing toward malignant transformation. This enables improved differentiation between transient infections and clinically significant disease, supporting more informed clinical decision-making and reducing unnecessary invasive procedures. The test can be performed directly from standard liquid-based cytology samples and delivers results within a few hours, making it suitable for integration into routine screening workflows.

IncellDx has also developed technologies for circulating tumor cell (CTC) analysis, including the bioINK PD-L1 CTC Core Kit, which enables sensitive detection and quantification of protein and mRNA biomarkers at single-cell resolution. The platform incorporates proprietary fixation and processing methods designed to preserve cellular integrity while minimizing background interference, supporting applications in immuno-oncology and biomarker research.

The company has expanded its capabilities in multi-omic analysis through collaborations aimed at integrating immunophenotyping with next-generation sequencing workflows. Its IncellMax-Seq technology enables in situ library preparation, allowing simultaneous analysis

of cellular phenotype and genomic information from the same sample. This approach offers advanced research applications and the development of more comprehensive cancer diagnostics.

IncellDx has broadened its product and technology portfolio with additional reagent kits and tools designed to support single-cell and multi-omic analysis workflows across both clinical and research environments

The company has focused on immune profiling, particularly in the analysis of cytokines and inflammatory markers associated with immune dysregulation. These capabilities are being applied to a growing range of clinical areas, including post-viral syndromes, chronic inflammatory diseases, and immune-mediated conditions, reflecting a broader shift toward immune-based diagnostics in precision medicine.

IncellDx has strengthened its strategic collaborations and global presence. Partnerships with international organizations have supported the expansion of its diagnostic technologies into new markets and clinical applications, including initiatives focused on long COVID and immune system monitoring. The company's collaboration efforts also extend to advanced molecular and sequencing technologies, further enhancing its role in precision oncology and biomarker discovery.

LGC SeraCare Life Sciences, Inc.

Milford, MA

www.seracare.com

In November 2018, SeraCare Life Sciences was acquired by LGC Group and now operates within LGC's Clinical Diagnostics division. For more than three decades, SeraCare has developed a comprehensive portfolio of quality control materials, reference standards, and biological products that support assay development, validation, and routine clinical testing across molecular diagnostics, immunoassays, and next-generation sequencing applications.

SeraCare's product portfolio includes ACCURUN quality controls, research panels, KPL antibodies and immunoassay reagents, SeraCon processed biological materials, specialty human blood products, and characterized disease-state specimens. These offerings are widely used by clinical laboratories, assay developers, and diagnostic manufacturers to ensure accuracy, reproducibility, and regulatory compliance.

The ACCURUN line remains a cornerstone of the company's quality control portfolio, providing third-party controls for infectious disease, molecular, and serology testing. Products such as ACCURUN controls for Chlamydia trachomatis and Neisseria gonorrhoeae are designed for use with nucleic acid amplification tests, while ACCURUN 611 supports the detection of key coagulation-related genetic variants, including Factor V Leiden, Factor II, and MTHFR mutations. These materials are derived from well-characterized human samples and validated across multiple assay platforms to ensure consistent and reliable performance.

SeraCare's Seraseq portfolio includes biosynthetic and cell line–derived reference materials designed to support next-generation sequencing and precision oncology applications. Products such as the Seraseq Solid Tumor Mutation Mix provide defined allele frequencies for evaluating assay sensitivity and performance. The company has expanded this portfolio with additional reference materials targeting clinically relevant genes, including BRCA1/2 large genomic rearrangements and DPYD mutations, supporting oncology and pharmacogenomics workflows. Newer additions also include carrier screening and inherited disease testing, reflecting the increasing demand for comprehensive multi-gene panels.

The company also offers AccuSpan viral molecular panels designed to assess assay linearity, sensitivity, and dynamic range for a variety of viral targets, including adenovirus, herpesviruses, and polyomaviruses. These panels are provided in standardized, ready-to-use formats with consistent concentrations across lots, enabling reliable benchmarking of molecular assays.

PreAnalytiX GmbH

Hombrechtikon, Switzerland

www.preanalytix.com

PreAnalytiX, established in 1999 as a joint venture between Becton, Dickinson and Company and QIAGEN N.V., continues to operate as of 2026 as a specialist provider of pre-analytical sample handling technologies. The company focuses on the collection, stabilization, and purification of nucleic acids from blood, bone marrow, tissue, and emerging sample types. Its products are primarily marketed and distributed through QIAGEN and are widely used in research, biobanking, and molecular testing workflows.

PreAnalytiX develops integrated systems designed to preserve the integrity of RNA, microRNA, and DNA from the point of collection through downstream processing. Its solutions serve healthcare institutions, academic researchers, clinical laboratories, and pharmaceutical companies, supporting applications in translational research, biomarker discovery, and molecular analysis.

The company's portfolio offers the PAXgene product family, which includes systems for blood and tissue collection and stabilization. Key products include the PAXgene Blood RNA system, PAXgene Blood DNA system, PAXgene Blood miRNA system, and the PAXgene Tissue platform. These systems standardize pre-analytical variables by stabilizing nucleic acids immediately upon collection, improving reproducibility and downstream assay performance. The PAXgene Blood DNA Tube enables collection of whole blood in a closed, evacuated system with stabilizing additives, allowing for high-quality genomic DNA isolation using silica membrane, magnetic bead, or precipitation-based extraction methods.

PreAnalytiX products are widely adopted in research and biobanking environments, where sample integrity and consistency are critical. While much of the portfolio is designated for research use, the systems are frequently integrated into regulated laboratory workflows when used in combination with automation platforms such as QIAsymphony and QIAcube systems.

PreAnalytiX has expanded its portfolio beyond traditional blood and tissue applications to support emerging liquid biopsy workflows. This includes the development of systems for

stabilization of cell-free DNA in urine and continued advancements in blood-based cfDNA collection technologies. The company has also introduced saliva-based collection solutions, enabling decentralized and population-scale genomic testing. These additions reflect a broader strategic shift toward supporting non-invasive sampling and expanding access to molecular diagnostics.

PreAnalytiX continues to refine its preanalytical workflows to improve nucleic acid yield, stability, and purity, including enhancements to automated extraction protocols that reduce genomic DNA contamination and improve RNA integrity. These improvements support high-performance downstream applications such as PCR, digital PCR, and next-generation sequencing.

Precipio, Inc.

New Haven, CT

www.precipiodx.com

In June 2017, Transgenomic, Inc. merged with Precipio, Inc. and the combined entity adopted the Precipio name. The legacy Transgenomic business contributed advanced molecular technologies, including ICE COLD-PCR, a highly sensitive method for enrichment and detection of low-frequency mutations, supporting applications such as liquid biopsy and early cancer detection.

Precipio, Inc. is a specialty diagnostics company focused on improving diagnostic accuracy in oncology, particularly in hematologic malignancies. The company offers a combination of diagnostic services and proprietary products designed to reduce diagnostic errors by integrating advanced molecular testing with expert pathology review. Its model incorporates collaborations with leading academic institutions, including the Yale School of Medicine, to provide enhanced diagnostic insight and second-opinion services.

HemeScreen platform, a suite of molecular assays designed for rapid detection of clinically relevant mutations associated with hematologic cancers is Precipio's flagship. The HemeScreen panels include assays for myeloproliferative neoplasms (MPN), acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL), and anemia/myelodysplastic syndromes (MDS). These assays are designed to deliver results within a few hours, supporting timely clinical decision-making. The platform has evolved with the introduction of streamlined, one-step assay formats that eliminate confirmatory testing steps required in earlier versions, enabling both positive and negative results to be obtained in a single run and improving laboratory efficiency.

Precipio has also expanded the analytical capabilities of its assays. Updates to its MPN panel enable differentiation between clinically significant mutation subtypes, such as CALR type 1 and type 2 variants, which are important for disease classification and prognosis. In addition to HemeScreen, the company markets IV-Cell, a proprietary reagent designed to improve sample preparation and reduce interference in molecular testing workflows.

The company has broadened its molecular diagnostics portfolio by introducing and expanding its Bloodhound assay platform, including assays designed for the sensitive detection and monitoring of leukemia-associated mutations, such as BCR::ABL1. These assays extend Precipio's capabilities beyond initial screening into disease monitoring and quantitative analysis, supporting treatment management and longitudinal patient assessment.

Quanterix Corporation

Lexington, MA

www.quanterix.com

Quanterix Corporation, established in 2007, is a life sciences company focused on ultra-sensitive protein detection using its proprietary Single Molecule Array (Simoa) technology. The Simoa platform enables single-molecule digital immunoassay measurements, allowing detection of proteins at concentrations significantly lower than those achievable with conventional ELISA methods. The technology is based on arrays of femtoliter-sized reaction wells, each capable of isolating and detecting individual target molecules, enabling highly sensitive and quantitative biomarker analysis.

Simoa assays utilize a sandwich immunoassay format adapted for digital detection, enabling both singleplex and multiplex protein measurements with high sensitivity and precision. The platform has been widely adopted in research and clinical settings for applications in neurology, oncology, immunology, and inflammatory disease, where detection of low-abundance biomarkers is critical.

Quanterix has developed a portfolio of instruments and assay kits based on the Simoa platform, including the Simoa HD-X and SR-X analyzers and the SP-X imaging and detection system for multiplex and planar assay applications. These platforms support a broad menu of assays and customizable workflows. Multiplexing capabilities enable simultaneous measurement of multiple biomarkers without compromising sensitivity.

The company has expanded its presence in neurology through the development of blood-based biomarker assays for neurodegenerative diseases. Its Simoa neurofilament light chain (NfL) assays are used to quantitatively measure neuronal damage and have received regulatory recognition for their potential clinical utility. Quanterix has also developed plasma-based assays for phosphorylated tau proteins, including pTau-181 and pTau-217. These assays are available as laboratory-developed tests and research-use kits and are being incorporated into clinical research and diagnostic evaluation workflows. The LucentAD test portfolio further evaluates Alzheimer's disease by offering blood-based biomarker testing to aid in assessing patients with cognitive impairment.

Quanterix has strengthened its position in precision diagnostics through strategic collaborations and licensing agreements, including partnerships to advance biomarker development in neurodegenerative diseases. The company continues to build clinical validation for its assays through collaborations with pharmaceutical companies and academic research institutions.

Recent strategic acquisitions have expanded Quanterix's capabilities beyond blood-based biomarker detection. The acquisition of Emission enhanced the company's technology base in ultrasensitive detection, while the acquisition of Akoya Biosciences in 2025 extended its capabilities into tissue-based and spatial biology analysis. This combination enables integrated analysis of biomarkers across blood and tissue, supporting a more comprehensive understanding of disease biology.

Quanterix has also continued to expand its technology platform by developing next-generation instrumentation to broaden access to ultra-sensitive biomarker detection, including systems designed to simplify workflows and support wider adoption in clinical and translational environments. The company has also advanced its assay portfolio with highly sensitive neurology biomarkers, including BD-Tau and other next-generation assays, reinforcing its leadership in neurodegenerative disease research.

Through the integration of its Simoa platform with newly acquired spatial biology capabilities, Quanterix is positioned to expand its offerings across both circulating and tissue-based biomarker analysis. This combined approach enables correlation of blood-based biomarkers with tissue-level expression, enhancing applications in neurology, oncology, and immunology, as well as in drug development and precision medicine.

Streck Inc.

La Viste, NE

www.streck.com

Streck, Inc. is a developer, manufacturer and marketer of products for clinical and research laboratories in cell stabilization technologies. The company's product portfolio offers applications in hematology, immunology, molecular diagnostics, and flow cytometry, with a strong emphasis on quality control materials, sample collection, and pre-analytical stabilization.

Streck's technology in cell stabilization dates back to the early development of automated hematology testing, where stabilized blood components enabled more accurate and reproducible cell counting. Since then, the company has expanded its product offerings, supplying reagents and controls for many leading diagnostic platforms from major instrument manufacturers. Its technologies are widely adopted in clinical laboratories to improve sample integrity, standardization, and assay performance.

The company offers a broad range of quality control products, including flow cytometry controls such as CD-Chex TdT Plus and CD-Chex CD103 Plus, which provide multi-parameter controls for evaluating intracellular and surface markers relevant to hematologic malignancies. These controls are designed to support assay validation and performance monitoring across major flow cytometry platforms.

In hematology and clinical chemistry, Streck provides stabilized whole-blood controls, such as A1c-Cellular, a glycated hemoglobin control with intact red blood cells that is compatible with a wide range of automated analyzers. These controls are used to ensure accuracy and consistency in HbA1c testing across multiple instrument platforms.

Streck has also expanded its presence in molecular diagnostics and sample stabilization. Its Cell-Free DNA Blood Collection Tube is widely used to stabilize circulating nucleic acids in liquid biopsy workflows, helping minimize pre-analytical variability and preserve sample integrity during transport and storage. The company has extended its stabilization technologies to additional sample types, including urine-based preservation systems for cell-

free DNA and RNA stabilization solutions for downstream sequencing and transcriptomic applications.

In infectious disease and molecular quality control, Streck has introduced products such as MDx-Chex controls designed to verify the performance of multiplex molecular assays, including blood culture identification panels used in sepsis diagnostics. The MDx-Chex portfolio has continued to expand to include controls for sexually transmitted infection panels and multiplex vaginal testing, extending the company's reach into women's health and syndromic molecular diagnostics. These controls are designed to function as patient-like materials, enabling evaluation of the entire testing workflow from extraction through detection.

Streck offers its sample collection and stabilization portfolio with products such as Protein Plus BCT, designed to maintain native plasma protein concentrations at the time of blood draw, supporting applications in proteomics and biomarker research.

In addition, the company has developed molecular assay kits targeting antimicrobial resistance, including ARM-D kits designed to detect clinically relevant resistance genes. Recent enhancements to these assays have expanded coverage to include additional gene families and variants, reflecting the growing importance of rapid resistance detection in clinical microbiology.

Streck has expanded into emerging areas such as cell and gene therapy through collaborations that integrate its flow cytometry controls with automated platforms, supporting quality control in advanced therapeutic workflows. At the same time, the company is reinforcing its leadership in liquid biopsy by advancing stabilization technologies for cell-free DNA and RNA, which are increasingly critical for next-generation sequencing and precision medicine applications.

Chapter 28: Test Service Providers

Scope

In this section, Kalorama has selected a group of companies that provide laboratory testing services. The chapter presents both established companies and new entrants that operate company-sponsored laboratories. The profiles include events that have occurred in the past several years; they are not a comprehensive review or history of the companies selected to appear in the section and are listed alphabetically.

Agendia BV

Huntington Beach, CA, and Amsterdam, The Netherlands

www.agendia.com

Agendia is a molecular diagnostics company specializing in genomic assays that offer personalized treatment decisions in oncology, particularly in breast cancer. The company develops and markets gene expression–based diagnostic tests primarily using FFPE tissue samples, enabling clinicians to assess tumor biology and guide therapy selection.

Agendia's core offering is its Symphony suite for breast cancer, which includes MammaPrint, BluePrint, and TargetPrint. MammaPrint is a widely adopted gene expression assay that stratifies early-stage breast cancer patients based on risk of recurrence, helping to determine whether patients are likely to benefit from adjuvant chemotherapy. BluePrint provides molecular subtyping of tumors into functional subgroups, offering additional insight into tumor biology beyond traditional pathology. TargetPrint complements these assays by quantitatively assessing ER, PR, and HER2 gene expression, supporting treatment selection decisions. Together, these tests provide a comprehensive genomic profile to guide personalized therapy strategies and reduce overtreatment.

Agendia also offers ColoPrint, a gene expression assay designed to assess recurrence risk in stage II colon cancer patients. The company continues to expand its oncology pipeline and has played a significant role in major clinical studies.

Agendia has advanced its technology platform with the introduction of Digital MammaPrint, an AI-enabled version of its flagship assay developed in collaboration with Paige. This digital approach is designed to integrate artificial intelligence with genomic testing workflows, enabling faster turnaround times and supporting decentralized testing models. The company has also expanded its collaboration with Illumina to support next-generation sequencing–based deployment of its assays, facilitating broader access to its tests in distributed laboratory settings.

Ambry Genetics

Aliso Viejo, CA

www.ambrygen.com

Ambry Genetics, founded in 1999, is a CAP-accredited and CLIA-certified clinical laboratory specializing in genetic testing and genomic services. The company is recognized as a leader in hereditary disease testing, with a strong focus on oncology, reproductive health, cardiology, and rare diseases. Ambry has played a pioneering role in the adoption of next-generation sequencing in clinical diagnostics and continues to expand its portfolio of comprehensive genetic testing solutions.

In 2017, Ambry Genetics was acquired by Konica Minolta as part of a strategy to build a global precision medicine platform. More recently, Ambry has been integrated into Tempus AI, reflecting a strategic shift toward combining genomic testing with advanced data analytics and artificial intelligence to support data-driven healthcare and personalized medicine.

Ambry's test portfolio includes a broad range of hereditary cancer panels, exome sequencing services, and reproductive carrier screening assays. The company was among the first to introduce clinical NGS-based diagnostic testing and early adopters of clinical exome sequencing, helping to establish these technologies as standards in medical genetics. Its CancerNext-Expanded panel analyzes a wide range of genes associated with hereditary cancer risk, supporting comprehensive risk assessment and clinical management. The company has also expanded its hereditary cancer offerings by introducing more flexible, customizable panel configurations to address increasingly complex clinical needs.

Ambry has advanced genomic testing by integrating RNA analysis with DNA sequencing. Its +RNAinsight platform enables simultaneous evaluation of DNA variants and RNA expression, improving variant interpretation and increasing diagnostic yield, particularly in genes such as BRCA1 and BRCA2. This approach has evolved into a core component of Ambry's testing strategy and is now broadly integrated across hereditary cancer and exome testing.

With this multiomic approach, Ambry has enhanced its exome sequencing services through RNA-enabled testing, enabling more comprehensive detection of clinically relevant variants in rare and inherited diseases. These advancements improve diagnostic accuracy, reduce variants of uncertain significance, and increase overall diagnostic yield. The company has also achieved large-scale adoption of its combined DNA and RNA testing approach, with more than one million such tests performed, adding to its growing clinical impact.

Ambry continues to expand its role in longitudinal genomic diagnostics through programs that enable ongoing reanalysis of patient data as new genetic insights emerge, improving diagnostic outcomes over time and supporting more equitable access to updated clinical information.

The company also offers a range of sequencing and molecular services supporting both clinical diagnostics and research applications, including targeted gene panels, whole exome sequencing, and specialized testing for inherited and somatic conditions. Ambry continues to support precision oncology initiatives through collaborations with biopharmaceutical companies, helping to identify patients for targeted therapies and clinical trials.

In addition to its laboratory services, Ambry has expanded into digital health and clinical workflow solutions. Its CARE program is designed to identify patients who may benefit from genetic testing and to streamline test ordering and integration into clinical practice, supporting broader adoption of genomic medicine.

Ambry has established strategic partnerships to expand access to its testing services globally, including collaborations with international laboratory networks and diagnostic providers supporting clinical trials and healthcare systems outside the United States.

ARUP Laboratories

Salt Lake City, UT

www.aruplab.com

ARUP Laboratories, founded in 1984, is a national reference laboratory and a nonprofit enterprise of the University of Utah and its Department of Pathology. ARUP offers an extensive test menu of more than 3,000 assays and test combinations, ranging from routine clinical tests to highly specialized molecular, genetic, and esoteric diagnostics. The laboratory serves a broad client base across the United States, including academic medical centers, children's hospitals, multihospital systems, commercial laboratories, government agencies, and large healthcare networks.

The laboratory has expanded its test menu in response to emerging clinical needs. In toxicology and newborn testing, ARUP introduced assays for detecting substances such as kratom in umbilical cord tissue. In coagulation and cardiovascular testing, the laboratory offers assays to measure levels of direct factor Xa inhibitors, including apixaban, edoxaban, and rivaroxaban, supporting therapeutic monitoring and patient management.

In infectious disease diagnostics, ARUP has expanded its molecular testing capabilities with assays, including a PCR-based test for Candida auris, enabling rapid and specific identification of this emerging pathogen. The laboratory has also introduced advanced influenza A assays, including subtyping for strains such as H5, as well as molecular testing for measles that can distinguish vaccine-related from infection-derived strains.

ARUP has also developed and supported companion diagnostic testing, including assays such as AAV5 DetectCDx for use in guiding gene therapy in hemophilia, reflecting its growing role in precision medicine and advanced therapeutics.

The organization is increasingly integrating digital pathology and artificial intelligence into its workflows. Collaborations with technology partners have supported the development of AI-enabled tools for hematopathology, including analysis of bone marrow biopsies, as well as the expansion of AI-augmented screening for gastrointestinal parasites across the full testing workflow. These initiatives will likely improve diagnostic accuracy, efficiency, and scalability.

ARUP is also advancing access to testing through partnerships that support at-home blood collection and decentralized testing. Additionally, the laboratory is expanding its capabilities in genomic medicine, including rapid whole-genome sequencing for critically ill patients, particularly in neonatal and acute-care settings.

In addition, ARUP has expanded its neurology and biomarker testing portfolio with assays such as plasma pTau 217, supporting the evaluation of Alzheimer's disease and other neurodegenerative conditions.

Aspira Women's Health

Austin, TX

www.aspirawh.com

Aspira Women's Health, formerly known as Vermillion, Inc., rebranded in 2020 to reflect an expanded focus on women's health and gynecologic disease diagnostics. The company is dedicated to the discovery, development, and commercialization of diagnostic tests designed to improve the detection and clinical management of gynecologic cancers and related conditions, with a particular emphasis on ovarian cancer risk assessment.

Aspira's product portfolio includes OVA1, a blood-based test used in the clinical assessment of women with adnexal masses to help determine the likelihood of malignancy prior to surgical intervention. OVERA serves as a second-generation multivariate index assay designed to maintain high sensitivity while improving specificity. The company also offers OVA1+, a reflex testing strategy that utilizes OVA1 as the primary test with OVERA as a confirmatory tool to enhance diagnostic accuracy and clinical decision-making.

In addition to protein biomarker–based testing, Aspira has expanded into genetic and multiomic diagnostics through its Aspira GenetiX platform, which provides genetic risk assessment for gynecologic and related cancers, including ovarian, breast, endometrial, and other reproductive system malignancies. The company is also developing its Aspira Synergy platform, a decentralized and cloud-based technology infrastructure designed to integrate diagnostic data, algorithms, and clinical decision support tools.

Aspira has continued to expand its ovarian cancer testing portfolio with the introduction of OvaWatch, a blood-based test designed to assess the risk of ovarian cancer in women with adnexal masses initially classified as indeterminate or likely benign. OvaWatch is intended for use in monitoring patients over time and supporting clinical decisions regarding surveillance versus surgical intervention. Recent enhancements to the OvaWatch platform incorporate longitudinal monitoring capabilities and advanced algorithmic analysis, including artificial intelligence–driven risk assessment models that evaluate changes in biomarker levels over time.

The company has strengthened commercialization of its OvaSuite portfolio through strategic partnerships that expand access to its tests across key U.S. markets and support broader clinical adoption. Regulatory milestones, including expanded state-level approvals, have further supported the uptake of OvaWatch and related assays.

Aspira is also advancing a pipeline of next-generation diagnostics, including a multiomic ovarian cancer test that integrates microRNA and protein biomarkers with clinical data to improve diagnostic accuracy and risk stratification. In addition, the company is developing a non-invasive blood test for endometriosis, targeting a significant unmet need in women's health and expanding its reach beyond oncology into broader gynecologic conditions.

The company has expanded its research and development efforts through collaborations with leading academic institutions, including partnerships aimed at developing microRNA-based diagnostic approaches for ovarian cancer detection. These initiatives reflect Aspira's broader strategy to integrate multiple biomarker modalities and data-driven analytics into its diagnostic offerings.

Blueprint Genetics Oy

Helsinki, Finland

http://blueprintgenetics.com

Blueprint Genetics, founded in 2012 and headquartered in Helsinki, Finland, is a global provider of genetic testing for inherited diseases. The company serves customers in more than 70 countries and offers a comprehensive portfolio of next-generation sequencing–based tests, including hundreds of gene panels spanning multiple medical specialties such as neurology, cardiology, oncology, ophthalmology, and metabolic disorders.

Blueprint Genetics specializes in high-quality variant interpretation and clinical reporting, combining advanced sequencing technologies with curated databases and bioinformatics tools to provide accurate diagnosis of rare and inherited conditions. Its test menu includes more than 200 targeted panels, as well as exome-based testing solutions, enabling both focused and broad genomic analysis.

The company expanded its reproductive and proactive genetic screening offerings through its Family Screening Tests portfolio, designed to offer family planning and early risk assessment. The reproductive screening category provides carrier testing for couples planning a pregnancy, identifying whether individuals carry genetic variants that could increase the risk of inherited disorders in their offspring. The proactive screening category offers individuals insight into their predisposition to hereditary conditions, including cancer, cardiovascular, and metabolic diseases.

Blueprint Genetics has further enhanced its carrier screening portfolio with DUO testing options, which assess the combined genetic risk of couples for autosomal recessive and X-linked conditions. These tests are designed to provide more comprehensive risk evaluation and support informed reproductive decision-making.

The company continues to expand its NGS-based testing capabilities with the addition of panels that incorporate repeat expansion analysis, including tests for conditions associated with FMR1 gene expansions. These include panels for X-linked intellectual disability, premature ovarian failure, and hereditary ataxias, reflecting the growing importance of detecting repeat expansion disorders alongside sequence variants.

In reproductive genetics, Blueprint Genetics markets expanded carrier screening options with multiple configurations, including comprehensive, core, and population-specific panels, as well as corresponding DUO formats. These tests include analysis of FMR1 repeat expansions and are designed to address diverse patient populations and clinical needs, including targeted screening for specific ethnic groups.

Blueprint Genetics has also significantly expanded its diagnostic capabilities through growth in its gene content and panel customization options, enabling access to tens of thousands of genes for tailored testing. The company is increasingly emphasizing broader genomic approaches, including whole exome sequencing, and enhanced detection of complex variant types such as repeat expansions and mitochondrial variants.

As part of Quest Diagnostics, Blueprint Genetics continues to strengthen its global reach and integration into large-scale genomics operations, supporting expanded access to advanced genetic testing services. At the same time, the company maintains a strong focus on preventive and proactive genomics through its growing screening portfolio.

Boston Heart Diagnostics

Framingham, MA

https://bostonheartdiagnostics.com/

Boston Heart Diagnostics, a subsidiary of Eurofins Scientific, focuses cardiovascular care through personalized diagnostic testing and integrated clinical insights. The company combines advanced biomarker analysis, genetic testing, and risk assessment tools to support more individualized prevention and management of cardiovascular and metabolic disease.

Boston Heart Diagnostics offers a broad portfolio of cardiovascular and metabolic tests designed to provide deeper insight into lipid metabolism, inflammation, and cardiometabolic risk. Its Cholesterol Balance test evaluates markers of cholesterol synthesis and absorption, including lathosterol and desmosterol, to guide more targeted lipid-lowering strategies. The Fatty Acid Balance test measures key fatty acids to support cardiovascular risk characterization and dietary intervention planning, while the Prediabetes Assessment provides insight into early metabolic dysfunction and diabetes risk.

The company has also developed pharmacogenomic testing capabilities, including its StatinSmart test, which analyzes variants in the SLCO1B1 gene associated with an increased risk of statin-induced myopathy. This test provides personalized statin therapy by identifying patients who may be more susceptible to adverse effects, thereby improving treatment adherence and outcomes.

Boston Heart has expanded its genomic testing portfolio with LipidSeq, a next-generation sequencing based test designed to identify genetic causes of lipid and lipoprotein disorders. The company has also introduced polygenic risk assessment tools, including its Polygenic Risk Map, which evaluates genetic risk across multiple variants to provide a more comprehensive assessment of susceptibility to complex cardiovascular and metabolic diseases.

Boston Heart has introduced at-home testing options using dried blood spot collection, enabling patients to collect samples remotely and send them to the laboratory for analysis. The company has significantly expanded this capability, offering a wide range of dried blood spot–based assays across cardiometabolic and wellness testing categories.

Boston Heart has advanced its platform with integrated risk assessment tools such as CVMap, which combines multiple advanced biomarkers to provide a more comprehensive and longitudinal evaluation of cardiovascular risk. These tools are designed to support personalized intervention strategies and ongoing monitoring of patient health.

The company has expanded its precision medicine approach by integrating genetic, biochemical, and lifestyle-related data into its diagnostic offerings. This includes increased use of polygenic risk scoring, expanded genomic panels, and enhanced reporting tools designed to support clinical decision-making and patient-provider communication.

Boston Heart has also expanded access to its services through integration with digital health and clinical workflow platforms, enabling more efficient test ordering, reporting, and interpretation within healthcare systems.

CareDx, Inc.

South San Francisco, CA

www.caredxinc.com

CareDx, Inc., originally founded in 2000 as XDx Inc., is a molecular diagnostics company focused on improving outcomes for transplant patients through non-invasive monitoring and data-driven clinical solutions. The company specializes in transplant diagnostics across heart, kidney, lung, and other organ transplants, combining genomic testing, digital health tools, and clinical services.

CareDx's flagship product, AlloMap, is a gene expression profiling test designed to assess immune activity in heart transplant recipients. The test helps identify patients with stable graft function who have a low risk of moderate-to-severe acute cellular rejection, enabling clinicians to reduce reliance on invasive biopsy procedures.

The company has expanded its transplant monitoring portfolio with AlloSure, a donor-derived cell-free DNA test used to detect early signs of organ rejection. AlloSure is used across multiple transplant types, including kidney, heart, and lung, with expanded clinical indications supporting broader patient populations, including pediatric heart transplant recipients and patients undergoing simultaneous pancreas-kidney transplantation.

CareDx offers next-generation innovations such as AlloSure Plus, an artificial intelligence–driven extension of its core platform that integrates biomarker data with clinical variables to provide personalized risk assessment for transplant rejection and improved clinical decision-making.

CareDx has also expanded into tissue-based diagnostics with the introduction of HistoMap Kidney, a gene expression profiling test designed to enhance biopsy interpretation and improve classification of rejection types, bridging molecular diagnostics with traditional histopathology.

The company has further broadened its portfolio into new clinical areas with the development of AlloHeme, a novel assay designed to detect relapse in hematologic cancers, representing an expansion beyond transplant diagnostics into oncology applications.

CareDx has also developed a suite of next-generation sequencing–based products under the AlloSeq brand, supporting both pre- and post-transplant testing. These include HLA typing solutions for donor-recipient matching, chimerism testing for hematopoietic cell transplantation, and cfDNA-based monitoring. Products include high-throughput HLA typing solutions, including updated assays with expanded genetic coverage, designed for large-volume laboratory environments.

In addition to diagnostics, CareDx has expanded into digital transplant management and clinical decision support. The acquisition of transplant management software platforms, including OTTR and XynManagement, has enabled the company to provide integrated solutions for patient tracking, outcomes management, and workflow integration with electronic medical records systems.

CareDx has incorporated artificial intelligence and predictive analytics into its offerings through partnerships and proprietary tools, combining biomarker data with clinical variables to predict rejection risk and long-term graft survival, supporting more personalized transplant care.

The company continues to strengthen its transplant system through strategic collaborations, including partnerships to advance HLA genotyping technologies and improve donor-recipient matching. It has also expanded reimbursement coverage for key assays, including broader payer support for AlloSure in lung transplantation.

Recent product and clinical updates include expanded indications for AlloSure across additional transplant populations, continued rollout of AlloSeq products in international markets, and ongoing development of integrated diagnostic and digital solutions for transplant care.

Predictive Oncology

Pittsburgh, PA

www.predicitve-oncology.com

Predictive Oncology offers its Comprehensive Tumor Profile, which includes: ChemoFx, BioSpeciFx and GeneFx Colon. This approach to precision medicine combines genomic expression and molecular information specific and clinically relevant to a patient's cancer, answering a broad range of clinical questions that physicians encounter every day while managing their patients' care.

Predictive Oncology is committed to individualizing cancer therapy through a proprietary platform. The company develops novel markers to help guide treatment decisions based on the biological processes of each individual's cancer.

Predictive Oncology's state-of-the-art bioinformatics, combined with the analysis of the functional molecular, genomic, and proteomic activity of each patient's cancer, offers an innovative foundation for further development and commercialization of novel predictive markers for cancer therapy.

Comprehensive Tumor Profiling combines three core platforms of personalized medicine to capture the total sum of genomic, proteomic and functional information for each patient's cancer through a portfolio of multi-platform tests for cancer treatment in multiple tumor types.

ChemoFx Chemoresponse Marker (ChemoFx), the company's flagship product, is a proprietary chemoresponse marker that helps improve patient outcomes by supporting physicians in the selection of effective treatments for their gynecologic cancer patients. The test measures an individual's malignant tumor response to a range of standard chemotherapies. The test offers a method of identifying cancer cell response and sensitivity to various chemotherapeutic and biologic agents at the biopsy stage -- long before a patient actually begins chemotherapy -- providing a custom blueprint of a patient's probable tumor response.

The diagnostic test works by taking a sample of a patient's tumor, which is removed during biopsy or surgery, and sending that sample to the Helomics laboratory for sensitivity and

resistance testing. In a controlled environment that closely parallels what happens within the human body, those cells are incubated and treated by a fully automated system using a number of chemotherapy and biologic agents selected by that patient's physician. Helomics then sends the physician a report that details how the cancerous cells responded to each drug or chemotherapy combination. Integrating the results with clinical judgment, the physician can then use the report to support his decision on a treatment regimen for the patient, with the tandem objective of eradicating the disease and optimizing quality of life during chemotherapy treatment.

The BioSpeciFx is a panel of 23 markers that identify molecular targets within a patient's cell (extracted from FFPE tissue) using microarray technology. By using the information generated by BioSpeciFx in combination with ChemoFx, physicians may gain a complementary sum of information, which will enable physicians to look at both the relevant molecular targets as well as the synergistic activity of drug combinations on the entire cell. BioSpeciFx provides proteomic and genomic information, while ChemoFx considers all of the functional characteristics of a tumor including those not captured by biomarker testing, providing both sensitivity and resistance information.

Predictive Oncology's GeneFx Colon signature complements its Comprehensive Tumor Profiling for stage II colon cancer. The test uses microarray analysis of FFPE tissue to establish gene signature information. GeneFx Colon is an addition to the to the BioSpeciFx portfolio. The test is designed to help physicians assess which patients are at higher risk of recurrence and may therefore be candidates for adjuvant chemotherapy treatment.

D-CHIP (Dynamic Clinical Health Insight Platform), Helomics' bioinformatics platform aimed at pharmaceutical and diagnostic companies, was launched in April 2017. D-CHIP is searchable and can be used to mine proprietary multi-omic and clinical data from cancer patients for biomarker discovery and development, virtual clinical trials, and patient recruitment and selection. The cloud-based platform is said to be secure and compliant with regulations and offers rich, de-identified patient demographic data with state-of-the-art analytics.

GeneFx Lung is a proprietary gene expression-based test to improve staging and identify patients with early-stage non-small-cell lung cancer (NSCLC) who, following surgical removal of their tumor, are at higher or lower risk of mortality. GeneFx Lung is expected to provide better-informed, personalized treatment decisions to assist in selecting patients for adjuvant chemotherapy. Patients classified by GeneFx Lung as high risk benefited from

adjuvant chemotherapy, and those classified as low risk did not benefit and may have experienced a detrimental effect from adjuvant chemotherapy.

Labcorp, Laboratory Corporation of America

Burlington, NC

www.Labcorp.com

Labcorp is one of the largest global providers of clinical laboratory services, offering a broad range of routine and specialized diagnostic testing. The company employs tens of thousands of people worldwide and performs hundreds of millions of tests annually for patients, healthcare providers, biopharmaceutical companies, and health systems. Labcorp operates an extensive network of patient service centers, hospital-based laboratories, and regional facilities, supporting both centralized and decentralized testing models.

Labcorp's business is organized into two primary segments: Diagnostic Laboratories, which includes routine and specialty clinical testing, and Biopharma Laboratory Services, which supports drug development through central laboratory and clinical trial services.

Labcorp has expanded its diagnostics footprint through acquisitions and strategic partnerships. The company has acquired multiple regional and outreach laboratory businesses, including assets from BioReference Health, Baystate Health, Providence health system laboratories, North Mississippi Health Services, and Incyte Diagnostics. These acquisitions have strengthened Labcorp's regional presence, expanded access to testing services, and enhanced its capabilities in oncology and anatomic pathology.

In addition, Labcorp completed the acquisition of Invitae, significantly expanding its capabilities in genetic testing, including oncology and rare disease diagnostics. The company has also entered into partnerships with healthcare systems to manage hospital laboratory operations, further integrating its services into clinical care delivery.

Labcorp continues to augment its test portfolio with a focus on molecular diagnostics, genomics, and precision medicine. The company markets a range of new assays, including liquid biopsy tests such as PGDx elio plasma focus Dx, a next-generation sequencing–based assay designed to detect multiple genomic alterations across solid tumors. It has also introduced Plasma Detect, a test designed to assess risk of disease recurrence in colorectal cancer patients and has expanded this platform to support minimal residual disease detection across multiple cancer types.

In neurology, Labcorp has expanded its biomarker testing with the introduction of advanced blood-based assays, including pTau-based testing for Alzheimer's disease. In infectious disease, the company has developed molecular assays for emerging pathogens, including tests for avian influenza. In women's health and reproductive testing portfolio, Lab Corp offers first-trimester preeclampsia screening and self-collection options for HPV and sexually transmitted infection testing, improving access and patient convenience.

Labcorp continues to build its oncology testing capabilities with expanded next-generation sequencing panels for solid tumors and hematologic malignancies, including myeloid, lymphoid, and pan-hematologic panels. These offerings support precision oncology by enabling comprehensive genomic profiling and therapy selection.

Additionally, Labcorp is advancing companion diagnostics and gene therapy support, including assays designed to identify patients eligible for targeted therapies. The company has received regulatory authorization for assays supporting gene therapy applications, reflecting its growing role in advanced therapeutics.

Labcorp is expanding into artificial intelligence–enabled diagnostics, including the deployment of digital pathology platforms to enhance diagnostic workflows and accuracy. These initiatives complement the company's broader efforts to integrate advanced analytics and data-driven insights into laboratory medicine.

Labcorp offers the first FDA-cleared rapid fentanyl test, Fentanyl Urine Visual Test. The test assesses fentanyl exposure by detecting norfentanyl in urine up to 48 hours after initial exposure. The test is CLIA certified and provides rapid screening with results obtained in 10 minutes. This provides fast, actionable answers for healthcare providers when treating suspected fentanyl exposure in emergency departments, hospitals and clinics.

Mayo Clinic Laboratories

Rochester, MN

www.mayoreferenceservices.org

Mayo Clinic Laboratories is the reference laboratory of the Mayo Clinic and is widely recognized as a leader in esoteric and advanced diagnostic testing. The laboratory provides an extensive test menu of more than 3,000 assays spanning all major areas of medicine, including molecular diagnostics, genetics, infectious disease, oncology, neurology, and endocrinology. It serves as a primary reference laboratory for healthcare providers across the United States and internationally, including hospitals, health systems, and laboratories with specialized testing and clinical expertise.

Mayo Clinic Laboratories is particularly known for its leadership in gene-based and precision diagnostics, with a continuously expanding genetic and molecular testing portfolio. The organization routinely introduces new assays across multiple clinical domains, reflecting its strong emphasis on innovation and translational research. Its services also include direct access to Mayo Clinic physicians and scientists for consultation on complex cases, supporting interpretation of results and clinical decision-making.

The laboratory has expanded its test offerings in both routine and esoteric areas, with ongoing additions in oncology, infectious disease, neurology, and rare genetic conditions. Developments include expanded next-generation sequencing panels for hereditary diseases, such as hereditary pancreatitis and connective tissue disorders, as well as continued growth in immunohistochemistry and biomarker-based oncology testing.

Mayo Clinic Laboratories has strengthened its position in precision oncology by integrating liquid biopsy technologies that detect circulating tumor DNA and RNA, enabling comprehensive cancer profiling. Partnerships with technology providers have expanded access to advanced multiomic cancer testing and broadened the laboratory's global reach.

In neurology, the laboratory has introduced advanced assays for neurodegenerative diseases, including seed amplification–based testing and cerebrospinal fluid assays that can distinguish prion disease from other causes of rapidly progressive dementia. These offerings reflect

increasing demand for highly sensitive and specific diagnostics in neurodegenerative disorders.

In women's health, the laboratory launched a preeclampsia-specific risk assessment test designed to stratify patients earlier in pregnancy, supporting improved maternal and fetal outcomes. Additional expansion in reproductive and genetic testing continues to support early detection and risk assessment across a range of conditions.

The company is also advancing infectious disease diagnostics by developing rapid antibody-based tests for conditions such as Valley fever, designed to deliver results within minutes and improve early diagnosis in endemic regions. Expanded molecular testing for emerging pathogens further supports public health and outbreak response.

Mayo Clinic Laboratories continues to invest in innovative diagnostic technologies, including advanced molecular assays, multiomic profiling, and AI-informed interpretation approaches. These efforts are complemented by the ongoing expansion of its test menu, with dozens of new assays introduced annually.

MDxHealth SA

Liege, Belgium

www.mdxhealth.com

MDxHealth is a molecular diagnostics company focused on developing and commercializing genomic and epigenetic tests for cancer assessment, with a primary emphasis on urologic oncology. The company applies proprietary DNA methylation and genomic technologies to support cancer detection, risk stratification, prognosis, and treatment decision-making.

MDxHealth's strategy combines the development of laboratory-developed tests and companion diagnostics with pharmaceutical partners, alongside commercialization of clinical diagnostic assays through its CLIA-certified laboratory and dedicated sales infrastructure in the United States. The company has increasingly focused its portfolio on prostate cancer diagnostics, positioning itself as a key player in precision urology.

The company's earlier epigenetic platform featured ConfirmMDx for Prostate Cancer, a tissue-based test designed to help reduce unnecessary repeat biopsies by detecting DNA methylation changes associated with cancer in histologically negative biopsy samples. The test evaluates methylation biomarkers such as GSTP1, APC, and RASSF1, providing clinicians with additional insight into cancer risk and helping guide clinical management decisions.

MDxHealth has since expanded beyond epigenetic-only testing to incorporate genomic profiling technologies. A major milestone was the acquisition of the Genomic Prostate Score test, now marketed as Oncotype DX GPS, which analyzes gene expression to assess the aggressiveness of prostate cancer and support treatment decisions, including active surveillance versus intervention. This acquisition significantly strengthened the company's position in the prostate cancer diagnostics market. The company also markets ResolveMDx for urinary tract infections.

The company has expanded and repositioned its portfolio through the acquisition of Exosome Diagnostics, adding the ExoDx Prostate test, a non-invasive urine-based liquid biopsy assay designed to assess the risk of high-grade prostate cancer.

OPKO Diagnostics/Opko Health

Miami, FL

www.opko.com

OPKO Health, Inc. is a diversified healthcare and medical technology company with operations spanning pharmaceuticals, biologics, laboratory medicine, medical devices, and in vitro diagnostics. The company's diagnostics activities are primarily conducted through its subsidiary BioReference Health, which provides a range of clinical testing services, including specialty and oncology diagnostics.

BioReference Health is known for its proprietary 4Kscore test, a blood-based assay used to assess the risk of aggressive prostate cancer. The test combines multiple biomarkers with clinical information to support biopsy decision-making and reduce unnecessary procedures. Recent enhancements to the 4Kscore test have improved its clinical usability and expanded its application in routine screening workflows, reinforcing its role as the company's primary diagnostic offering.

OPKO has also developed point-of-care diagnostic technologies through its Claros Diagnostics platform, a microfluidics-based system designed for rapid testing of multiple analytes in near-patient settings. The Claros 1 Analyzer, paired with the Sangia PSA Test, enables quantitative measurement of prostate-specific antigen from a fingerstick blood sample, supporting decentralized prostate cancer screening and monitoring.

OPKO has streamlined its diagnostics operations through the divestiture of selected BioReference Health assets, including clinical diagnostics, oncology, and women's health testing services. This restructuring has allowed the company to focus on higher-value specialty diagnostics and core laboratory services while improving operational efficiency.

As part of this strategic shift, OPKO is increasingly concentrating on its 4Kscore franchise and select specialty testing services, aligning its diagnostics business with a more focused, higher-margin model. At the same time, the company continues to support regional laboratory operations and maintain its presence in clinical testing.

Quest Diagnostics

Madison, NJ

www.questdiagnostics.com

Quest Diagnostics is a leading provider of diagnostic information services, offering a broad range of laboratory testing, information, and services to patients, physicians, hospitals, employers, insurers, and biopharmaceutical companies. The company operates an extensive network of laboratories and patient service centers across the United States and internationally, supported by a large medical and scientific staff that provides consultative expertise and interpretation of complex test results.

Quest Diagnostics offers a comprehensive test menu ranging from routine clinical assays, such as lipid panels, cytology testing, and complete blood counts, to advanced molecular, genetic, and oncology diagnostics. The company has expanded its capabilities in precision medicine, including next-generation sequencing, companion diagnostics, and advanced biomarker testing to personalize treatment decisions.

Through its specialized reference laboratory, Nichols Institute, Quest provides advanced esoteric testing services to hospitals and laboratories worldwide, supporting complex diagnostic needs across the Americas, Europe, and Asia. The company maintains an international presence with laboratory operations and partnerships in multiple countries, supporting global clinical trials and diagnostic services.

Quest Diagnostics also offers a broad range of population health and employer-focused solutions, including workplace drug testing, wellness screening programs, and risk assessment services for the insurance industry. Its Blueprint for Wellness program provides employers with health insights to improve workforce health and productivity.

The company is recognized for its large-scale data analytics capabilities, leveraging one of the largest clinical laboratory databases in the United States. Through initiatives such as its Health Trends reports and Drug Testing Index, Quest provides insights into disease prevalence, public health patterns, and workforce drug use trends, supporting clinical research, policy development, and public health decision-making.

Quest Diagnostics has continued to invest in advanced diagnostics, digital health integration, and data-driven healthcare solutions. The company is expanding its offerings in areas such as oncology, infectious disease, and genetic testing, while also enhancing access through patient-centric services, including convenient testing locations and digital engagement tools.

Key Acquisitions, Alliances, and Partnerships

Quest Diagnostics continues to enter into targeted acquisitions and strategic collaborations designed to expand its geographic footprint, enhance service capabilities, and strengthen its position in advanced diagnostics. The company regularly evaluates both domestic and international opportunities to broaden access to laboratory services and add differentiated capabilities in areas such as oncology, digital pathology, and precision medicine.

Quest has completed a series of acquisitions focused on expanding its outreach laboratory services and strengthening regional market presence. These include acquisitions of hospital-based outreach laboratory businesses, such as those from University Hospitals in Ohio and OhioHealth, which extend Quest's access to hospital networks and patient populations in key U.S. regions. The company has also expanded into specialty diagnostics through the acquisition of kidney disease and dialysis-related laboratory assets, strengthening its capabilities in chronic disease testing.

Quest has complemented acquisitions with strategic collaborations and joint ventures to expand access to diagnostic services. These include multi-year partnerships with healthcare systems and payers to broaden laboratory access across multiple regions, as well as large-scale joint ventures with health systems to manage laboratory operations and develop regional testing infrastructure.

In advanced diagnostics, Quest has strengthened its capabilities through innovation-focused collaborations. With PathAI, the company has integrated digital and artificial intelligence–enabled pathology into clinical workflows, improving diagnostic efficiency and accuracy. In oncology, the acquisition of Haystack Oncology has expanded Quest's capabilities in minimal residual disease testing and liquid biopsy, reinforcing its position in precision oncology.

Quest strengthened its specialty genetics portfolio through the acquisition of Blueprint Genetics, enhancing its capabilities in rare disease and inherited condition testing. The company continues to integrate prior acquisitions to drive growth in new geographies and expand advanced diagnostic offerings.

Products and Services

Quest Diagnostics offers a comprehensive range of diagnostic testing services in the United States through a national network of approximately 2,000–2,200 patient service centers and an extensive team of physicians and scientific experts. The company provides services to a significant portion of the U.S. population, including a large share of hospitals and healthcare providers, and remains primarily focused on the domestic market while maintaining selective international operations.

Quest's test menu spans a broad spectrum of clinical areas, including anatomic pathology, genetic and hereditary disease testing, oncology, dermatology, hematology, cardiovascular disease, endocrinology, infectious disease, toxicology, and neurology. The company continues to emphasize the development of less invasive diagnostic approaches, including blood-based and molecular tests that support earlier detection and improved patient compliance.

Through the QuestDirect offering, the company has expanded its direct-to-consumer and patient-initiated testing capabilities. The program allows retail partners to provide access to a wide range of health tests across categories such as general wellness, women's health, allergy, digestive health, and infectious disease.

In infectious disease diagnostics, Quest offerings include molecular PCR-based assays for emerging pathogens. Its dual-target PCR test for orthopoxviruses enabled differentiation of specific viral strains and supported public health response efforts.

Quest continues to expand its portfolio with new diagnostic offerings across multiple specialties. In oncology, the company markets MelaNodal Predict, a gene expression profiling test designed to help guide treatment decisions in melanoma. The company has also expanded its oncology capabilities with advanced minimal residual disease testing, including both ctDNA-based assays for solid tumors and a novel blood-based test for multiple myeloma that enables ultrasensitive detection of residual disease using non-invasive samples.

In neurology, Quest has advanced its Alzheimer's disease testing portfolio with blood-based biomarker assays, including the AD-Detect platform, which combines amyloid and tau biomarkers to support assessment of amyloid pathology. The company has also expanded into advanced genomics through collaborations aimed at evaluating whole genome sequencing as a first-line diagnostic approach for developmental disorders, reflecting a broader shift toward comprehensive genomic testing in clinical practice.

In women's health, Quest has introduced HPV self-collection solutions to support cervical cancer screening, improving access and convenience for patients. Additionally, the company continues to enhance its patient engagement offerings, including personalized health coaching programs.

Sonic Healthcare

Sydney, Australia

www.sonichealthcare.com

Sonic Healthcare is a leading international provider of medical diagnostics services, with operations spanning laboratory medicine, radiology, and primary care. The company serves well over 100 million patients annually through a global network of laboratories, imaging centers, and clinics. Sonic operates a significant primary care network in Australia, comprising more than 150 clinics and thousands of affiliated physicians, alongside a large workforce that includes pathologists, medical scientists, and technical staff.

Sonic Healthcare offers an extensive test menu of more than 3,000 diagnostic assays, ranging from routine clinical testing to highly specialized esoteric and molecular diagnostics. The company is widely recognized for its expertise in complex testing, including genomics, infectious disease diagnostics, and advanced pathology services. Its client base includes physicians, hospitals, community health providers, and patients across multiple regions.

Geographically, Sonic Healthcare maintains a strong presence in Australia, Europe, the United States, and New Zealand, with Europe representing its largest market, followed by Australia and North America.

Sonic has made acquisitions and strategic investments. Recent acquisitions include regional laboratory groups in Germany, strengthening its European footprint, as well as U.S.-based diagnostic companies that expand capabilities in specialty and oncology testing. These investments allow Sonic's transition toward advanced diagnostic technologies and more integrated testing services.

The company has further strengthened its position in oncology diagnostics through the acquisition of Cairo Diagnostics, a hematology and oncology diagnostics provider in the United States. This acquisition enables more comprehensive cancer diagnostic workflows and faster turnaround times for complex cases.

Sonic is also advancing its capabilities in digital pathology, integrating imaging, automation, and artificial intelligence–enabled tools to improve diagnostic accuracy and efficiency. The

continued integration of digital pathology platforms, including dermatopathology solutions, provides the company's transition toward more scalable and data-driven diagnostic services.