

Molecular Diagnostics Market to Surpass USD 43.4 Billion by 2035 | Analysis Report by TMR

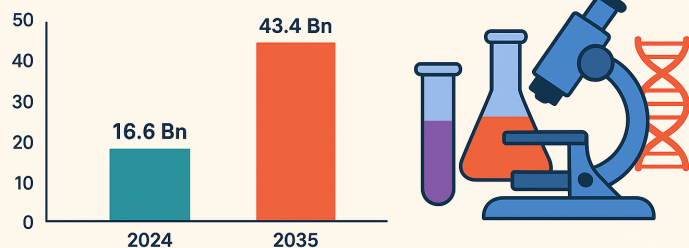
The growing disease burden is boosting demand for rapid, precise diagnostics, driving molecular diagnostics market growth.

WILMINGTON, DE, UNITED STATES, September 4, 2025 /EINPresswire.com/ -- The global [molecular diagnostics market](#), valued at USD 16.6 billion in 2024, is expected to surpass USD 43.4 billion by 2035, expanding at a CAGR of 9.1% from 2025 to 2035. Rising cases of infectious and chronic diseases, advancements in technologies like PCR and NGS, and the increasing adoption of precision medicine and liquid biopsy solutions fuel growth.

Molecular Diagnostics Market Outlook 2035

Global molecular diagnostics industry was valued at USD 16.6 Bn in 2024 and cross USD 43.4 Bn by the end of 2035

It is projected to grow at a **CAGR** of 9.1% from 2025 to 2035



Molecular Diagnostics Market

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Global Molecular Diagnostics Industry Set for 9.1% CAGR Growth Through 2035”

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resulting in an increased need for quick and precise diagnostics. Technological advancements in PCR, liquid biopsy, next-generation sequencing (NGS), and point-of-care diagnostics are enhancing diagnostic efficiency and expanding application areas, including advances in personalized medicine, which cater to the market.

The global molecular diagnostics market has its limitations, including the capital cost of equipment and reagents,

regulatory frameworks, reimbursement policies, and the fact that the developing parts of the world have limited skilled professionals.

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The market for rapid diagnostics is projected to develop, including ascendance in certain segments like minimal residual disease (MRD) testing and companion diagnostics segments projected to realize the greatest growth in revenue and consumption trends, and pharma companies pivoting diagnostics into point-of-need solutions.

Market Segmentation

The molecular diagnostics market can be segmented based on several key factors:

By Service Type: The market is primarily segmented into reagents & kits, instruments, and services. The reagents & kits segment is expected to hold the largest market share throughout the forecast period due to their recurring purchase nature and high consumption in diagnostic tests. This is followed by instruments and services, which are crucial for the implementation and maintenance of molecular diagnostic testing.

By Sourcing Type: The market is dominated by laboratory testing, which accounts for a substantial share of the market due to its established infrastructure and high throughput. However, point-of-care (POC) testing is emerging as a high-growth segment, driven by the demand for rapid, decentralized, and accessible diagnostic solutions. Self-testing or over-the-counter (OTC) kits also represent a smaller but growing segment.

By Application: Applications of molecular diagnostics are diverse and expanding. The infectious diseases segment, particularly for respiratory infections and sexually transmitted diseases, holds the largest market share. However, the oncology and genetic testing segments are projected to grow at the fastest rate, driven by the increasing use of companion diagnostics and the growing focus on precision medicine for cancer and inherited disorders. Other key applications include blood screening and neurological diseases.

By Industry Vertical/End-User: The market is primarily segmented into diagnostic laboratories, hospitals, academic and research institutes, and pharmaceutical and biotechnology companies. Diagnostic laboratories are anticipated to maintain the largest market share due to their high testing volumes and specialized infrastructure. The hospitals and clinics segment is also a major end-user, especially with the growing adoption of POC devices.

By Region: The market exhibits significant regional variations. North America holds the largest market share, driven by a well-established healthcare infrastructure, high healthcare expenditure, and the presence of key market players. The Asia-Pacific region is projected to be the fastest-growing market, primarily due to rising healthcare investments, a large and growing population, increasing prevalence of infectious diseases, and improving healthcare infrastructure. Europe, Latin America, and the Middle East & Africa also contribute significantly to the market.

Regional Analysis

North America: The dominant market player, characterized by the early adoption of advanced technologies, favorable reimbursement policies, and a strong focus on research and development.

Asia-Pacific: A high-growth market with immense potential. Factors such as increasing healthcare awareness, a rising geriatric population, and government initiatives to improve healthcare infrastructure are propelling market expansion.

Europe: A mature market with robust healthcare systems and a growing emphasis on personalized medicine. The region's market is supported by strong R&D, strategic collaborations, and a high prevalence of chronic diseases.

Latin America & Middle East and Africa (MEA): These regions are experiencing steady growth driven by increasing healthcare investments, a rising burden of infectious diseases, and improving access to advanced diagnostic technologies.

Market Drivers and Challenges

Market Drivers:

Increasing Prevalence of Infectious and Chronic Diseases: The rising global burden of infectious diseases and chronic conditions like cancer and cardiovascular diseases is a primary driver for the molecular diagnostics market.

Technological Advancements: Continuous innovations in technologies such as Polymerase Chain Reaction (PCR), Next-Generation Sequencing (NGS), and liquid biopsy are improving the speed, accuracy, and efficiency of molecular tests.

Growing Adoption of Personalized Medicine: The shift from a "one-size-fits-all" approach to personalized treatments based on genetic and molecular profiles is a key growth driver.

Expansion of Point-of-Care Testing: The demand for rapid, portable, and easy-to-use diagnostic devices is driving the growth of POC molecular diagnostics, especially in resource-limited settings.

Market Challenges:

High Cost of Equipment and Tests: The significant upfront investment required for advanced molecular diagnostic instruments and the high cost of reagents and consumables can limit adoption, particularly in developing regions.

Stringent Regulatory Frameworks: Navigating complex and time-consuming regulatory approval

processes can delay the commercialization of new products.

Shortage of Skilled Professionals: A lack of trained personnel to operate and interpret results from sophisticated molecular diagnostic equipment poses a challenge to widespread adoption.

Reimbursement Issues: Inadequate or complex reimbursement policies for certain molecular tests can hinder their accessibility and market growth.

Market Trends

Integration of AI and Machine Learning: Artificial Intelligence (AI) and Machine Learning (ML) are being integrated into molecular diagnostics to enhance data analysis, improve diagnostic accuracy, and accelerate the discovery of new biomarkers.

Rise of Liquid Biopsy: This non-invasive technique is gaining traction for cancer diagnosis and monitoring, providing a less painful alternative to traditional tissue biopsies.

Growing Significance of Companion Diagnostics: The development of companion diagnostics, which identify patients who will benefit from a specific therapeutic drug, is a major trend driven by the rise of targeted therapies.

Emergence of CRISPR-based Diagnostics: CRISPR technology is being explored for the development of highly specific and rapid diagnostic tests for a range of diseases.

Future Outlook

The future of the molecular diagnostics market is promising, with continuous innovation and a growing emphasis on precision medicine. The market is expected to witness further advancements in automation, miniaturization of devices, and the development of multiplex assays that can detect multiple pathogens or genetic markers simultaneously. The integration of molecular diagnostics into routine clinical practice, coupled with favourable government policies and increased public awareness, will further fuel market growth.

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Key Market Study Points

The market is characterized by a strong focus on R&D and strategic collaborations among key players.

The reagents and kits segment will continue to dominate due to high consumption rates.

The shift toward POC testing will create significant growth opportunities.

North America will remain a leading market, while Asia-Pacific will emerge as the fastest-growing region.

Overcoming challenges related to cost and regulatory hurdles is crucial for sustained market growth.

Competitive Landscape

The global molecular diagnostics market is highly competitive, featuring a mix of established multinational corporations and emerging startups. Key players are focusing on strategic initiatives such as product launches, mergers and acquisitions, and geographic expansion to strengthen their market position. Companies are heavily investing in R&D to introduce new and advanced diagnostic tests and systems that meet evolving healthcare needs.

Recent Developments

Abbott: In April 2025, Abbott announced the launch of a new CE-marked HPV assay in Europe.

QIAGEN: In September 2024, QIAGEN introduced the QIAcuityDx Digital PCR System, an IVDR-approved digital PCR solution for clinical diagnostics.

Illumina: In 2025, Illumina partnered with European oncology centers to advance genomics-based cancer screening solutions.

Siemens Healthineers: In 2025, Siemens Healthineers introduced a next-gen PET-CT scanner, which offers faster scans with lower radiation exposure.

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Contact:

Transparency Market Research Inc.

CORPORATE HEADQUARTER DOWNTOWN,
1000 N. West Street,
Suite 1200, Wilmington, Delaware 19801 USA
Tel: +1-518-618-1030
USA – Canada Toll Free: 866-552-3453
Website: <https://www.transparencymarketresearch.com>
Email: sales@transparencymarketresearch.com
Follow Us: [LinkedIn](#) | [Twitter](#) | [Blog](#) | [YouTube](#)

Atil Chaudhari
Transparency Market Research Inc.
+1 518-618-1030

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