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Molecular Diagnostics Market by Product & Service (Reagents, Kits), Test Type (Lab, PoC), Sample Type (Blood, Urine), Technology (PCR, INAAT), Application (Infectious, Oncology), End User (Diagnostic Labs, Hospitals), Region - Global Forecast to 2028

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Abstracts

The molecular diagnostics market is valued at an estimated USD 16.6 billion in 2023 and is projected to reach USD 28.6 billion by 2028 at a CAGR of 11.4% during the forecast period. Diseases such as tuberculosis, HIV/AIDS, hepatitis, sexually transmitted infections, and respiratory infections require an accurate and timely diagnosis for effective treatment and control. Molecular diagnostics play a crucial role in the detection and monitoring of these infectious diseases, driving the growth of the market in this area.

Apart from infectious disease diagnostics, molecular diagnostic techniques are increasingly being used to enhance patient management, particularly in the field of cancer. The growing prevalence of cancer globally will increase the number of specimens tested, thus creating a demand for new diagnostic procedures, including molecular diagnostics.

“Blood, serum, and plasma segment accounted for the highest growth rate in the molecular diagnostics market, by sample type, during the forecast period”

The molecular diagnostics market is bifurcated into blood, serum, and plasma, urine, and other sample types on the basis of sample type. The blood, serum, and plasma segment in molecular diagnostics is experiencing substantial growth, largely driven by the increased demand for infectious disease testing. Infectious diseases pose significant global health challenges, and the accurate and timely diagnosis of these

conditions is crucial for effective disease management and public health measures.

Plasma and serum samples provide several advantages for infectious disease testing. Plasma and serum samples have wide-ranging diagnostic applications in infectious diseases, including viral, bacterial, fungal, and parasitic infections. They aid in early diagnosis, appropriate treatment selection, and the assessment of treatment response. Moreover, Blood-based molecular diagnostics have demonstrated clinical utility across a broad range of applications, including genetic testing, infectious disease diagnosis, cancer diagnostics, and monitoring disease progression.

“Oncology testing segment accounted for the highest growth rate in the molecular diagnostics market, by application, during the forecast period”

The global molecular diagnostics market is bifurcated into infectious disease diagnostics, oncology testing, genetic testing, and other applications. Oncology testing segment is currently witnessing the highest growth rate within the molecular diagnostics market, reflecting the increasing importance of precision medicine and personalized approaches in cancer care. The surge in demand for oncology testing is fueled by various factors that are transforming the landscape of cancer diagnostics and treatment. Molecular diagnostic tests enable physicians to study the predisposition of genetic materials to diseases and diagnose diseases, such as cancer, at an early stage.

Through various strategic developments, pharmaceutical companies and molecular diagnostic manufacturers have increasingly focused on integrating their synergies to develop personalized medicine and companion diagnostic assays that can support the monitoring of a patient’s response to a given drug therapy. This is a major factor boosting the growth of the oncology testing segment. The growth of this segment is also driven by technological advancements and the increasing incidence of cancer.

“Asia Pacific: The fastest-growing region molecular diagnostics market”

The global molecular diagnostics market is segmented into North America, Europe, the Asia Pacific, Latin America, and the Middle East & Africa. The Asia Pacific region is projected to register the highest CAGR during the forecast period. Emerging countries in this region have witnessed growth in their GDPs and a significant rise in disposable income levels. This has led to increased healthcare spending by a larger population base, healthcare infrastructure modernization, and the rising penetration of cutting-edge clinical laboratory technologies in the Asia Pacific countries. These factors are expected to provide significant growth opportunities for molecular diagnostic companies operating in this region.

The Asia Pacific, which has become a medical tourism hub, is considered one of the fastest-growing markets for medical procedures and devices. Low infrastructure and treatment costs and the availability of highly educated physicians have driven medical tourists to these countries, which is a major factor driving the growth of the molecular diagnostics market in this region.

The break-up of the profile of primary participants in the molecular diagnostics market:

- By Company Type: Tier 1 - 40%, Tier 2 - 30%, and Tier 3 – 30%
- By Designation: C-level - 27%, D-level - 18%, and Others - 55%
- By Region: North America - 51%, Europe - 21%, Asia Pacific - 18%, Latin America – 6%, and Middle East & Africa- 4%

The key players in this market are F. Hoffmann-La Roche Ltd. (Switzerland), Hologic, Inc. (US), Thermo Fisher Scientific Inc. (US), Abbott Laboratories (US), bioM?rieux (France), QIAGEN (Netherlands), PerkinElmer Inc. (US), Myriad Genetics, Inc. (US), Siemens Healthineers AG (Germany), Danaher (US), Illumina, Inc. (US), Becton, Dickinson and Company (US), Grifols, S.A. (Spain), QuidelOrtho Corporation (US), Agilent Technologies, Inc. (US), DiaSorin S.p.A. (Italy), Exact Sciences Corporation (US), Genetic Signatures (Australia), MDx Health (Belgium), Biocartis (Belgium), TBG Diagnostics Limited (Australia), HTG Molecular Diagnostics, Inc. (US), Vela Diagnostics (Singapore), Amoy Diagnostics Co., Ltd. (China), ELITechGroup (France), Molbio Diagnostics Pvt. Ltd. (India), Savyon Diagnostics (Israel), Abacus Diagnostica Oy (Finland), and geneOmbio Technologies Pvt. Ltd. (India).
Research Coverage:

This research report categorizes the molecular diagnostics market by product & service (reagents & kits, instruments, and services & software), test type (lab tests and PoC tests), sample type (blood, serum, and plasma, urine, and other sample types), application (infectious disease diagnostics (hepatitis, HIV, CT/NG, HAI, HPV, tuberculosis, influenza, and other infectious diseases), oncology testing (breast cancer, colorectal cancer, lung cancer, prostate cancer, and other cancer testing), genetic testing, and other applications, technology (polymerase chain reaction, isothermal nucleic acid amplification technology, DNA sequencing & next-generation sequencing, in situ hybridization, DNA microarrays, and other technologies), end user (diagnostic laboratories, hospitals & clinics, and other end users), and region (North America, Europe, Asia Pacific, Latin America, and the Middle East & Africa). The scope of the report covers detailed information regarding the major factors, such as drivers, restraints, challenges, and opportunities, influencing the growth of the molecular diagnostics market. A detailed analysis of the key industry players has been done to provide insights into their business overview, solutions, and services; key strategies; acquisitions, agreements. new product & service launches, and recent developments associated with the molecular diagnostics market. Competitive analysis of upcoming startups in the molecular diagnostics market ecosystem is covered in this report.

Reasons to buy this report:

The report will help the market leaders/new entrants in this market with information on the closest approximations of the revenue numbers for the overall molecular diagnostics market and the subsegments. This report will help stakeholders understand the competitive landscape and gain more insights to position their businesses better and to plan suitable go-to-market strategies. The report also helps stakeholders understand the pulse of the market and provides them with information on key market drivers, restraints, challenges, and opportunities.

The report provides insights on the following pointers:

> Analysis of key drivers (increasing prevalence of infectious diseases and cancer globally, rising focus on R&D and growing funding in molecular diagnostics by healthcare-based companies, growing awareness of early disease diagnosis in developing countries, rising technological advancements in molecular diagnostics in recent years, and increasing use of PoC diagnostic tests in homecare settings and hospitals), restraints (unfavorable reimbursement scenario for diagnostic companies and high cost of molecular diagnostic instruments), opportunities (growing significance of companion diagnostics in drug development process and growth opportunities for molecular diagnostic companies in emerging economies), and challenges (changing regulatory landscape for IVD and molecular diagnostics in US and European Union, operational barriers and shortage of skills across major markets, and introduction of alternative technologies for disease detection and diagnosis) influencing the growth of the molecular diagnostics market

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Product Development/Innovation: Detailed insights on upcoming technologies, research & development activities, and new product launches in the molecular diagnostics market.

Market Development: Comprehensive information about lucrative markets – the report analyses the molecular diagnostics market across varied regions.

Market Diversification: Exhaustive information about new products & services, untapped geographies, recent developments, and investments in the molecular diagnostics market

Competitive Assessment: In-depth assessment of market shares, growth strategies and service offerings of leading players like F. Hoffmann-La Roche Ltd. (Switzerland), Hologic, Inc. (US), Thermo Fisher Scientific Inc. (US), Abbott Laboratories (US), and bioM?rieux (France), among others in the molecular diagnostics market strategies.

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About

Molecular diagnostic tests are the tests that access the biological makeup at genetic level to identify the predisposition of an individual to a particular disease and to diagnose it.

The global molecular diagnostics market size, in terms of value, is expected to grow from $XX billion in 2013 to $XX billion by 2018, at a CAGR of XX% from 2013 to 2018.

This market is driven by the increasing prevalence of chronic diseases, augmented awareness and acceptance of personalized medicine and companion diagnostics, advancements in molecular techniques, inherited disease testing, and prenatal testing. However, persistent reimbursement issues and delay in approvals of molecular diagnostic tests are expected to curb the growth of this market.

Market dynamics

The molecular diagnostics market progresses with the advancement in the technology. New tests and new instruments to perform these advanced molecular diagnostic tests, automated analysis along with the rise in chronic infections, increasing investments in R&D, growing geriatric population, increasing demand for personalized medicines, and rising R&D activities for biomarker identification are the major influencing factors for the growth of the molecular diagnostics market.

As awareness and interest among patients for personalized medicine increases, the use of molecular diagnostics and genetic testing is bound to grow in the near future. In a recent survey conducted by the United Health Center for Health Reform & Modernization, more than XX% respondents agreed that genetic testing allows physicians to offer personalized treatment. Personalized medicine also involves pharmacogenomic tests, also considered as molecular diagnostic tests. They ensure maximum efficacy and safety, and are used in association with a drug. This field of personalized medicine is called companion diagnostics. As these tests increase in number, the molecular diagnostics market will also grow. Industry experts comment that in the coming decade, there will only be a handful of drugs without associated diagnostic tests.

New genes and biomarkers are continuously being identified and clinically validated, increasing the number of different molecular diagnostic tests available. The biomarker discovery and identification market has been showcasing a high double-digit CAGR of XX% since the recent past, and will continue to display the same over the next five years, thus highlighting the potential for growth in molecular tests.

Market share analysis

Novartis, with its Vaccines and Diagnostics division that was established after the acquisition of Chiron, followed at the number two position with a XX% share in the global market. Chiron offers Novartis access to its blood testing business in molecular diagnostics. Novartis has gained this position with its Procleix portfolio of systems, assays, and software. The company is also actively following a strategy of developing partnerships and signing agreements globally to expand its reach in the MDx market. The company, along with Gen-Probe with which it has collaborated to develop and market molecular technologies, has captured about two-thirds of the global blood screening MDx market. Novartis also signed an agreement with Grifols in early 2011 and Cepheid in 2010 to market their molecular diagnostics products in the U.S.Gen-Probe (now a part of Hologic) closely followed Novartis occupying a XX% share with its market leadership in CT/NG assays. It also has a significant presence in virology assays for diagnosis of HPV, HCV, and HIV.

Qiagen accounted for a share about XX% of the global MDx market with its leadership in HPV testing with a share of about XX%. Abbott occupied XX% of the MDx market with its PCR portfolio for a gamut of infectious disease testing and oncology. BD and Cepheid followed with a share of about XX%. Cepheid is the world leader in MRSA testing accounting for a share of more than XX% with its Xpert product line.

Molecular diagnostic laboratories and tests

The number of laboratories performing molecular diagnostics tests in 2013 in U.S. was XX and is estimated to reach XX in 2018 with a CAGR of XX%. In Europe, XX laboratories were performing molecular diagnostics tests in 2013. These laboratories are expected to reach XX in 2018 with CAGR of XX%.

Global molecular diagnostics market, by application

The infectious diseases application is leading the global molecular diagnostics market. It commanded the largest share of XX% of the market in 2013, valued at $XX million and is expected to reach $XX million by 2018, at a CAGR of XX% from 2013 to 2018. The growth is due to the development of advanced new assays and technologies, unprecedented occurrence of infections, and rising awareness for the need to control widespread infectious diseases.

Infectious diseases

The CT/NG tests market size, in terms of value, is estimated to grow from $XX million in 2013 to $XX million by 2018, at a CAGR of XX%. The markets for MRSA and HPV testing are estimated to grow at higher CAGRs of XX% and XX%, respectively from 2013 to 2018. This growth is attributed to the increasing test volumes of MRSA and HPV due to extensive screening programs in the U.S.

Global molecular diagnostics market, by technology

Molecular diagnostic tests are widely preferred for the detection of various pathogenic mutations in DNA/RNA samples in order to facilitate, diagnose, provide a prognosis, and monitor an individual's response to therapy. These instruments leverage multiple technologies to identify genetic variations. The major molecular diagnostic technologies studied in this report include polymerase chain reaction (PCR), isothermal nucleic acid amplification technology (INAAT), microarray, hybridization, DNA sequencing, and next-generation sequencing (NGS). The other technologies associated with molecular diagnostics (MDx), but not as significant as the ones mentioned above, are electrophoresis, flow cytometry, and mass spectrometry.

PCR accounted for the largest share of XX% of the global MDx market in 2013, followed by INAAT (XX%) and hybridization (XX%). In the coming years, the MDx market will be driven by the microarray technology segment, which is poised to grow at a CAGR of XX% from 2013 to 2018.

Global molecular diagnostics market, by product type

The reagents segment accounted for the largest share of the molecular diagnostics market size, in terms of value, in 2013. This segment is expected to reach $XX million by 2018, at a CAGR of XX% from 2013 to 2018. As reagents are consumables, the growth in this market is attributed to the increase in the volumes of molecular diagnostic tests. The molecular diagnostics instruments market size is estimated to grow at a CAGR of XX% from 2013 to 2018.

Instruments

The instruments market accounted for a XX% share of the molecular diagnostics market in 2013. This market is vast, consisting of different technologies such as polymerase chain reaction, DNA sequencing, hybridization, electrophoresis, mass spectrometry, flow cytometry, and so on. The instruments used as platforms for molecular diagnostic test include amplifiers, thermal cyclers, DNA sequencers, DNA analyzers, and electrophoresis instruments, among others.

The instruments market is growing at a steady pace due to the continuous requirement for biotechnology instruments in laboratories, pharmaceutical, and biotechnology companies. The molecular diagnostic instrument market size, in terms of value, is poised to grow from $XX million in 2013 to $XX million by 2018, at a CAGR of XX% from 2013 to 2018. Automated and advanced instruments with high-throughput capacities, increase in number of biotechnology firms across the world, advances in life science research and technology innovations with human genome mapping, and emergence of omics technologies have enabled industry growth.

Geographic analysis

In this report, the molecular diagnostics market is divided into four major geographies, namely, North America, Europe, Asia, and the Rest of the World (RoW). The global molecular diagnostics market was valued at $XX million in 2013; North America was the largest market with a share of XX%, followed by Europe. In the next five years, the Asian region is estimated to register the highest CAGR of XX%, primarily due to the increasing investments by major players.

New product launch

Driven by research and innovation in the molecular diagnostics market, new product launch accounted for XX% all the strategies adopted by players to achieve growth in this market. Product launch proved to be very efficient in enhancing the company’s growth. This strategy mainly helped in increasing the customer base and application areas. Major players such as Becton, Dickinson and Company (U.S.), QIAGEN (Germany) and Roche (Switzerland) implemented this strategy successfully.

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