

Molecular Diagnostics Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Products and Services (Reagents and Kits, Instruments, Services and Software), By Technology (Polymerase Chain Reaction (PCR), Sequencing, In-situ hybridization, Chips and microarrays, Mass spectrometry, Others), By Application (Infectious disease, Oncology testing, Genetic testing, Blood screening, Others), By End User (Hospitals, Academic & Reference Laboratories, Others), By Region and Competition

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Abstracts

Global Molecular Diagnostics Market has valued at USD 15.28 Billion in 2022 and is anticipated to project impressive growth in the forecast period with a CAGR of 7.14% through 2028. Molecular diagnostics, as a term, encompasses techniques utilized for the analysis of biological markers implicated in a broad spectrum of human diseases. These diagnostic tests hold pivotal significance within a well-established healthcare system. By providing crucial information, molecular diagnostics aid healthcare providers and patients in making informed medical decisions, resulting in successful outcomes. Moreover, the quantitative measurements offered by molecular diagnostics facilitate comprehensive care management and effective control of various health conditions.

In the clinical setting, molecular diagnostics tools have proven to be beneficial by enabling rapid and sensitive detection methods, thereby facilitating monitoring of a wide array of infectious diseases, including cancers and other chronic illnesses. Genetic

testing, microbiology, STDs, oncology, blood screening, virology, tissue typing, and prenatal diagnostics are among the medical conditions successfully detected through the extensive application of molecular diagnostics. Laboratory-based molecular diagnostics serve as indispensable tools for disease identification in humans, employing the analysis of DNA, RNA, or proteins. Reagents and kits specifically designed for molecular diagnostics vary depending on the intended application, with probes targeting specific viral, bacterial, and parasitic sequences. The increasing utilization of biomarker-specific testing kits is poised to drive the growth of the Molecular Diagnostics Market, as these tests prove invaluable prior to the initiation of any therapy or treatment.

Key Market Drivers

Boosting Prevalence of Chronic Ailments

Due to the rapid mechanization of various industries, the concept of manual work has gradually diminished from people's daily lives. As a result, sedentary lifestyles and poor dietary habits have become prevalent, leading to an alarming increase in needle-stick diseases like cancer. In fact, according to a recent report by the World Health Organization (WHO), an estimated 10 million people worldwide succumbed to cancer in the year 2021 alone, losing their precious lives to this devastating disease. Of these cases, around 1.9 million were reported in the United States, highlighting the urgent need for effective measures to combat this widespread health crisis.

Furthermore, the rise in infectious diseases and other communicable ailments has contributed to the growing demand for molecular diagnostics. Conditions such as kidney disease, respiratory infections, and chronic obstructive pulmonary disease have become all too common. Shockingly, statistics indicate that approximately 37 million individuals in the United States are expected to be affected by chronic kidney disease (CKD) in the year 2021. The prevalence of these diseases is projected to reach epidemic proportions, especially considering the rapidly aging global population, which is anticipated to surpass 2 billion in the near future.

The implications of these health challenges are far-reaching, affecting individuals, families, and communities worldwide. It is crucial for medical professionals, researchers, and policymakers to focus on preventive measures, early detection, and effective treatment strategies to mitigate the impact of these diseases and improve overall public health.

Modernizing Healthcare Infrastructure

In the wake of the overwhelming burden that the ongoing pandemic has placed on the healthcare sector, governments worldwide have recognized the urgent need to expand their healthcare spending. The United States, with its staggering spending of over \$4 trillion, stands as the largest healthcare spender among all countries. This commitment to healthcare is projected to grow further, as the overall American healthcare spending is estimated to reach a remarkable \$6.2 trillion by the year 2028.

Meanwhile, China has also witnessed a significant increase in healthcare expenditure. In 2020, there was a notable spike of 12.6 percent, with the Chinese healthcare spending reaching a substantial \$926.8 billion. In addition, the total public healthcare spending in China crossed 1.9 trillion yuan in 2021, highlighting the country's dedication to improving its healthcare infrastructure and services.

As the demand for robust healthcare systems continues to rise, countries like India are also amplifying their efforts to enhance their existing healthcare infrastructure. These initiatives aim to ensure that the population has access to quality healthcare services, especially during times of crisis. The global healthcare landscape is witnessing a transformative shift, as governments worldwide recognize the importance of investing in healthcare to protect and improve the well-being of their citizens.

Large Outbreaks of Bacterial and Viral Epidemics

The rising prevalence of numerous bacterial or viral epidemics, such as the recent outbreaks of influenza and COVID-19, has heightened the global demand for point-of-care diagnostics. In response to these challenges, there have been significant advancements in pharmacogenomics, leading to the development and launch of novel molecular diagnostic products. These advancements are expected to drive the expansion of the global molecular diagnostic market throughout the forecast period.

In a groundbreaking development on March 15, 2023, a team of researchers successfully created a quick and effective point-of-care molecular diagnostic tool. This innovative tool specifically identifies a subset of individuals who are highly likely to benefit from hypnotherapy interventions for pain treatment. The researchers also made a remarkable discovery during their study, published in *The Journal of Molecular Diagnostics*, indicating that a subpopulation of highly hypnotizable people may be more prone to experiencing intense postoperative pain.

To further enhance their research, the scientists designed an SNP genotyping assay

utilizing a massive magneto-resistive (GMR) biosensor array. This cutting-edge technology allows for the identification of the most optimal combination of COMT SNPs in patient DNA samples. The GMR biosensor arrays can be easily and conveniently installed in point-of-care settings, utilizing either saliva or blood samples. Not only are these biosensor arrays highly dependable and sensitive, but they are also cost-effective, making them an ideal solution for widespread implementation. With the continuous advancements in molecular diagnostics and the integration of point-of-care technologies, the healthcare industry is poised to revolutionize the diagnosis and treatment of various diseases, improving patient outcomes and overall healthcare efficiency.

Rising Technological Advancements

The molecular diagnostics market presents a growing opportunity, driven by advancements in technology and product launches by key players. Additionally, the increasing prevalence of infectious and cardiovascular disorders serves as a market trend propelling this industry.

In March 2023, the Korea Institute of Science and Technology (KIST) announced the development of ultrafast PCR technology. By incorporating photothermal nanomaterials, this innovative approach reduces test time by tenfold compared to existing methods. The new test can be completed in just 5 minutes while maintaining diagnostic performance comparable to traditional techniques. Notably, the KIST research group has successfully created a polymer composite capable of physically holding and stabilizing photothermal nanoparticles. Leveraging this advancement, they have devised a portable PCR machine without a heat plate, integrated within a PCR setup. Furthermore, their utilization of multiplex diagnostic methods enables simultaneous detection of multiple genes and differentiation between various COVID-19 variant types within a single result.

Key Market Challenges

High Cost of Molecular Diagnostics

Although immensely useful, molecular diagnostics do have some restrictions and drawbacks. One of the main limitations is the higher cost compared to more established conventional methods. The expenses involved in molecular diagnostics include not only the cost of equipment and supplies but also the need for highly specialized personnel and maintenance. These factors can make it financially prohibitive for some labs,

especially those with limited resources. However, it is important to note that as molecular techniques become more widespread and adopted by a larger number of labs, the costs are expected to decrease. This is due to economies of scale and advancements in technology that can lead to more affordable equipment and reagents. As a result, labs that currently find the cost of molecular diagnostics prohibitive may choose to outsource their molecular specimens to external reference labs.

Despite these challenges, the field of molecular diagnostics continues to show great potential and has already made significant contributions to healthcare. It is anticipated that as the costs decrease and the technology becomes more accessible, the market for molecular diagnostics will expand further, benefiting patients and healthcare providers alike.

High Initial Installation Costs

The cost of setting up a facility with state-of-the-art technologies like FISH (Fluorescence In Situ Hybridization), NGS (Next-Generation Sequencing), and others is indeed on the higher side. Millions of dollars are required to invest in procuring the necessary machinery, building the facility, and hiring professionals with an adequate amount of knowledge and expertise in these advanced techniques. The implementation of such cutting-edge technologies demands meticulous planning and meticulous execution to ensure accurate and reliable results.

Additionally, the cost of the treatment itself can be quite high, especially for individuals in low-income countries, which can pose a significant challenge to the overall growth of the market. It highlights the need for affordable options and innovative solutions to bridge the gap and make these advanced diagnostic and treatment methods accessible to a wider population. For instance, the expenses associated with acquiring sophisticated instruments can be substantial. A triple quadrupole mass spectrometer, known for its exceptional sensitivity and precise quantification capabilities, can cost around \$350,000, depending on the specific features it offers. Similarly, a high-resolution time-of-flight instrument, renowned for its accurate mass measurement and comprehensive analysis, can range from \$350,000 to \$400,000. And an Orbitrap extended-mass-range model, with its superior resolution and mass accuracy, can have a price tag ranging from \$400,000 to \$800,000. These hefty costs further underline the significant capital requirements involved in establishing and operating state-of-the-art facilities.

Considering the financial challenges and the increasing demand for advanced

diagnostics and treatments, it becomes crucial for stakeholders to explore sustainable approaches that balance cost-effectiveness, accessibility, and quality. This can involve collaborations, strategic partnerships, and innovative financing models that ensure the benefits of these cutting-edge technologies reach a larger population, regardless of their economic background.

Key Market Trends

Increasing Demand for Point-of-Care Diagnostics

The increasing demand for point-of-care (POC) diagnostics has significantly driven the demand for molecular diagnostics, reshaping the landscape of medical testing and healthcare delivery. Several key factors contribute to this growing trend. POC diagnostics offer the advantage of delivering rapid and accurate test results at or near the patient's location, often within minutes. This immediacy is critical in emergency situations, for monitoring chronic diseases, or when making time-sensitive treatment decisions. Molecular diagnostics, with its precision and sensitivity, plays a pivotal role in POC testing by enabling the detection of specific genetic material or biomarkers associated with various diseases, including infectious diseases, cancer, and genetic disorders.

Additionally, as healthcare systems strive to improve patient outcomes while reducing costs, the shift towards decentralized testing at the POC has gained momentum. Molecular diagnostics offers the capability to identify diseases at earlier stages, aiding in personalized treatment plans and ultimately reducing the burden of advanced disease cases and hospitalizations. The evolving landscape of telemedicine and remote healthcare delivery also plays a role in driving the demand for molecular diagnostics at the point of care. Patients in remote or underserved areas can benefit from POC molecular tests that provide timely insights into their health conditions, enabling healthcare providers to make informed decisions and recommendations from afar.

Recent Advancements in Pharmacogenomics

Recent advancements in pharmacogenomics, the study of how an individual's genetic makeup influences their response to medications, have significantly increased the demand for molecular diagnostics. This emerging field of medicine is revolutionizing healthcare in several keyways. Pharmacogenomics allows for highly personalized medicine. By analyzing an individual's genetic profile, healthcare providers can gain insights into how a patient is likely to respond to a particular medication. This

information can help tailor treatment plans, ensuring that patients receive the most effective drugs at the right dosages while minimizing the risk of adverse reactions or inefficacy. Molecular diagnostics, such as genetic testing and next-generation sequencing, are essential tools in uncovering these genetic variations that influence drug metabolism and efficacy.

Pharmacogenomics has the potential to enhance patient safety. By identifying genetic variants that may cause severe adverse reactions to certain medications, healthcare providers can proactively avoid prescribing those drugs to patients at risk. This proactive approach reduces the likelihood of harmful side effects and improves patient outcomes.

Segmental Insights

Products and Services Insights

Based on the products and services, owing to the substantial cost of equipment and the need for frequent replacement or updates, the instruments category accounted for the largest revenue share of the market in 2022. The demand for molecular diagnostic tools is also projected to increase due to the growing prevalence of chronic diseases such as cancer, genetic disorders, and infectious diseases, necessitating more advanced diagnostic methods. During the forecast period, the reagents & kits segment is anticipated to exhibit the highest revenue growth. This growth can be attributed to the rising demand for companion diagnostics and personalized medicine, both of which require specially formulated reagents and kits for specific applications. The market for reagents and kits is also expected to expand with the introduction of novel and cost-effective diagnostic assays for infectious diseases, genetic disorders, and cancer.

The software segment is expected to experience significant expansion throughout the forecast period due to the increasing use of Laboratory Information Management Systems (LIMS) and electronic health record (EHR) systems. The integration of molecular diagnostic software with electronic medical records is anticipated to enable more precise and effective patient diagnosis and treatment. Moreover, the development of Artificial Intelligence (AI) and Machine Learning (ML) technologies is expected to fuel the expansion of molecular diagnostic software, enabling automated analysis of large datasets.

Application Insights

Based on the application segment, application-based divisions of the global molecular diagnostics market encompass infectious diseases, cancer, genetic testing, blood screening, and others. The infectious diseases segment is projected to lead the market in 2028 in terms of revenue share. This growth can be attributed to the increased prevalence of infectious diseases worldwide, particularly in underserved regions. The expanding market is driven by the growing demand for timely and accurate diagnosis of infectious diseases, aided by cutting-edge molecular diagnostic technologies such as PCR and NGS.

During the forecast period, the oncology segment is also expected to experience significant expansion. This can be attributed to the rising incidence of cancer worldwide and the growing need for personalized therapy. Molecular diagnostic techniques have revolutionized the field of oncology by providing precise and detailed information about the genetic makeup of tumors. These tests assist in determining the most effective treatment approach and monitoring treatment efficacy. The availability of immunotherapies and targeted treatments has further increased the demand for molecular diagnostics in oncology. The genetic testing segment is also anticipated to undergo substantial growth during the forecast period. This market is expanding due to the increasing demand for prenatal and newborn screening, as well as the rising prevalence of genetic diseases. The accessibility of advanced molecular diagnostic procedures like whole genome sequencing and gene editing technologies further fuels the expansion of the molecular diagnostics market.

Regional Insights

The North American region dominates the molecular diagnostic market, accounting for the largest revenue share. This can be attributed to the presence of a robust healthcare system, an aging population, and increasing R&D spending. Favorable government policies and growing public awareness of the benefits of molecular diagnostics are also expected to drive market growth in this region.

The Asia Pacific region is anticipated to experience significant expansion in the molecular diagnostics market. This is primarily driven by the increasing incidence of infectious diseases and the demand for personalized therapy in developing countries such as China and India. Furthermore, the adoption of advanced technologies such as Digital PCR and next-generation sequencing in this region is expected to facilitate market expansion.

Europe is projected to witness moderate growth in the molecular diagnostics industry.

The market in this region is expected to grow due to the rising need for early disease detection and the presence of well-established healthcare infrastructure in countries like Germany and the UK. Additionally, the increasing utilization of molecular diagnostic tests by pharmaceutical companies and research laboratories is expected to create new growth opportunities for market participants in this region.

Key Market Players

F Hoffmann-la Roche Ltd

Illumina Ltd

Hologic Corporation

Agilent Technologies Inc.

Qiagen NV

Grifols S.A.

Becton, Dickinson and Company

Abbott Laboratories, Inc.

Biomerieux SA

Bio-Rad Laboratories Inc.

Sysmex Corporation

Report Scope:

In this report, the Global Molecular Diagnostics Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Molecular Diagnostics Market, By Products and Services:

Reagents and Kits

Instruments

Services & Software

Molecular Diagnostics Market, By Technology:

Polymerase Chain Reaction (PCR)

Sequencing

In-situ hybridization

Chips and microarrays

Mass spectrometry

Others

Molecular Diagnostics Market, By Application:

Infectious disease

Oncology testing

Genetic testing

Blood screening

Others

Molecular Diagnostics Market, By End User:

Hospitals

Academic & Reference Laboratories

Others

Molecular Diagnostics Market, By Region:

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia-Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Kuwait

Turkey

Egypt

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Molecular Diagnostics Market.

Available Customizations:

Global Molecular Diagnostics market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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