

Molecular Diagnostics- Market Insights, Competitive Landscape and Market Forecast–2026

https://marketpublishers.com/r/M8326AD8A403EN.html

Date: January 2022

Pages: 100

Price: US\$ 4,750.00 (Single User License)

ID: M8326AD8A403EN

Abstracts

This report can be delivered to the clients within 7-10 Business Days

Molecular Diagnostic Market By Product Type (Instruments, Reagents And Others), By Technology (Polymerase Chain Reaction [PCR], Sequencing, In-Situ Hybridization, Microarray Analysis, And Others), By Application (Infectious Disease Diagnosis, Oncology Testing, Genetic Testing, Pharmacogenomics, Histology, And Others), By End-User (Hospitals, Pathology Labs, And Others), by geography, is expected to grow at a significant CAGR forecast till 2026 owing to the increase in incidence of infectious diseases and growing cases of cancer across the globe

The global molecular diagnostic market was valued at USD 9.56 billion in 2020, growing at a CAGR of 9.21% during the forecast period from 2021 to 2026, to reach USD 16.12 billion by 2026. The increase in demand for molecular diagnostic is primarily attributed to the growing incidence of infectious diseases such as the sudden outbreak of COVID-19 and the rising burden of cancers across the globe. Moreover, rapid technological advancement in the molecular diagnostic product arena and increasing demand for point-of-care diagnostics along with rising consumer awareness regarding quick diagnostics, among others are some of the key factors responsible for the molecular diagnostic market growth during the forecasted period.

Molecular Diagnostic Market Dynamics:

The market for the molecular diagnostic is gaining momentum at present owing to the surge in the worldwide occurrence of cancer cases among the population. This is because molecular tests are routinely utilized for the diagnosis of cancer and other infectious disease also. Also, molecular testing for cancer detection enables clinicians to



a personalized selection of cancer drugs based on the presence of actionable mutations. According to the statistics published by the Global Cancer Observatory (GLOBOCAN) in the year 2020, an estimated 19,292,789 new cancer cases were reported worldwide in the year 2020.

Additionally, the rising significance of liquid biopsy, molecular analysis in biological fluids such as blood, saliva, and urine for the detection of circulating tumor cells (CTC) and circulating tumor DNA (CtDNA) biomarkers is also expected to contribute to the market growth of molecular diagnostic products. For instance, on August 26, 2020, FDA approved liquid biopsy next-generation sequencing-based FoundationOne Liquid CDx test as a companion diagnostic to identify mutations in BRCA1 and BRCA2 genes in cell free-DNA isolated from plasma specimens of metastatic castration-resistant prostate cancer (mCRPC) patients.

Furthermore, rising cases of infectious diseases across the globe are also expected to raise the demand for molecular diagnosis to ensure an effective treatment. According to the 2021 data published by the UNAIDS, the Joint United Nations Programme on HIV/AIDS, an innovative joint venture of the United Nations family, approximately 37.7 million population globally were living with HIV and around 1.5 million new HIV cases were reported in the year 2020.

Additionally, product approval for the detection and differentiation of HIV infection for personalized management of patients with HIV will also bolster the molecular diagnostic market. For instance, on September 01, 2020, Roche received FDA approval for its first HIV-1/HIV-2 Qualitative Test on the Cobas 6800/8800 Systems. The test supports rapid molecular detection of acute HIV infection, confirms and differentiates HIV-1 and HIV-2 infections into one single test.

Thus, all the aforementioned factors are anticipated to augment the market for molecular diagnostics in the forthcoming years.

However, certain factors such as false-negative or false-positive results with some molecular diagnostic technology, and the high cost of the instruments are likely to impede the molecular diagnostic market growth.

The unprecedented COVID-19 pandemic has positively affected the molecular diagnostic market. This is owing to the increase in the demand for molecular testing across the globe for early detection of the infection. Moreover, the rise in emergency use authorizations (EUAs) for molecular diagnostic tests for SARS-CoV-2 has also led



to market growth during the pandemic crisis. For instance, in August 2020, MiraDx SARS-CoV-2 RT-PCR assay was approved by the US FDA for qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens. Also, in February 2020, the Logix Smart COVID-19 Test kit received CE marking approval which operates using a single step real-time reverse transcriptase polymerase chain reaction (RT-PCR) process in lower respiratory tract fluids.

Furthermore, rapid use of molecular diagnostic methods for detection of COVI-19 infection has also spiked the market for molecular diagnostic. According to the Indian Council of Medical Research 2021 data, approximately 63,59,24,763 samples have been tested for the novel coronavirus up to NOVEMBER 24, 2021.

Also, manufacturers have taken strategic development initiatives to introduce COVID-19 rapid tests to sustain their revenues and thus, nullifying the impact of COVID-19 on their operational capabilities.

Molecular Diagnostic Market Segment Analysis:

Molecular Diagnostic Market By Product Type (Instruments, Reagents and Others), By Technology (Polymerase Chain Reaction [PCR], Next Generation Sequencing, In-Situ Hybridization, Microarray Analysis, And Others), By Application (Infectious Disease Diagnosis, Oncology Testing, Genetic Testing, And Others), By End-User (Hospitals, Pathology Labs, And Others), and By Geography (North America, Europe, Asia-Pacific, and Rest of the World).

In the Molecular Diagnostic technology segment, the polymerase chain reaction (PCR) technology is anticipated to hold a significant market share during the forecasted period. This is because the sudden outbreak of the pandemic has increased the real-time reverse transcriptase-polymerase chain reaction (RT-PCR) test rate across the globe, as the technique is highly sensitive and specific and can deliver a reliable diagnosis of the infection in in as little as two to three hours.

Furthermore, partnerships among governmental organizations for the rapid detection and management of COVID-19 by using RT-PCR technology are further projected to bolster the demand for PCR technology-based products as well as its market during the forthcoming years.

For instance, in the year 2020, the International Atomic Energy Agency (IAEA) partnered with the United Nations Food and Agriculture Organization (FAO) to help



countries use real-time reverse transcription-polymerase chain reaction (real-time RT-PCR).

Furthermore, the increase in Emergency use Authorizations (EUA) test by the US FDA for the detection of COVID-19 will also contribute to the segmental growth. Recently, on November 10, 2021, Meridian Bioscience received FDA Emergency Use Authorization for Revogene® SARS-CoV-2 molecular assay which is a real-time RT-PCR test for the qualitative detection of RNA from COVID suspected patient's nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate nasal swab specimens.

Also, the benefits associated with multiplex PCR over conventional PCR methodologies and its wide application such as detection of cancer cells and other pathogens by amplifying analyzing gene expression are expected to spur the segmental growth of the molecular diagnostic market.

North America is expected to dominate the Overall Molecular Diagnostic Market:

Among all the regions, North America is expected to occupy a major share in the overall molecular diagnostic market during the forecasted period. This domination is owing to the growing burden of infectious disease in the region. Moreover, the rise in the incidence of cancer, the presence of key market players and leading national clinical laboratories, and growing demand for technologically advanced point-of-care diagnostics platforms, among others are expected to fuel the overall molecular diagnostic market in the region.

For instance, as per the data revealed by the Centres for Disease Control and Prevention (CDC) 2021, there were 37,377 people diagnosed with HIV in the US in the year 2018. Moreover, the data also revealed the new salmonella cases and Lyme disease cases in the region were 60,999 and 33,666 respectively in 2018.

Additionaly, as per the World Health Organization 2021 statistics, from 3 January 2020 to 24 November 2021, there have been 47,599,296 confirmed cases of COVID-19. Thus, rising pandemic cases in the region is likely to soar the molecular diagnostic market.

Also, the rapidly increasing burden of cancer in the region will contribute to the molecular diagnostic market in the region. According to the GLOBOCAN 2020 statistics, a total of 2,281,658 new cancer cases were reported in the US in the year 2020.



Furthermore, the rise in prevalence of congenital defects in the US is also anticipated to bolster the demand for molecular diagnosis thereby surging its market. According to the CDC 2020 data, about 3% of all the babies born in the US each year are affected with congenital defects.

Additionally, the presence of key manufacturers in the region and their strategic business activities will also contribute to the molecular diagnostic market growth. For instance, on March 27, 2020, Abbott received emergency use authorization (EUA) for its new Abbott ID NOW COVID-19 test, the fastest available molecular point-of-care test for the detection of COVID-19.

Hence, all the above-mentioned factors are projected to fuel the molecular diagnostic market in the country.

Further, the Europe and Asia Pacific regions have the future potential for the molecular diagnostic market. This is mainly due to the rising cases of various zoonotic and infectious diseases, increase in cancer burden in the region. According to the Australian Federation of AIDS Organisations (AFAO) 2019 statistics, there were about 29,045 people with HIV in Australia in the year 2019. Also, among the top five countries which were devastated by the COVID-19 pandemic due to high cases three were from APAC and Europe region with India being the second-worst affected along with the UK and Russia being in fourth and fifth position. Thus, the rising infectious disease burden in the regions will escalate the demand for molecular diagnosis. In addition, the presence of global as well as regional manufacturers such as Qiagen, Roche, Molbio Diagnostics Pvt. Ltd., among others active in developing the molecular diagnostic product. Also, improving healthcare infrastructure, and government initiatives in raising awareness regarding molecular diagnosis will contribute to the molecular diagnostic market growth in these regions.

Molecular Diagnostic Market Key Players:

Some of the key market players operating in the Molecular Diagnostic market include F. Hoffmann-La Roche Ltd, Hologic, Inc., bioM?rieux SA, Abbott, QIAGEN, Thermo Fisher Scientific Inc., Siemens Healthcare GmbH, Danaher., Myriad Genetics, Inc., Agilent Technologies Inc., Illumina, Inc., Becton, Dickinson and Company, DiaSorin Inc., MDxHealth., Genetic Signatures., Biocartis, Exact Sciences Corporation, Amoy Diagnostics Co., Ltd., Molbio Diagnostics Pvt. Ltd., Savyon Diagnostics, TBG Diagnostics Limited., Quidel Corporation, ELITechGroup, Seegene, Inc., Abacus Diagnostica Oy, and others.



Recent Developmental Activities in the Molecular Diagnostic Market:

In November 2021, Roche launched the cobas® 5800 System, a new molecular laboratory instrument, in countries accepting the CE mark.

In October 2021, Hologic has launched its molecular diagnostic system, Novodiag, for on-demand molecular testing in Europe. The system combines real-time polymerase chain reaction (PCR) with microarray capabilities to enable the identification of multiple pathogens in a single sample.

In March 2021, Materials and Machines Corporation (MatMaCorp) introduced its new handheld device MY Real-Time Analyzer (MYRTA), which can carry out polymerase chain reaction (PCR) amplification and real-time fluorescent detection.

Key Takeaways from the Molecular Diagnostic Market Report Study

- ? Market size analysis for current market size (2020), and market forecast for 5 years (2021-2026)
- ? The effect of the COVID-19 pandemic on this market is significant. To capture and analyze suitable indicators, our experts are closely watching the Molecular Diagnostic market.
- ? Top key product/services/technology developments, merger, acquisition, partnership, joint venture happened for last 3 years
- ? Key companies dominating the Global Molecular Diagnostic Market.
- ? Various opportunities available for the other competitor in the Molecular Diagnostic Market space.
- ? What are the top-performing segments in 2020? How these segments will perform in 2026.
- ? Which are the top-performing regions and countries in the current market scenario?



? Which are the regions and countries where companies should have concentrated on opportunities for Molecular Diagnostic market growth in the coming future?

Target Audience who can be benefited from the Molecular Diagnostic Market Report Study

- ? Molecular Diagnostic providers
- ? Research organizations and consulting companies
- ? Molecular Diagnostic-related organization, association, forum, and other alliances
- ? Government and corporate offices
- ? Start-up companies, venture capitalists, and private equity firms
- ? Distributors and Traders in Molecular Diagnostic
- ? Various End-users who want to know more about the Molecular Diagnostic Market and the latest technological developments in the Molecular Diagnostic market.

Frequently Asked Questions for the Molecular Diagnostic Market:

1. What is Molecular Diagnostic?

Molecular diagnostic tests use highly sensitive and specific laboratory methods to detect and identify biomarkers at the nucleic acid (DNA and RNA) level. Typical molecular-based applications include medical diagnosis, prognosis, disease monitoring, and optimal treatment.

2. What is the market for Global Molecular Diagnostic?

The global molecular diagnostic market was valued at USD 9.56 billion in 2020, growing at a CAGR of 9.21% during the forecast period from 2021 to 2026, to reach USD 16.12 billion by 2026.

3. What are the drivers for the Global Molecular Diagnostic?

The major factors driving the demand for molecular diagnostic are the rising cases of



infectious diseases such as Lyme diseases, COVID-19 pandemic, and others. In addition, technological advancement, increasing incidence of cancer across the globe, and rapid product approvals in the molecular diagnostic product arena are expected to augment the global molecular diagnostic market.

4. What are the key players operating in Global Molecular Diagnostic?

Some of the key market players operating in the Molecular Diagnostic market include F. Hoffmann-La Roche Ltd, Hologic, Inc., bioM?rieux SA, Abbott, QIAGEN, Thermo Fisher Scientific Inc., Siemens Healthcare GmbH, Danaher., Myriad Genetics, Inc., Agilent Technologies Inc., Illumina, Inc., Becton, Dickinson and Company, DiaSorin Inc., MDxHealth., Genetic Signatures., Biocartis, Exact Sciences Corporation, Amoy Diagnostics Co., Ltd., Molbio Diagnostics Pvt. Ltd., Savyon Diagnostics, TBG Diagnostics Limited., Quidel Corporation, ELITechGroup, Seegene, Inc., Abacus Diagnostica Oy, and others.

5. Which region has the highest share in the Molecular Diagnostic market?

Among all the regions, North America is expected to occupy a major share in the overall molecular diagnostic market during the forecasted period, 2021-2026. This domination is owing to the growing burden of infectious disease in the region. Moreover, the rise in the incidence of cancer, the presence of key market players and leading national clinical laboratories, and growing demand for technologically advanced point-of-care diagnostics platforms, among others are expected to fuel the overall molecular diagnostic market in the region.



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