

North America Molecular Diagnostics - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2025 - 2030)

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Report description:

The North America Molecular Diagnostics Market size is estimated at USD 11.52 billion in 2025, and is expected to reach USD 15.87 billion by 2030, at a CAGR of 6.63% during the forecast period (2025-2030).

COVID-19 had a profound impact on the studied market. Molecular diagnostics has been widely used in the past few years to detect COVID-19. Various market players were launching innovative point-of-care molecular diagnostics to meet the rising demand for rapid diagnostics of infectious diseases. For instance, in July 2022, BioGX, a global provider of easy molecular diagnostic solutions, launched a point-of-care (POC) CE-marked, three-gene multiplex COVID-19 test on its pixl platform. Also, in April 2021, Thermo Fisher Scientific Inc. was granted emergency use authorization (EUA) from the FDA for its amplitude solution with the TaqPath COVID-19 high-throughput combo kit, a tool for rapidly scaling high-sensitivity PCR testing. The growth of the molecular diagnostics market is slightly subsidized currently due to the decrease in the number of COVID -19 cases. However, the studied market is expected to report stable growth over the forecast period owing to the high demand for molecular diagnostics in multiple applications and technological advancements in molecular diagnostic products in the region.

The market is mainly driven by increasing demand for point-of-care diagnostics, recent advancements in pharmacogenomics, and large outbreaks of bacterial and viral epidemics.

The molecular diagnostics test must be precise, rapid, and also be able to measure the infectious burden. The increase in infectious diseases and cancer cases in the United States has led to trends shifting from traditional diagnostic methods to molecular diagnostics. For instance, according to data published by the American Academy of Pediatrics, in March 2022, more than 1 million people in the United States have long-term hepatitis B infections, and people who are infected with hepatitis B as a baby have a 90% chance of developing severe, chronic conditions like liver cancer in their lifetime. The identification of these

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diseases at an early stage has become easy using molecular tests, coupled with pharmacogenomics, which is expected to fuel market growth.

In situ hybridization is a growing technology in the molecular diagnostics branch that is used to locate and detect specific mRNA sequences in preserved tissue sections or cell preparations. The launches by several market players are expected to boost the availability of products for molecular diagnostics. For instance, in April 2021, BIO-TECHNE launched NOVEL DNASCOPE In Situ Hybridization assays for chromogenic detection of DNA copy numbers and structural variations. The RNAscope technology is an advanced in situ hybridization (ISH) assay that enables visualization of single-molecule gene expression with single-cell resolution directly in intact cells and tissues. The advancements in technology and product launches are expected to propel the usage of in situ hybridization for various applications such as genetic disease screening and cancer detection.

The strategic initiatives taken by the market players are also propelling the growth of the market. For instance, in February 2021, Bio-Rad Laboratories Inc. received EUA approval from the FDA for multi-target Reliance SARS-CoV-2, FluA, FluB, RT-PCR, and Reliance SARS-CoV-2 RT-PCR assay kits. The multi-target assay kit simultaneously detects and differentiates SARS-CoV-2, influenza A, and influenza B in a single multiplex reaction. Such launches are also expected to contribute to the growth of the market during the forecast period.

Therefore, owing to the aforementioned factors such as the high burden of infectious diseases, and the rising demand for molecular diagnostics leading to increasing product launches, the studied market is anticipated to witness growth over the analysis period. However, the stringent regulatory framework is likely to impede the market growth.

North American Molecular Diagnostics Market Trends

Oncology Segment Expected to Hold a Significant Market Share Over The Forecast Year

Oncology deals with the diagnosis and treatment of tumors and cancers. The segment's high growth is attributed to the rising burden of various types of cancer worldwide. Cancer is one of the leading causes of morbidity and mortality.

According to the American Cancer Society, cancer statistics 2022, 1,918,030 new cancer cases are predicted to occur in the United States in 2022. Breast cancer is estimated to be 290,560 new cases, leukemia with 60,650 new cases, and lymphoma with 89,010 new cases in the United States in 2022. Also, according to the Canadian Cancer Statistics November 2021 report, an estimated 2 in 5 Canadians were likely to be diagnosed with cancer in their lifetime. It stated that an estimated 229,200 Canadians was predicted to be diagnosed with cancer in 2021. Thus, the increasing burden of cancer and rising awareness among people for early cancer detection is estimated to increase the usage of molecular diagnostics over the forecast period.

The strategic initiatives adopted by market players in the region to expand molecular diagnostics products for oncology purposes are expected to fuel market growth. For instance, in November 2022, Roche received FDA approval for VENTANA FOLR1 (FOLR1-2.1) RxDx assay as the first IHC-based companion diagnostic to identify ovarian cancer patients eligible for ELAHERE. Such advancements and approvals are expected to boost segment growth during the forecast period.

Therefore, owing to the factors such as the high prevalence of cancer, the benefits of molecular diagnostics in cancer detection, and strategic initiatives adopted by market players are expected to augment the segment during the forecast period.

United States is Expected to Hold a Significant Market Share Over The Forecast Period

The United States is expected to hold a significant market share owing to factors such as the rising incidence of cancer and infectious diseases, better healthcare infrastructure, awareness among people and healthcare industry stakeholders about

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available technologies, and the strong presence of industry players in the region.

The spending on research studies in the country on various diseases involves the use of molecular diagnostics which is expected to propel market growth. For instance, according to the National Institutes of Health (NIH) 2022 update, research expenditure in the United States for genetic testing was USD 212 million in 2021 and USD 4,666 million for emerging infectious diseases in 2021. Thus, the high spending on the research of various diseases uses molecular diagnostics such as in-situ hybridization, sequencing, and PCR which is expected to augment the market growth in the country during the forecast period.

The strategic initiatives the market players take also propel the market segment's growth. For instance, in June 2022, one of the medical diagnostic companies Visby Medical raised funding of USD 135 million. Through this funding, Visby Medical planned to scale production capacity, increase the number of products it offers and bring PCR diagnostics to consumers' homes.

Also, in December 2022, Alercell, a United States-based start-up reported launching LENA Q51(R) in January 2023. It is a leukemia diagnostic test based on sequencing DNA that will detect up to 51 gene mutations in leukemia patients. The innovation in molecular diagnostics products and expansions through initiating funding for molecular diagnostics in the country is expected to propel the market growth in the country during the forecast period.

Therefore, the high utility of PCR in recent times for the diagnosis of various infectious diseases such as HIV, hepatitis, human papillomavirus, and multiple types of cancer along with the high prevalence of such diseases in the country is expected to propel the molecular diagnostics market growth in the United States during the forecast period.

North American Molecular Diagnostics Industry Overview

The North American molecular diagnostics market is moderately competitive due to the region's many local and global level companies. The international players in the market studied include Abbott Laboratories, Agilent Technologies, Becton, Dickinson and Company, Danaher Corporation (Cepheid Inc.), EXACT Sciences Corporation, F. Hoffmann-la Roche Ltd, Hologic Corporation, Illumina Inc., Myriad Genetics Inc., and Qiagen.

Additional Benefits:

- The market estimate (ME) sheet in Excel format
- 3 months of analyst support

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