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North America Point-of-Care Molecular Testing for Infectious Diseases Market Size and Forecast (2021-2031), Regional Share, Trend, and Growth Opportunity Analysis Report Coverage By: Diseases (HIV Testing, Influenza Testing, Sexually Transmitted Diseases Testing, Hepatitis C Virus Testing, Tropical Diseases Testing, Respiratory Infection Testing, Hospital Acquired Infections, Strep, Others), Technology (Lateral Flow Assay, Dipsticks, Microfluidics, Molecular Diagnostics, Immunoassays, Solid Phase, Others), Prescription Testing (Prescription Based Testing, OTC Testing), Sample (Blood Sample, Urine Sample, Nasal and Oropharyngeal Swabs Sample, Others), End User (Hospitals and Clinics, Home Care Settings, Ambulatory and Urgent Care Facilities, Nursing Home and Assisted Living Facilities, Research Laboratories, Diagnostics Centers), Distribution Channel (E-Com Platforms, Retail Channel and Pharmacies, Others), and Country

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Abstracts

The global North America point-of-care molecular testing for infectious diseases market is expected to reach US$ 2.63 billion in 2031 from US$ 1.09 billion in 2023. The market is estimated to grow with a CAGR of 11.1% from 2023 to 2031.

The North America point-of-care molecular testing for infectious diseases market forecast presented in this report can help stakeholders in this marketplace plan their growth strategies. The surging prevalence of infectious diseases and preference for rapid diagnostic solutions are the key factors propelling the market development. However, inadequate reimbursement scenarios impede the North America point-of-care molecular testing for infectious diseases market growth.

Market Opportunities of North America Point-Of-Care Molecular Testing For Infectious Diseases Market

Research and development (R&D) is an essential component of pharmaceutical and biopharmaceutical companies. R&D enables market players to develop new products for various therapeutic applications with significant medical and commercial potential. The following table displays the annual funding for various research and disease categories based on contracts, grants, and other funding mechanisms adopted by the NIH.

Table 1. Infectious Diseases and Fundings

Research/Disease Areas 2019 (US$ Million) 2020 (US$ Million) 2021 (US$ Million) 2022 (US$ Million)

Emerging Infectious Diseases 2,950 4,867 5,069 4,318

Infectious Diseases 6,313 8,301 8,599 8,019

Sexually Transmitted Infections 354 394 404 419

Note: The current conversion rate is considered for the currencies.

Source: Annual Reports and The Insight Partners Analysis

In response to the shortage of laboratory capabilities and molecular testing reagents, coupled with the rising cases of infectious diseases, diagnostic testing manufacturers offer fast and easy-to-use devices to facilitate out-of-laboratory testing. Following is a list of a few key funding initiatives undertaken by manufacturers in the North America point-of-care testing for infectious diseases market.

• In August, the US Department of Health and Human Services (HHS) awarded Cue Health a new contract worth ~US$ 28 million under the Biomedical Advanced Research and Development Authority (BARDA), a division of the Administration for Strategic Preparedness and Response. The contract was presented to develop a molecular multiplex test that can be used for point-of-care (POC) and over-the-counter (OTC) purposes for COVID-19, respiratory syncytial virus (RSV), and influenza A/B diagnoses. Cue's test would provide results to linked smart devices in nearly 25 minutes, simultaneously detecting and differentiating between COVID-19, respiratory syncytial virus (RSV), influenza A, and influenza B.

• In January 2023, 19 to Zero, a non-profit behavioral sciences initiative group, received financing from BD through an educational grant for a point-of-care testing pilot in the primary care environment. A financial award was accompanied by the provision of multiple BD Veritor Plus System Analyzers and BD Veritor System for Rapid Detection Assays to facilitate point-of-care diagnostic testing for influenza A and B, RSV, SARS-CoV-2, Group A Strep, and triplex.

• In March 2022, the Global Fund to Fight AIDS, Malaria, and Tuberculosis acclaimed the decision by Canada to contribute CAD 60 million (US$ 43.99 million) to the Global Fund’s COVID-19 Response Mechanism (C19RM). The funding was provided to support efforts made to provide life-saving diagnostic tests, treatments, and personal protective equipment (PPE) to low- and middle-income countries.

• In September 2021, the Biden-Harris Administration invested US$ 2.1 billion to enhance infection control and prevention activities across the US public health and healthcare sectors. The Biden-Harris administration, operating through the CDC, invested in US rescue programs to address state, local, and territorial health departments and other partner organizations regarding infectious diseases in the US.

Thus, rising focus on R&D and funding in infectious disease diagnostics is expected to create lucrative opportunities for the growth of North American point-of-care testing in the infectious disease market in the coming years.

Factor Hampering North American Point-Of-Care Testing In The Infectious Disease Market

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The possibility of reimbursement remains low if there exists data that does not indicate the cost-effectiveness of new tests or prove the existing tests are expensive. Thus, low reimbursement rates for most diagnostic tests discourage manufacturing companies from investing large resources in developing new tests. Difficulties and concerns about reimbursing new or expensive diagnostic tests pose significant challenges to the widespread deployment of diagnostic technologies. In the US, reimbursement comprises coverage by third-party payers coding health services or conditions to determine payment level. For outpatient tests with Current Procedural Terminology (CPT) codes, the Medicare Coverage Advisory Committee promotes the Centers for Medicare & Medicaid Services (CMS) regarding diagnostic test coverage, including determining sufficient evidence and health benefits. However, most Medicare reimbursement decisions are made locally and not nationally. Coverage for diagnostic tests differs as per region. Also, the lack of standards in determining coverage can challenge the development and availability of a new diagnostic product.

In some cases, the reimbursement does not cover test costs, which limits laboratories in offering the test and reduces test availability and use. In other cases, test charges may be high but may leave a considerable cost to the patient, which limits physicians from ordering the test routinely.

• Based on disease, the North America point-of-care molecular testing for infectious diseases market is divided into HIV testing, influenza testing, sexually transmitted diseases testing, hepatitis C virus testing, tropical diseases testing, respiratory infection testing, hospital-acquired infections, strep, and others. The market is further divided on the basis of molecular diagnostics into polymerase chain reactions (PCR), isothermal nucleic acid amplification technology (INAAT), and others. The respiratory infection testing segment held the largest market share in 2023.

• By technology, the market is segmented into lateral flow assay, dipsticks, microfluidics, molecular diagnostics, immunoassays, solid phase, and others. The lateral flow assay segment held the largest share of the market in 2023.

• In terms of sample, the market is segmented into blood samples, urine samples, nasal and oropharyngeal swabs, and others. The blood sample segment held the largest market share in 2023.

• In terms of end user, the market is segmented into hospitals and clinics, home care settings, ambulatory and urgent care facilities, nursing homes and assisted living facilities, research laboratories, and diagnostics centers. The market is further divided on the basis of hospitals and clinics into clinical laboratories, professional physician offices, and others. The hospitals and clinics segment held the largest market share in 2023.

North America Point-Of-Care Molecular Testing for Infectious Diseases Market: Regional Overview

The increasing prevalence of infectious diseases, the rising geriatric population, and a surging number of product launches by key players are the primary contributors to the point-of-care testing for infectious diseases market growth in the US. Aging is a prominent risk factor for infectious diseases, as people aged more than 60 may have compromised immunity. According to a study published by the Population Reference Bureau in 2020, the population of individuals aged 65 and above was 55 million in the US in 2020, and the number is expected to reach 95 million by 2060. Regulatory agencies in the US rigorously monitor the development of point-of-care (POC) testing products. For instance, in March 2021, the US Food Drug Administration (FDA) authorized Binx Health IO CT/NG Assay for community-based clinics, urgent care settings, and outpatient healthcare facilities; it is the first POC testing product for diagnosing chlamydial and gonorrheal infections.

A few of the major primary and secondary sources referred to while preparing the report on the North America point-of-care molecular testing for infectious diseases market are the World Bank Data, National Health Service (NHS), US Department of Health and Human Services (HHS), and WHO (World Health Organization).

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