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In-Vitro Diagnostic Market - North America and Country Analysis: Focus on Product, Test Type, Application, End User, and Country Analysis - Analysis and Forecast, 2025-2035

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Abstracts

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This report will be delivered in 7-10 working days.Introduction to North America In-Vitro Diagnostic Market

In-vitro diagnostics (IVD) refers to tests and procedures conducted outside the human body, typically in a laboratory setting, to diagnose diseases, conditions, or infections. These tests involve analyzing biological samples such as blood, urine, or tissue to provide valuable insights into a patient's health. IVDs are commonly used for detecting infections, monitoring chronic diseases, and assessing overall health, and they include tools like test kits, reagents, and diagnostic devices.

Several factors, including the rising prevalence of chronic diseases, technological advancements, and the shift toward personalized medicine, are driving the growth of the in-vitro diagnostics (IVD) market in North America. According to data published by the CDC in 2024, approximately 129 million people in the US have at least one major chronic disease, which has led to an increased adoption of IVD. Additionally, as reported by CRA International, Inc., around 3.3 billion IVD tests are performed annually in the US.

Innovation in IVD technologies is another key driver of market growth. The integration of next-generation sequencing (NGS), molecular diagnostics, and point-of-care (POC) testing has revolutionized the speed, accuracy, and convenience of diagnostic

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procedures. For instance, Thermo Fisher Scientific's Oncomine Dx Target Test is a NGS-based test that allows the detection of multiple cancer mutations in a single test, enabling more targeted treatment strategies. It helps doctors personalize treatment options for patients with advanced lung cancer, offering more effective therapies tailored to their specific genetic mutations.

Moreover, personalized medicine, which tailors treatments to individual genetic profiles, is gaining traction, and IVD plays a crucial role in this shift. The demand for genetic testing, biomarker detection, and molecular diagnostics is rising, enabling healthcare providers to offer more precise and effective treatment options. For example, Genomic Health's Oncotype DX test is used to personalize breast cancer treatment by assessing the risk of recurrence, highlighting the growing importance of IVD in personalized care.

In addition, regulatory agencies like the FDA in the U.S. have been instrumental in fostering the growth of the IVD market by providing clear guidelines and fast-tracking approvals for new diagnostic technologies. For instance, in August 2024, the FDA approved the first at-home, over-the-counter syphilis test developed by NOWDiagnostics. This test detects syphilis antibodies in about 15 minutes, identifying current or past infections. While it provides rapid results, confirmation through additional testing is required for a definitive diagnosis. The FDA believes that easier access to home tests could increase initial screening, especially for individuals hesitant to consult healthcare providers.

In the North American in vitro diagnostics (IVD) market, companies are actively engaging in product development, partnerships, and technological advancements to capitalize on the growing demand for advanced diagnostic solutions. For instance, Illumina, a leader in genomic sequencing, continues to expand its presence in the IVD space with new regulatory approvals. In 2024, the company received FDA approval for its NextSeq 1000/2000 Sequencing Systems, which enable rapid sequencing for genetic testing. These systems provide labs with the ability to detect a wide range of conditions, including cancer, inherited genetic disorders, and rare diseases, helping clinicians offer personalized treatment plans based on genomic data.

Key players in the market are Abbott Laboratories, Inc., Becton, Dickinson and Company, F. Hoffmann-La Roche, Illumina, Inc., Qiagen N.V., Thermo Fisher Scientific, Inc., Danaher Corporation, Laboratory Corporation of America Holdings, Siemens Healthineers, Inc., Bio-Rad Laboratories, Inc., DiaSorin S.p.A, Agilent Technologies, Inc.

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Market Segmentation:

Segmentation 1: by Product

- Instruments
- Consumables
- Software

Consumables to Lead the North America In-Vitro Diagnostics Market (by Product)

Consumables are dominating the North American IVD market due to their essential role in the daily operations of diagnostic laboratories, hospitals, and healthcare facilities. These products, including reagents, test kits, and disposables, are critical for the accurate and efficient functioning of diagnostic tests. For example, Abbott Laboratories and Roche Diagnostics offer a wide range of consumables, such as reagents for immunoassays and test strips for glucose monitoring, which are used extensively across healthcare settings in North America. As diagnostic testing continues to increase in demand, especially for chronic diseases like diabetes and cardiovascular conditions, the need for consumables has grown. Additionally, the shift towards point-of-care (POC) testing, including home-use diagnostic kits like OraQuick's at-home HIV test, has further boosted the demand for consumables. Their consistent use in routine diagnostic procedures makes them a significant and growing segment of the IVD market.

Segmentation 2: by Test Type

- Core Laboratory Diagnostics
- Point of Care Testing
- Molecular Diagnostics

Segmentation 3: by Application

- Diabetes

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Infectious Disease

Oncology/Cancer

Cardiology

Other Application

Segmentation 4: by End User

Hospitals and Clinics

Diagnostics Laboratories

Academic and Research Institutions

Others

Segmentation 5: by Country

U.S.

Canada

U.S. Region to Lead the North America In-Vitro Diagnostics Market (by Country)

The U.S. dominates the North America In-Vitro Diagnostics Market due to advanced healthcare infrastructure, robust regulatory framework, high healthcare spending, technological innovations, and a strong market presence of major diagnostic companies The U.S. is a global hub for innovation in IVD technologies. The presence of major companies such as Abbott Laboratories, Roche Diagnostics, Thermo Fisher Scientific, and Siemens Healthineers has fueled the development of advanced diagnostic platforms. For instance, Abbott's Alinity m Molecular Diagnostic System, which received FDA approval in 2024, is designed for high-throughput testing of infectious diseases such as HIV, hepatitis, and respiratory infections. This molecular platform enables healthcare providers to obtain accurate and timely results, helping clinicians manage

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chronic conditions like HIV and Hepatitis B & C with better precision and efficiency.

Moreover, personalized medicine is increasingly shaping the U.S. in vitro diagnostics (IVD) market, driving the demand for advanced genetic testing and molecular diagnostics. Leading U.S.-based companies such as Illumina and Thermo Fisher Scientific are at the forefront of providing next-generation sequencing (NGS) platforms for precision medicine. For example, Illumina's NovaSeq System, a high-throughput sequencer, is widely utilized by U.S. clinicians and researchers to analyze genetic data for various applications, including cancer genomics, rare genetic disorders, and pharmacogenomics. This system enables personalized treatment plans by providing detailed insights into genetic mutations, helping healthcare providers tailor interventions based on a patient's unique genetic makeup, thus enhancing treatment efficacy and patient outcomes.

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