# North America In-vitro Diagnostics Market Report and Forecast 2024-2032

Market Report | 2024-09-30 | 150 pages | EMR Inc.

**AVAILABLE LICENSES:**

- Single User License $3999.00
- Five User License $5299.00
- Corporate License $6299.00

**Report description:**

North America In-vitro Diagnostics Market Report and Forecast 2024-2032
The North America in-vitro diagnostics market is expected to grow at a CAGR of 3% during the period 2024-2032 driven by the increasing prevalence of chronic diseases across the region.
North America In-vitro Diagnostics Market Analysis
The North American in-vitro diagnostics (IVD) market is a significant segment of the global healthcare industry, encompassing a wide array of diagnostic tests and tools used to detect diseases, conditions, and infections. These diagnostics are crucial in the medical field, aiding in disease prevention, diagnosis, and treatment. The market includes various tests performed on blood, tissues, and other samples collected from the human body. The increasing prevalence of chronic diseases, advancements in diagnostic technologies, and rising awareness about early disease detection drive the market growth in this region.
Market Drivers
-Technological Advancements: The continuous innovation and development of new diagnostic technologies, such as next-generation sequencing (NGS), point-of-care testing, and molecular diagnostics, are significantly boosting the market. These advancements provide more accurate, efficient, and faster diagnostic results, improving patient outcomes.
-Increasing Prevalence of Chronic Diseases: The rising incidence of chronic diseases such as diabetes, cancer, and cardiovascular diseases necessitates early and accurate diagnostics. IVD plays a crucial role in early detection and monitoring of these conditions, thus driving the market growth.
-Growing Geriatric Population: An ageing population in North America is more susceptible to various diseases, thereby increasing the demand for diagnostic tests. The need for regular health check-ups and disease monitoring among the elderly fuels the IVD market.
-Government Initiatives and Funding: Supportive government policies and increased funding for healthcare research and diagnostics infrastructure contribute to market expansion. Initiatives aimed at improving healthcare access and quality further enhance market growth.
Challenges
-Regulatory Hurdles: The stringent regulatory requirements for the approval of new diagnostic tests can delay market entry and increase costs for manufacturers. Compliance with diverse regulatory standards across North America poses a significant

challenge.
-High Costs: The development and implementation of advanced diagnostic technologies involve substantial costs, making them expensive for end-users. High costs can limit the adoption of these tests, particularly in low-income populations.
-Data Privacy Concerns: The increasing use of digital technologies in diagnostics raises concerns about data privacy and security. Ensuring the confidentiality and protection of patient data is a critical challenge for market players.
-Limited Reimbursement: Inadequate reimbursement policies for certain diagnostic tests can hinder market growth. Limited coverage and low reimbursement rates can discourage patients from opting for advanced diagnostic procedures.
Future Opportunities
-Personalised Medicine: The growing trend towards personalised medicine, which tailors treatment plans based on individual genetic profiles, offers significant opportunities for the IVD market. Advances in genetic and molecular diagnostics will play a key role in this area.
-Point-of-Care Testing (POCT): The increasing demand for POCT, which allows for rapid and convenient diagnostic testing at or near the point of care, presents a major growth opportunity. POCT is particularly valuable in remote and underserved areas, enhancing healthcare accessibility.
-Integration of Artificial Intelligence (AI): The integration of AI and machine learning in diagnostics can revolutionise the IVD market. AI-powered tools can enhance diagnostic accuracy, predict disease outbreaks, and provide personalised treatment recommendations.
-Expansion in Emerging Markets: While North America remains a dominant player, expanding into emerging markets within the region, such as Mexico, offers growth potential. These markets have a growing need for advanced diagnostics due to improving healthcare infrastructure and rising healthcare awareness.
-Collaborations and Partnerships: Strategic collaborations between diagnostic companies, research institutions, and healthcare providers can foster innovation and accelerate the development and adoption of new diagnostic tests. Partnerships can also facilitate market entry and expansion.
North America In-vitro Diagnostics Market Trends
The North American in-vitro diagnostics (IVD) market is experiencing significant growth, driven by advancements in technology and a rising emphasis on early disease detection. This sector is witnessing several key trends that are shaping its future trajectory.
-Adoption of Next-Generation Sequencing (NGS): NGS is revolutionising the IVD market by providing detailed genetic information that aids in personalised medicine. This technology is increasingly being used for diagnosing complex genetic disorders, cancer, and infectious diseases, offering precise and comprehensive insights.
-Rise of Point-of-Care Testing (POCT): There is a growing demand for POCT due to its convenience, speed, and ability to deliver immediate results. This trend is particularly evident in rural and remote areas where access to traditional laboratory facilities is limited, improving patient care and health outcomes.
-Integration of Artificial Intelligence (AI) and Machine Learning: AI and machine learning are being integrated into diagnostic tools to enhance accuracy and efficiency. These technologies enable predictive analytics, automate complex data analysis, and support personalised treatment plans, leading to better patient management.
-Expansion of Home-Based Testing: The COVID-19 pandemic has accelerated the adoption of home-based diagnostic testing. Consumers are increasingly opting for at-home test kits for various conditions, including chronic disease monitoring and infectious disease detection, driven by convenience and safety concerns.
-Focus on Biomarker Discovery and Validation: There is a growing emphasis on discovering and validating new biomarkers for various diseases. This trend is crucial for the development of more specific and sensitive diagnostic tests, improving early detection and treatment outcomes.
North America In-vitro Diagnostics Market Segmentation
Market Breakup by Product Type
-Reagents and Kits
-Instruments
-Software and Services

The North American in-vitro diagnostics (IVD) market is segmented into reagents and kits, instruments, and software and services. Reagents and kits dominate due to their extensive use in diagnostic tests, driven by the rising prevalence of chronic diseases. Instruments are witnessing growth due to technological advancements and the increasing adoption of automated systems. Software and services are expanding rapidly, fuelled by the integration of AI and data analytics, enhancing diagnostic accuracy and efficiency. These segments collectively propel market growth, with a forecasted increase due to advancements in technology, rising healthcare awareness, and a growing emphasis on early disease detection.

Market Breakup by Technology
-Immunoassay/ Immunochemistry
-Clinical Chemistry
-Molecular Diagnostics
-Haematology
-Microbiology
-Blood Glucose Self-Monitoring
-Coagulation and Haemostasis
-Urinalysis
-Others

The North American in-vitro diagnostics (IVD) market is segmented by technology into immunoassay/immunochemistry, clinical chemistry, molecular diagnostics, haematology, microbiology, blood glucose self-monitoring, coagulation and haemostasis, urinalysis, and others. Immunoassays and immunochemistry lead due to their widespread application in disease detection and monitoring. Molecular diagnostics is growing rapidly, driven by advancements in genetic testing and personalised medicine. Clinical chemistry and haematology benefit from routine use in hospitals and laboratories. Blood glucose self-monitoring sees significant demand due to rising diabetes prevalence. The growth in these technologies is poised to drive market expansion, emphasising technological innovation and improved healthcare outcomes.

Market Breakup by Therapeutic Area
-Infectious Diseases
-Diabetes
-Cardiology
-Oncology
-Autoimmune Diseases
-Nephrology
-Others

The North American in-vitro diagnostics (IVD) market is segmented by therapeutic area into infectious diseases, diabetes, cardiology, oncology, autoimmune diseases, nephrology, and others. Infectious diseases dominate due to the ongoing need for rapid and accurate diagnostic tests, especially highlighted by the COVID-19 pandemic. Diabetes diagnostics see sustained demand driven by the high prevalence of the condition. Cardiology and oncology are experiencing growth due to advancements in biomarkers and personalised medicine approaches. Autoimmune diseases and nephrology segments are expanding as awareness and early diagnosis improve. These therapeutic areas collectively drive market growth, emphasising the importance of early and precise disease detection.

Market Breakup by End User
-Hospitals
-Laboratories

-Homecare
-Others

The North American in-vitro diagnostics (IVD) market is segmented by end user into hospitals, laboratories, homecare, and others. Hospitals dominate due to the high volume of diagnostic tests performed in these settings, driven by the need for accurate and timely disease diagnosis. Laboratories also hold a significant share, benefiting from advancements in automation and high-throughput technologies. Homecare diagnostics are rapidly growing, spurred by the increasing preference for convenient and cost-effective home-based testing, particularly for chronic disease management. These end-user segments collectively propel market growth, with innovations in technology and a focus on patient-centric care driving future expansion.

Market Breakup by Country
-United States
-Canada

The North American in-vitro diagnostics (IVD) market is segmented by country into the United States and Canada. The United States leads the market due to its advanced healthcare infrastructure, significant investments in research and development, and the presence of major IVD companies. The high prevalence of chronic diseases and the adoption of advanced diagnostic technologies further drive market growth. Canada, while smaller, is experiencing steady growth fueled by increasing healthcare spending, advancements in diagnostic technologies, and a growing focus on preventive healthcare. Both countries contribute to the overall market expansion, with innovations and healthcare improvements driving future growth.
North America In-vitro Diagnostics Market Competitive Landscape

The competitive landscape of the North American in-vitro diagnostics (IVD) market is robust, with key players including F. Hoffmann-La Roche Ltd, Becton, Dickinson and Company, Bio-Rad Laboratories, Inc., Siemens Healthineers AG, bioMerieux SA, Abbott Laboratories, Quidel Corporation, OraSure Technologies, Inc., Thermo Fisher Scientific Inc, Hologic, Inc., and Cepheid Inc (Danaher Corp.). These companies engage in various market activities such as mergers and acquisitions to expand their market presence and capabilities, extensive research initiatives to innovate and improve diagnostic solutions, and frequent product introductions to meet evolving healthcare needs. Strategic partnerships and collaborations are also common, facilitating advancements in technology and expanding the reach of diagnostic products. This dynamic environment fosters continuous growth and innovation within the IVD market, ensuring the development of cutting-edge diagnostic tools and enhanced healthcare outcomes.
Key Questions Answered in the Report
?What is the current and future performance of the North America In-vitro Diagnostics market?
?What are the main challenges facing the North America In-vitro Diagnostics market?
?What are the key drivers of the North America In-vitro Diagnostics market?
?What emerging trends are shaping the future of the North America In-vitro Diagnostics market?
?How is the trend towards personalised medicine influencing the development of companion diagnostics?
?Why do reagents and kits dominate the IVD market, and how are instruments evolving?
?How are molecular diagnostics, clinical chemistry, and haematology evolving in the IVD market?
?What factors are driving the sustained demand for diabetes diagnostics?
?Why do hospitals dominate the IVD market in terms of diagnostic test volumes?
Key Benefits for Stakeholders
?The industry report offers a comprehensive quantitative analysis of various market segments, historical and current market trends, market forecasts, and dynamics of the North America In-vitro Diagnostics market from 2017-2032.
?The research report provides the latest information on the market drivers, challenges, and opportunities in the North America In-vitro Diagnostics market.
?The study maps the leading, as well as the fastest-growing, regional markets. It further enables stakeholders to identify the key

country-level markets within each region.
?Porter's five forces analysis assists stakeholders in assessing the impact of new entrants, competitive rivalry, supplier power, buyer power, and the threat of substitution. It helps stakeholders to analyze the level of competition within the North America In-vitro Diagnostics industry and its attractiveness.
?The competitive landscape allows stakeholders to understand their competitive environment and provides insight into the current positions of key players in the market.

**Table of Contents:**


1Preface
1.1Objectives of the Study
1.2Key Assumptions
1.3Report Coverage - Key Segmentation and Scope
1.4Research Methodology
2Executive Summary
3 In-vitro Diagnostics Market Overview
3.1Global In-vitro Diagnostics Market
3.1.1Global In-vitro Diagnostics Market Historical Value (2017-2023)
3.1.2Global In-vitro Diagnostics Market Forecast Value (2024-2032)
3.2North America In-vitro Diagnostics Market
3.2.1North America In-vitro Diagnostics Market Historical Value (2017-2023)
3.2.2North America In-vitro Diagnostics Market Forecast Value (2024-2032)
4Vendor Positioning Analysis
4.1Key Vendors
4.2Prospective Leaders
4.3Niche Leaders
4.4Disruptors
5North America In-vitro Diagnostics Market Landscape*
5.1North America In-vitro Diagnostics: Developers Landscape
5.1.1Analysis by Year of Establishment
5.1.2Analysis by Company Size
5.1.3Analysis by Region
5.2North America In-vitro Diagnostics: Product Landscape
5.2.1Analysis by Product Type
5.2.2Analysis by Technology
5.2.3Analysis by Therapeutic Area
5.2.4Analysis by End User
6North America In-vitro Diagnostics Market Dynamics
6.1Market Drivers and Constraints
6.2SWOT Analysis
6.2.1Strengths
6.2.2Weaknesses
6.2.3Opportunities
6.2.4Threats
6.3PESTEL Analysis

6.3.1 Political
6.3.2 Economic
6.3.3 Social
6.3.4 Technological
6.3.5 Legal
6.3.6 Environment
6.4 Porter's Five Forces Model
6.4.1 Bargaining Power of Suppliers
6.4.2 Bargaining Power of Buyers
6.4.3 Threat of New Entrants
6.4.4 Threat of Substitutes
6.4.5 Degree of Rivalry
6.5 Key Demand Indicators
6.6 Key Price Indicators
6.7 Industry Events, Initiatives, and Trends
6.8 Value Chain Analysis
7 North America In-vitro Diagnostics Market: Trade Data Analysis (HS Code- 38220090)
7.1 Major Exporting Countries
7.1.1 By Value
7.1.2 By Volume
7.2 Major Importing Countries
7.2.1 By Value
7.2.2 By Volume
8 North America In-vitro Diagnostics Market Segmentation (2017-2032)
8.1 North America In-vitro Diagnostics Market (2017-2032) by Product Type
8.1.1 Market Overview
8.1.2 Reagents and Kits
8.1.3 Instruments
8.1.4 Software and Services
8.2 North America In-vitro Diagnostics Market (2017-2032) by Technology
8.2.1 Market Overview
8.2.2 Immunoassay/ Immunochemistry
8.2.3 Clinical Chemistry
8.2.4 Molecular Diagnostics
8.2.5 Haematology
8.2.6 Microbiology
8.2.7 Blood Glucose Self-Monitoring
8.2.8 Coagulation and Haemostasis
8.2.9 Urinalysis
8.2.10 Others
8.3 North America In-vitro Diagnostics Market (2017-2032) by Therapeutic Area
8.3.1 Market Overview
8.3.2 Infectious Diseases
8.3.3 Diabetes
8.3.4 Cardiology
8.3.5 Oncology
8.3.6 Autoimmune Diseases

8.3.7 Nephrology
8.3.8 Others
8.4 North America In-vitro Diagnostics Market (2017-2032) by End User
8.4.1 Market Overview
8.4.2 Hospitals
8.4.3 Laboratories
8.4.4 Homecare
8.4.5 Others
8.5 North America In-vitro Diagnostics Market (2017-2032) by Country
8.5.1 Market Overview
8.5.2 United States
8.5.3 Canada
9 United States In-vitro Diagnostics Market Segmentation (2017-2032)
9.1 United States In-vitro Diagnostics Market (2017-2032) by Product Type
9.1.1 Market Overview
9.1.2 Reagents and Kits
9.1.3 Instruments
9.1.4 Software and Services
9.2 United States In-vitro Diagnostics Market (2017-2032) by Technology
9.2.1 Market Overview
9.2.2 Immunoassay/ Immunochemistry
9.2.3 Clinical Chemistry
9.2.4 Molecular Diagnostics
9.2.5 Haematology
9.2.6 Microbiology
9.2.7 Blood Glucose Self-Monitoring
9.2.8 Coagulation and Haemostasis
9.2.9 Urinalysis
9.2.10 Others
9.3 United States In-vitro Diagnostics Market (2017-2032) by Therapeutic Area
9.3.1 Market Overview
9.3.2 Infectious Diseases
9.3.3 Diabetes
9.3.4 Cardiology
9.3.5 Oncology
9.3.6 Autoimmune Diseases
9.3.7 Nephrology
9.3.8 Others
9.4 United States In-vitro Diagnostics Market (2017-2032) by End User
9.4.1 Market Overview
9.4.2 Hospitals
9.4.3 Laboratories
9.4.4 Homecare
9.4.5 Others
10 Canada In-vitro Diagnostics Market Segmentation (2017-2032)
10.1 Canada In-vitro Diagnostics Market (2017-2032) by Product Type
10.1.1 Market Overview

10.1.2 Reagents and Kits
10.1.3 Instruments
10.1.4 Software and Services
10.2 Canada In-vitro Diagnostics Market (2017-2032) by Technology
10.2.1 Market Overview
10.2.2 Immunoassay/ Immunochemistry
10.2.3 Clinical Chemistry
10.2.4 Molecular Diagnostics
10.2.5 Haematology
10.2.6 Microbiology
10.2.7 Blood Glucose Self-Monitoring
10.2.8 Coagulation and Haemostasis
10.2.9 Urinalysis
10.2.10 Others
10.3 Canada In-vitro Diagnostics Market (2017-2032) by Therapeutic Area
10.3.1 Market Overview
10.3.2 Infectious Diseases
10.3.3 Diabetes
10.3.4 Cardiology
10.3.5 Oncology
10.3.6 Autoimmune Diseases
10.3.7 Nephrology
10.3.8 Others
10.4 Canada In-vitro Diagnostics Market (2017-2032) by End User
10.4.1 Market Overview
10.4.2 Hospitals
10.4.3 Laboratories
10.4.4 Homecare
10.4.5 Others
11 Regulatory Framework
11.1 Regulatory Overview
11.2 FDA
12 Patent Analysis
12.1 Analysis by Type of Patent
12.2 Analysis by Publication Year
12.3 Analysis by Issuing Authority
12.4 Analysis by Patent Age
12.5 Analysis by CPC Analysis
12.6 Analysis by Patent Valuation
12.7 Analysis by Key Players
13 Strategic Initiative
13.1 Analysis by Partnership Instances
13.2 Analysis by Type of Partnership
13.3 Analysis by Leading Players
13.4 Analysis by Geography
14 Supplier Landscape
14.1 Market Share Analysis, By Region (Top 5 Companies)

14.1.1 Market Share Analysis: North America
14.2 F. Hoffmann-La Roche Ltd
14.2.1 Financial Analysis
14.2.2 Product Portfolio
14.2.3 Demographic Reach and Achievements
14.2.4 Mergers and Acquisitions
14.2.5 Certifications
14.3 Becton, Dickinson and Company
14.3.1 Financial Analysis
14.3.2 Product Portfolio
14.3.3 Demographic Reach and Achievements
14.3.4 Mergers and Acquisitions
14.3.5 Certifications
14.4 Bio-Rad Laboratories, Inc .
14.4.1 Financial Analysis
14.4.2 Product Portfolio
14.4.3 Demographic Reach and Achievements
14.4.4 Mergers and Acquisitions
14.4.5 Certifications
14.5 Siemens Healthineers AG
14.5.1 Financial Analysis
14.5.2 Product Portfolio
14.5.3 Demographic Reach and Achievements
14.5.4 Mergers and Acquisitions
14.5.5 Certifications
14.6 bioMerieux SA
14.6.1 Financial Analysis
14.6.2 Product Portfolio
14.6.3 Demographic Reach and Achievements
14.6.4 Mergers and Acquisitions
14.6.5 Certifications
14.7 Abbott Laboratories
14.7.1 Financial Analysis
14.7.2 Product Portfolio
14.7.3 Demographic Reach and Achievements
14.7.4 Mergers and Acquisitions
14.7.5 Certifications
14.8 Quidel Corporation
14.8.1 Financial Analysis
14.8.2 Product Portfolio
14.8.3 Demographic Reach and Achievements
14.8.4 Mergers and Acquisitions
14.8.5 Certifications
14.9 OraSure Technologies, Inc .
14.9.1 Financial Analysis
14.9.2 Product Portfoliozz
14.9.3 Demographic Reach and Achievements

14.9.4 Mergers and Acquisitions
14.9.5 Certifications
14.10 Thermo Fisher Scientific Inc
14.10.1 Financial Analysis
14.10.2 Product Portfolio
14.10.3 Demographic Reach and Achievements
14.10.4 Mergers and Acquisitions
14.10.5 Certifications
14.11 Hologic, Inc .
14.11.1 Financial Analysis
14.11.2 Product Portfolio
14.11.3 Demographic Reach and Achievements
14.11.4 Mergers and Acquisitions
14.11.5 Certifications
14.12 Cepheid Inc (Danaher Corp .)
14.12.1 Financial Analysis
14.12.2 Product Portfolio
14.12.3 Demographic Reach and Achievements
14.12.4 Mergers and Acquisitions
14.12.5 Certifications
15 North America In-vitro Diagnostics Market - Distribution Model (Additional Insight)
15.1 Overview
15.2 Potential Distributors
15.3 Key Parameters for Distribution Partner Assessment
16 Key Opinion Leaders (KOL) Insights (Additional Insight)
*Additional insights provided are customisable as per client requirements.

* The coverage of the Market Landscape section depends on the data availability and may cover a minimum of 80% of the total market. The EMR team strives to make this section as comprehensive as possible.
**The supplier list is not exhaustive. Moreover, we can provide analysis of companies as per custom requests.

SCOTTS INTERNATIONAL

# North America In-vitro Diagnostics Market Report and Forecast 2024-2032

Market Report | 2024-09-30 | 150 pages | EMR Inc.

To place an Order with Scotts International:

- - Print this form
- - Complete the relevant blank fields and sign
- - Send as a scanned email to support@scotts-international.com

**ORDER FORM:**

| Select license | License | Price |
|---|---|---|
| | Single User License | $3999.00 |
| | Five User License | $5299.00 |
| | Corporate License | $6299.00 |
| | VAT | |
| | Total | |

*Please circle the relevant license option. For any questions please contact support@scotts-international.com or 0048 603 394 346.

** VAT will be added at 23% for Polish based companies, individuals and EU based companies who are unable to provide a valid EU Vat Numbers.

| | | | |
|---|---|---|---|
| Email* | | Phone* | |
| First Name* | | Last Name* | |
| Job title* | | | |
| Company Name* | | EU Vat / Tax ID / NIP number* | |
| Address* | | City* | |
| Zip Code* | | Country* | |
| | | Date | 2025-05-04 |
| | | Signature | |