

United States In Vitro Diagnostics Market Report and Forecast 2025-2034

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Report description:

The United States in vitro diagnostics market was valued at USD 19.84 Billion in 2024, driven by the increasing adoption of advanced molecular diagnostics and the growing prevalence of chronic diseases across the region. The market is anticipated to grow at a CAGR of 6.30% during the forecast period of 2025-2034, with the values likely to reach USD 36.55 Billion by 2034. The market is growing due to a robust healthcare infrastructure and continuous technological innovation. Additionally, growing demand for rapid, accurate testing fuels market expansion during the forecast period.

United States In Vitro Diagnostics Market Overview

In vitro diagnostics (IVD) encompass tests performed on biological samples, such as blood or tissue, outside the human body to detect diseases, infections, or medical conditions. These tests play a crucial role in clinical decision-making by delivering accurate and timely results. The in vitro diagnostics market in the United States was valued at USD 19.84 Billion in 2024 and is driven by rapid technological advancements, growing prevalence of chronic diseases, and increasing healthcare awareness. The market is growing due to robust demand for innovative diagnostic solutions and ongoing product development across the healthcare industry.

United States In Vitro Diagnostics Market Growth Drivers

Rapid Diagnostic Launches to Strengthen the In Vitro Diagnostics Market Growth in the United States

The introduction of innovative diagnostic products is driving the market growth. For instance, in August 2024, InBios International launched the Strongy Detect IgG ELISA. It is a rapid serological test for the diagnosis of strongyloidiasis, delivering results in under 75 minutes. As a CLIA-classified test for high-complexity labs, this launch addresses critical diagnostic gaps and supports market expansion through improved infectious disease detection.

United States In Vitro Diagnostics Market Trends

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The market is experiencing key trends such as the approval of advanced genomic diagnostics and the expansion of diagnostic access through decentralized molecular testing collaborations.

Approval of Advanced Genomic Diagnostics Set to Enhance Market Expansion

A major market trend includes an increase in the approval of advanced genomic testing tools that improve cancer diagnostics and personalized treatment. For instance, in January 2025, Tempus AI received FDA approval and launched its xT CDx test nationwide. This 648-gene next-generation sequencing assay enhances solid tumor profiling. Such regulatory milestones are expected to accelerate innovation and drive market expansion.

Preference for Decentralized Molecular Testing to Enhance United States In Vitro Diagnostics Market Demand

The market is witnessing a strategic shift towards decentralized molecular testing to improve access and turnaround times. For instance, in November 2023, Veracyte Inc., announced a multi-year agreement with Illumina to develop decentralized IVD tests using Illumina's NextSeq 550Dx NGS platform. This collaboration is poised to expand global access to Veracyte's high-performing oncology tests. Such innovations are expected to significantly boost market growth.

United States In Vitro Diagnostics Market Segmentation

The market report offers a detailed analysis of the market based on the following segments:

Market Breakup by Product & Services

- Reagents and Kits
- Instruments
- Software and Services

Market Breakup by Technology

- Immunodiagnosics
 - ??- Enzyme-Linked Immunosorbent Assay (ELISA)
 - ??- Enzyme-Linked Immunospot (ELISPOT)
 - ??- Rapid Tests
 - ??- Radioimmunoassay (RIA)
 - ??- Western Blotting
 - ??- Others
- Clinical Chemistry
 - ??- Basic Metabolic Panels
 - ??- Liver Panels
 - ??- Renal Profiles
 - ??- Lipid Profiles
 - ??- Thyroid Function Panels
 - ??- Electrolyte Panels
 - ??- Specialty Chemical Tests

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- Molecular Diagnostics
- ??- Polymerize Chain Reaction (PCR)
- ??- Isothermal Nucleic Acid Amplification Technology (INAAT)
- ??- Hybridization
- ??- DNA Diagnostics
- ??- Microarray
- ??- Others

- Hematology
- Microbiology
- Coagulation and Haemostasias
- Urinalysis
- Others

Market Breakup by Application

- Infectious Diseases
- Diabetes
- Oncology
- Cardiology
- Drug Testing/Pharmacogenomics
- HIV/AIDS
- Autoimmune Diseases
- Nephrology
- Others

Market Breakup by End User

- Hospitals
- Diagnostic Centers
- Point-of-Care Testing
- Academic Institutes
- Others

United States In Vitro Diagnostics Market Share

Immunodiagnosics to Dominate the Market by Technology

In the evolving landscape of diagnostic technologies, immunodiagnosics is emerging as the frontrunner in the market. Apart from immunodiagnosics, the market is segmented into clinical chemistry, molecular diagnostics, hematology, microbiology, coagulation and haemostasias, urinalysis, and others. Immunodiagnosics stands out due to its precision, adaptability, and expanding role in detecting complex conditions. A notable example is Quest Diagnostics' AAVrh74 ELISA assay, which received FDA Breakthrough Device Designation in August 2023, reinforcing the segment's pivotal role in advancing personalized medicine.

Leading Players in the United States In Vitro Diagnostics Market

The key features of the market report comprise patent analysis, funding and investment analysis, and strategic initiatives by the

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leading players. The major companies in the market are as follows:

bioMerieux SA

bioMerieux SA, established in 1963 and headquartered in Marcy l'Etoile, France, is a global leader in in vitro diagnostics. In January 2025, it expanded its presence in the IVD market by acquiring SpinChip Diagnostics, a company specializing in rapid, high-sensitivity immunoassay platforms for point-of-care testing. This acquisition enhances bioMerieux's offerings with fast, precise cardiac biomarker tests, advancing acute care diagnostics.

Sysmex Corporation

Founded in 1968 and headquartered in Kobe, Japan, Sysmex Corporation is a key player in the in vitro diagnostics market. In August 2024, the company broadened its partnership with QIAGEN to advance genetic testing, emphasizing precision medicine and liquid biopsy technologies. Sysmex leverages its state-of-the-art laboratories in both Japan and the United States to support clinical trials and drive innovation in diagnostic testing.

Thermo Fisher Scientific Inc.

Thermo Fisher Scientific Inc. is a global leader in scientific services, headquartered in Waltham, Massachusetts. In October 2023, the company gained prominence through its partnership with Boehringer Ingelheim to develop companion diagnostics (CDx) for non-small cell lung cancer. This includes the Oncomine Dx Express Test and Genexus Dx System, offering rapid and precise genomic testing to support targeted therapies. Thermo Fisher's continued innovation strengthens its critical role in advancing precision oncology diagnostics across U.S. healthcare settings.

QIAGEN

QIAGEN is headquartered in Venlo, Netherlands, was founded in 1984. In August 2023, the company gained FDA approval for its therascreen PDGFRA RGQ PCR kit, a companion diagnostic to identify PDGFRA D842V mutations in gastrointestinal stromal tumors. This approval strengthens QIAGEN's presence in the market and highlights its leadership in precision medicine.

Other key players in the market include F. Hoffmann-La Roche Ltd., Bio-Rad Laboratories, Inc., Abbott, Quidel Corporation, and Danaher Corporation.

Key Questions Answered in the United States In Vitro Diagnostics Market Report

- What was the United States in vitro diagnostics market value in 2024?
- What is the United States in vitro diagnostics market forecast outlook for 2025-2034?
- What major factors aid the United States in vitro diagnostics market demand?
- How has the market performed so far, and how is it anticipated to perform in the coming years?
- What are the market's major drivers, opportunities, and restraints?
- What are the major trends in the United States in vitro diagnostics market?
- Which product & services is expected to dominate the market segment?
- Which technology is projected to lead the market segment?
- Which application is anticipated to drive the market segment?
- Which end user is likely to dominate the market segment?
- Who are the key players involved in the United States in vitro diagnostics market?
- What are the current unmet needs and challenges in the market?

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- How are partnerships, collaborations, mergers, and acquisitions among the key market players shaping the market dynamics?

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