

In-Vitro Diagnostics Market Poised for 6.2% CAGR Growth Through 2032, Notes Persistence Market Research

The in-vitro diagnostics market is growing with advances in molecular testing, precision medicine, and rapid point-of-care solutions driving globally

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/EINPresswire.com/ -- The global [in-vitro diagnostics \(IVD\) market](#) is projected to grow significantly from an estimated value of US\$ 77.4 billion in 2025 to US\$ 117.9 billion by 2032, registering a CAGR of 6.2% during the

forecast period. This expansion is fueled by rising investments in precision medicine, increasing patient awareness, and global health policies prioritizing early disease detection. The market is also witnessing an ongoing transition from centralized lab diagnostics to decentralized and patient-centric models, amplified by the integration of digital technologies, molecular diagnostics, and AI-driven test platforms.

IVD plays a critical role in clinical decision-making by providing actionable insights through the analysis of biological specimens such as blood, urine, and tissue samples. The continued innovation in reagents, automation, and real-time analytics is redefining the diagnostic landscape, making IVD indispensable in routine testing and complex disease profiling.

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Key Industry Highlights

Governments across regions are embedding national screening programs for diseases such as HIV, HPV, hepatitis, and tuberculosis, sustaining the volume of diagnostic tests and fostering accessibility. The direct-to-consumer (DTC) diagnostics trend is transforming healthcare delivery by empowering patients to engage directly in health monitoring. Collaborations between IVD



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Research Report On

In-vitro Diagnostics (IVD) Market

Forecast (2025-2032)

The Ultimate & Practical Overview

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in-vitro diagnostics (IVD) market

manufacturers and pharmaceutical companies are expanding the companion diagnostics ecosystem, particularly in oncology and immunotherapy.

Reagents continue to dominate product revenues due to the need for frequent replenishment and customization across test types, expected to hold 66.4% market share in 2025.

Immunoassays, driven by their high sensitivity and broad clinical applicability, are steadily gaining preference among healthcare providers.

Market Dynamics

Driver – Rising Burden of Chronic and Genetic Disorders

The IVD market is experiencing upward momentum due to the increasing global prevalence of chronic illnesses such as diabetes, cardiovascular diseases, and neurodegenerative conditions. The growing recognition of genetic disorders like Turner syndrome and Alzheimer's disease further underscores the need for early, accurate, and frequent diagnostic intervention.

For instance, the launch of the PrecivityAD2 blood test by C2N Diagnostics in 2023 offers a non-invasive solution for Alzheimer's diagnostics by detecting amyloid plaque and tau proteins. Similarly, research on IVD markers for Parkinson's disease—such as misfolded alpha-synuclein—illustrates the potential of blood-based and cerebrospinal fluid-based diagnostics to replace costly and less accessible imaging-based methods.

Restraint – Pricing Barriers and Diagnostic Gaps Hinder Reach

Despite the benefits, the affordability and scalability of advanced IVD solutions remain significant challenges. High costs associated with specialized assays, digital PCR platforms, and molecular profiling tests limit adoption in low- and middle-income economies. A single genomic test for cancer diagnostics can exceed US\$ 5,000, placing it out of reach for many health systems.

In addition, diagnostic gaps persist due to physiological complexities that in-vitro systems cannot fully replicate. False negatives and limited clinical context can affect the reliability of test results, particularly in complex pathologies requiring multi-marker validation. Infrastructure limitations in developing markets further hinder large-scale implementation of IVD technologies.

Opportunity – Decentralized and Rapid Testing Trends

Decentralized diagnostics present a transformative opportunity for the IVD market, aligning with the demand for fast, scalable, and patient-centric solutions. Point-of-care (PoC) platforms, such as Abbott's ID NOW, which delivers results within 13 minutes, highlight the growing demand for real-time molecular testing across both clinical and non-clinical settings.

Emerging solutions in microfluidics and lab-on-a-chip devices are enabling IVD in locations

previously underserved by traditional labs. Startups and med-tech innovators are focusing on multiplexed, portable diagnostics that combine speed and sensitivity with affordability. For example, LumiraDx's PoC immunoassay platform is expanding the scope of near-patient testing, especially in rural or resource-constrained environments.

Category-wise Analysis

Product Type Insights

The IVD market is segmented by product type into instruments, reagents, and others. Reagents are forecast to dominate the market with a 66.4% share in 2025, driven by their recurring use across molecular, immunoassay, and microbiology platforms. High-throughput screening and precision testing are increasing demand for specialized reagent kits tailored for specific diseases.

Instruments are witnessing growth through increased adoption of automation and modular testing platforms. High-end analyzers with LIS integration, real-time diagnostics, and minimal manual intervention are being adopted by hospitals and diagnostic chains. In emerging markets, compact, portable analyzers are gaining traction amid growing investment in public health labs.

Technology Insights

By technology, the market comprises immunoassay, clinical chemistry, molecular diagnostics, hematology, microbiology, coagulation, and others. Immunoassay leads the segment with an anticipated 35.6% share in 2025 due to its high sensitivity, broad diagnostic scope, and compatibility with automation. These tests are widely used in hormone profiling, fertility tracking, infectious disease diagnostics, and oncology.

Coagulation diagnostics are gaining prominence due to rising cardiovascular diseases and bleeding disorders. Increasing demand for aPTT and D-dimer testing in both outpatient and critical care settings is boosting the need for accurate and responsive coagulation platforms.

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Regional Insights

North America

North America is poised to capture 48.2% of the global market in 2025, led by the U.S., with its advanced healthcare infrastructure, rapid adoption of molecular diagnostics, and favorable reimbursement systems. Home-based and decentralized testing solutions are increasingly integrated into chronic disease management, particularly for oncology and metabolic

disorders.

Recent innovations such as Roche's Digital LightCycler and Thermo Fisher's Genexus System underscore the region's commitment to advancing NGS, real-time PCR, and automated sequencing platforms. These technologies are enhancing diagnostic speed and reducing turnaround time from sample collection to report generation.

Europe

Europe is undergoing structural changes due to the implementation of the In Vitro Diagnostic Regulation (IVDR), effective since May 2022. The new conformity assessment has disrupted smaller manufacturers, many of whom have paused product development due to increased certification costs. However, this regulatory realignment is enabling larger players to consolidate their market positions through compliance-ready portfolios.

Germany, France, and Nordic nations are advancing precision diagnostics through public-private collaborations. Germany's diagnostic ecosystem is supported by state-backed initiatives in Berlin and Munich, while Scandinavian countries are leveraging national health databases to integrate diagnostics with personalized care strategies.

Asia Pacific

Asia Pacific is becoming a strategic growth hub due to increasing healthcare investments, rapid diagnostics infrastructure upgrades, and strong government support. China is fostering local manufacturing to reduce reliance on imported reagents and equipment, with CE-marked kits now entering Western markets. India's fragmented yet high-growth market is witnessing local innovation through companies like Molbio Diagnostics, whose Truenat platform is now being repurposed for multiple diseases.

National health initiatives like India's Digital Health Mission are improving interoperability and data flow between labs and hospitals, enhancing the role of diagnostics in public healthcare. Other countries, including Thailand and Vietnam, are building diagnostic ecosystems through PPP models and medical tourism.

Competitive Landscape

The IVD market is characterized by a competitive mix of multinational corporations, mid-sized innovators, and regional manufacturers. Key players are accelerating their focus on molecular diagnostics, companion diagnostics, and point-of-care testing to align with evolving clinical and patient needs. Strategic partnerships, acquisitions, and regulatory readiness are key pillars of competitive advantage.

Diagnostic firms are collaborating with pharmaceutical companies to develop companion

diagnostics that facilitate precision medicine, especially in oncology and autoimmune therapies. These partnerships help identify patient subpopulations best suited for targeted treatments, thus improving therapeutic outcomes and reducing healthcare costs.

Key Players

Abbott Laboratories
Siemens Healthineers AG
Bio-Rad Laboratories, Inc.
F. Hoffmann-La Roche Ltd.
Quidel Corporation
QIAGEN
Becton, Dickinson and Company
Danaher
BIOMÉRIEUX
Agilent Technologies, Inc.
Quest Diagnostics Incorporated

These players are expanding their product portfolios, investing in automation and AI-based platforms, and entering emerging markets to boost revenue growth. Digital integration and remote diagnostic capabilities are central to their product development strategies.

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Recent Developments

In May 2025, Diagnostics.ai introduced the industry's first transparent machine learning platform tailored for real-time PCR diagnostics, addressing compliance challenges under the IVDR framework. The platform improves diagnostic reproducibility and algorithm explainability—critical under new EU guidelines.

Also in May 2025, Nepal launched its National Essential In-vitro Diagnostics List (NEIDL), a milestone in its public health reform, with support from WHO and The Pandemic Fund. The initiative included the deployment of critical diagnostic equipment and standardized reagent kits for national labs.

Market Segmentation

By Product Type

Instruments
Reagents
Others

By Technology

- Immunoassay
- Hematology
- Clinical Chemistry
- Molecular Diagnostics
- Coagulation
- Microbiology
- Others

By Test

- Point-of-care
- Home Care
- Others

By Application

- Infectious Diseases
- Diabetes
- Oncology
- Cardiology
- Nephrology
- Autoimmune Diseases
- Drug Testing
- Others

By End-use

- Hospitals
- Laboratories
- Home Care
- Others

By Region

- North America
- Europe
- East Asia
- South Asia and Oceania
- Latin America
- Middle East and Africa

Future Outlook

Between 2025 and 2032, the IVD market is expected to evolve rapidly under the influence of personalized healthcare, regulatory convergence, and digital transformation. The move toward home-based and decentralized testing will accelerate product innovation, especially in PoC and wearable diagnostics. AI and machine learning will increasingly be embedded into diagnostic platforms to enable predictive analytics and improve clinical outcomes.

Emerging markets will play a key role in driving volume, while developed economies will lead in technological sophistication. With healthcare systems increasingly leaning on diagnostics for preventive care and early intervention, IVD is poised to remain a cornerstone of next-generation healthcare delivery.

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