

In-Vitro Diagnostics Market to Cross USD 216.9 Billion by 2035, Expanding at 6.1% CAGR from 2025 | TMR

Global in-vitro diagnostics market valued at US\$ 113.3 Bn in 2024, forecasted to grow at 6.1% CAGR and surpass US\$ 216.9 Bn by 2035.

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EINPresswire.com/ -- The role of diagnostics in healthcare has never been more important. From early detection of cancer to monitoring infectious diseases, diagnostics shape clinical decision-making, enable personalized medicine, and improve patient outcomes. In-vitro diagnostics (IVD)—tests performed on samples such as blood, saliva, or tissue outside the human body—are at the core of this healthcare revolution.



The global [in-vitro diagnostics market](#) was valued at US\$ 113.3 billion in 2024 and is projected to expand at a CAGR of 6.1% from 2025 to 2035, surpassing US\$ 216.9 billion by 2035. This growth trajectory reflects not only rising disease burdens but also breakthroughs in molecular diagnostics, point-of-care testing (POCT), next-generation sequencing (NGS), and AI-enabled platforms.

As healthcare systems worldwide shift toward preventive, personalized, and value-based care, IVD has become a strategic enabler of improved clinical outcomes and reduced healthcare costs. Despite regulatory and cost challenges, the long-term outlook for IVD remains robust.

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Analysts' Viewpoint

The IVD market is evolving rapidly under the combined forces of technology convergence, patient-centric care, and global health challenges. Analysts highlight several defining trends:

Chronic & Infectious Disease Burden – Chronic diseases such as diabetes, cardiovascular illnesses, and cancer are rising globally. Simultaneously, infectious diseases—COVID-19, tuberculosis, HIV, and re-emerging pathogens—underscore the need for rapid, reliable diagnostics.

Technological Leapfrogging – Molecular diagnostics, NGS, POCT, and at-home testing are advancing accessibility, accuracy, and speed. Artificial intelligence and digital platforms are improving interpretation, enabling decentralized diagnostics, and integrating data into care pathways.

Personalized Medicine Adoption – As oncology, cardiology, and infectious disease treatments become more targeted, companion diagnostics and pharmacogenomics are reshaping therapy pathways.

Expanding Access in Emerging Markets – Governments in Asia-Pacific, Latin America, and Africa are investing in healthcare infrastructure, creating new markets for diagnostic kits, reagents, and instruments.

Regulatory and Cost Challenges – Stringent frameworks like EU's IVDR and the FDA's evolving stance on laboratory-developed tests (LDTs) create compliance hurdles. High implementation costs and shortages of skilled professionals add complexity.

Despite these barriers, analysts agree that the diagnostic industry's resilience and innovation pipelines position it for long-term growth.

Market Introduction

In-vitro diagnostics (IVD) involve medical tests performed on human samples to detect diseases, conditions, or infections. They include a broad spectrum of technologies and tools, ranging from simple glucose meters to advanced genomic sequencing platforms.

Key uses of IVD include:

Disease detection and monitoring – e.g., detecting infections, cancer, cardiovascular disease.

Precision medicine – identifying genetic markers to guide therapy choices.

Public health strategies – screening for pandemics, managing outbreaks, and population health surveillance.

Self-testing and preventive health – consumer-based at-home diagnostics for chronic conditions or early screening.

IVD has transformed from laboratory-bound processes into decentralized, accessible, and consumer-friendly solutions. This evolution aligns with global healthcare trends toward early intervention, patient empowerment, and preventive medicine.

Market Drivers

Rising Prevalence of Chronic and Infectious Diseases

The world faces a dual burden: chronic disease prevalence and recurring infectious outbreaks.

Chronic conditions: Aging populations, poor diet, and sedentary lifestyles contribute to higher cases of diabetes, cardiovascular disorders, and cancer. For instance, the CDC reported in 2024 that 6 in 10 Americans live with at least one chronic disease, while 4 in 10 have two or more.

Infectious diseases: COVID-19 highlighted vulnerabilities in diagnostics. Tuberculosis, hepatitis, and sexually transmitted infections (STIs) remain global challenges, with 2.5 million STI cases recorded in the U.S. in 2022.

These trends make timely, accurate diagnostics a cornerstone of modern healthcare.

Growing Demand for Early, Accurate, and Non-Invasive Diagnostic Tools

Patients and providers increasingly prefer non-invasive, rapid diagnostic tests. Advances in microfluidics and molecular biology allow minimal samples—such as saliva or a single blood drop—to provide accurate results.

This demand is especially high in oncology and infectious diseases, where early detection drastically improves treatment outcomes. Point-of-care solutions and home-based kits are expanding this accessibility beyond hospital labs.

Technological Advancements

The IVD sector is undergoing a technological renaissance, with innovations in:

Molecular diagnostics – including PCR, qPCR, and isothermal amplification.

Next-generation sequencing (NGS) – enabling genomic profiling for cancer and rare diseases.

Point-of-care testing (POCT) – portable kits delivering immediate results.

Digital health integration – AI-driven analytics for test interpretation, cloud-based health data, and connected devices.

These technologies improve accuracy, speed, and patient experience, while also reducing system-wide healthcare costs.

Market Segmentation Insights

By Product & Services

Reagents & Kits – The largest segment, accounting for recurring demand. Used in immunoassays, molecular diagnostics, and POCT.

Instruments – Platforms like PCR machines, sequencing systems, and analyzers.

Services & Software – Data management, test interpretation, and integration with electronic health records.

The reagents & kits segment dominates due to continuous consumption in diagnostic workflows.

By Technology

Immunoassay – Still widely used for infectious disease testing.

Clinical Chemistry – Common for blood and metabolic panels.

Molecular Diagnostics – Rapidly growing with applications in oncology, infectious disease, and genetic testing.

Hematology & Coagulation – Key in monitoring blood disorders and treatment efficacy.

Microbiology & Urinalysis – Essential in hospitals for routine screening.

Molecular diagnostics and NGS are projected to be the fastest-growing categories.

By Application

Oncology – Personalized cancer care and companion diagnostics.

Infectious Diseases – From pandemic testing to tuberculosis and HIV.

Diabetes & Cardiology – Routine monitoring and risk assessment.

Pharmacogenomics & Autoimmune Diseases – Expanding use in targeted therapies.

By End-user

Hospital Laboratories – The largest consumer base.

Point-of-Care Centers & Home Testing – Fastest-growing segment.

Academic Institutes – Contributing to R&D.

Clinical Laboratories – Handling routine and specialized diagnostics.

Regional Outlook

North America – Market Leader

Accounts for the largest share of the global IVD market.

Supported by advanced healthcare infrastructure, widespread insurance coverage, and early adoption of new technologies.

The U.S. FDA provides a stringent yet supportive regulatory framework.

Strong R&D culture and companies like Abbott, Thermo Fisher, and Roche drive innovation.

Europe

Growth shaped by regulatory restructuring under the EU IVDR.

Germany, France, and the U.K. remain innovation hubs.

Public healthcare systems emphasize preventive care and population screening.

Asia-Pacific

Fastest-growing region due to large populations, rising income levels, and healthcare investment.

China, India, Japan, and South Korea lead adoption of IVD technologies.

Local manufacturing of reagents and affordable POCT kits creates accessibility.

Latin America & Middle East & Africa

Gradual expansion driven by improving healthcare access.

Brazil, Mexico, South Africa, and GCC countries show strong potential for infectious disease diagnostics.

Competitive Landscape

The IVD industry is highly competitive, with global leaders and specialized players focusing on innovation, partnerships, and global expansion.

Key Players:

Siemens Healthineers AG

Abbott Laboratories

Roche Diagnostics (F. Hoffmann-La Roche Ltd.)

Thermo Fisher Scientific

Danaher Corporation

Becton, Dickinson and Company

QIAGEN N.V.

Sysmex Corporation

bioMérieux

Illumina, Inc.

Bio-Rad Laboratories

QuidelOrtho Corporation

Agilent Technologies, Inc.

Emerging innovators such as Devyser, Accelerate Diagnostics, and Caris Life Sciences are focusing on specialized niches like oncology and microbial resistance.

Key Market Developments

QIAGEN (Sept 2024): Launched QIAcuityDx Digital PCR System, providing precise quantitation of DNA/RNA for cancer monitoring. FDA-exempt and IVDR-approved.

ELITechGroup (Jan 2024): Introduced GI Bacterial PLUS ELITe MGB Kit, targeting major gastrointestinal bacterial infections.

Illumina: Continues to expand its NGS platforms for oncology and rare genetic disease testing.

Abbott & Roche: Investing heavily in at-home and POCT platforms.

These developments highlight the sector's focus on personalized medicine, infectious disease management, and digital-enabled diagnostics.

Challenges

Regulatory Complexity – Global inconsistencies in diagnostic regulations delay product launches.

High Costs – Advanced molecular platforms and NGS remain expensive for developing markets.

Workforce Limitations – Shortages of skilled professionals to interpret complex tests.

Data Privacy Concerns – Integration with digital health platforms raises cybersecurity risks.

Opportunities

Decentralized Diagnostics – Expansion of POCT and home testing.

AI & Big Data Integration – Enabling predictive, real-time diagnosis.

Emerging Markets – Local reagent manufacturing in Asia-Pacific and Africa.

Partnerships – Between diagnostic companies, pharma firms, and digital health platforms to expand companion diagnostics.

The global in-vitro diagnostics market is entering a transformative phase. By 2035, it is expected to more than double in size, powered by rising disease prevalence, rapid technological advancements, and the shift toward preventive and personalized medicine.

While regulatory hurdles and cost barriers remain, the long-term fundamentals are strong. Companies investing in molecular diagnostics, NGS, POCT, and AI-driven solutions will be best positioned to capture market opportunities.

As healthcare continues to decentralize and digitalize, IVD will remain at the center of global health strategies, enabling earlier diagnoses, better treatment decisions, and improved patient outcomes worldwide.

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