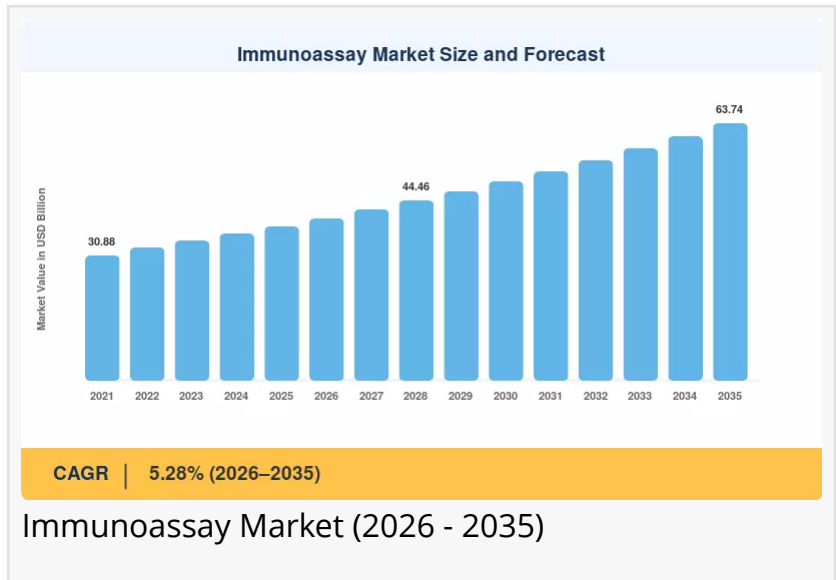


Immunoassay Market to reach USD 63.74 Billion by 2035 at 5.28% CAGR

Immunoassay Market to Expand from USD 38.10 Billion in 2025 to USD 63.74 Billion by 2035—Driven by Laboratory Automation, Oncology Biomarker Demand

NY, CA, UNITED STATES, September 11, 2026 /EINPresswire.com/ -- As per Market Research Future, the [global Immunoassay Market size](#) is projected to reach USD 63.74 Billion by 2035 from USD 38.10 Billion in 2025, at a CAGR of 5.28% during the forecast period 2026–2035. The market base was estimated at USD 38.10 Billion in 2025.



The 5.28% CAGR—anchored by structural shifts in diagnostic testing infrastructure—is propelled by three converging forces: the rising global burden of chronic and infectious diseases, with the International Diabetes Federation projecting roughly 783 million adults living with diabetes by 2045, driving healthcare providers to increasingly adopt automated immunoassay platforms for high-throughput screening and longitudinal therapy monitoring; advancements in detection technologies, particularly chemiluminescence immunoassay (CLIA) systems and microfluidic cartridge readers, which significantly improve analytical sensitivity, turnaround time, and patient access; and the decentralisation of testing from central laboratories toward point-of-care and home-care settings, supported by CLIA-waived cartridge readers and expanded reimbursement for near-patient workflows.

Global diagnostics companies and health organizations are amplifying this momentum. Roche Diagnostics holds an estimated 17–21% revenue share with its broadest automated assay menu and strongest central-laboratory installed base. Abbott Laboratories commands approximately 13–16% share, uniquely positioned with equal strength in core laboratory and point-of-care immunoassay systems. According to WHO data, more than 55 million people are living with dementia worldwide, while the U.S. Centers for Medicare & Medicaid Services continues expanding coverage for protein-based tumor-marker panels. These forces are creating the

clinical infrastructure and testing demand on which the Immunoassay Market depends.

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Key Market Trends & Growth Drivers

Rising Demand for Oncology Biomarker and Companion Diagnostics

The market is witnessing increasing demand for protein-marker quantification to support longitudinal therapy monitoring. The U.S. Food and Drug Administration cleared 14 companion diagnostics between 2023 and 2025, several pairing protein-marker immunoassays with checkpoint-inhibitor regimens requiring quarterly reassessment. Medicare reimbursement for tumor-marker panels rose approximately 8% in aggregate schedule value over the same interval, improving laboratory margins on high-sensitivity assays and accelerating menu adoption in community oncology networks. Roche Diagnostics continues advancing blood-based neurology biomarkers through its Elecsys phosphorylated tau plasma assay pathway.

Advancements in Chemiluminescence and Automation Platforms

Innovations in detection technologies are becoming a hallmark of the industry. Diagnostic majors committed roughly USD 4.6 billion in combined capital and R&D spending to immunodiagnostic platform refresh cycles across 2023–2025. European and Asian reference laboratories are consolidating plate-based workflows onto random-access chemiluminescence tracks, with Germany's statutory laboratory sector reporting a 12% year-on-year increase in automated immunodiagnostic run volume in 2024. Vendors bundle five-to-seven-year reagent-rental contracts with instrument placement, converting capital objections into operating-expense commitments. Chemiluminescence immunoassay posts a 5.70% CAGR, the strongest technology growth rate in the Immunoassay Market.

Integration of AI-Enabled Automation and Middleware

The incorporation of artificial intelligence and laboratory information middleware into diagnostic workflows is gaining traction. Autoverification now performs on a majority of routine immunoassay results in large U.S. health systems, releasing normal values without technologist review. One multi-site deployment documented a 27% reduction in manual result touches and a 19% drop in repeat testing after algorithmic flagging of interference patterns. Siemens Healthineers continues investing in middleware intelligence through Atellica platform enhancements adding algorithmic run scheduling and predictive maintenance.

Increasing Prevalence of Infectious and Chronic Diseases

The rising incidence of infectious diseases, diabetes, and neurological conditions is a primary driver. According to WHO, more than 55 million people worldwide are living with dementia, while the International Diabetes Federation projects roughly 783 million adults with diabetes by 2045. Global Fund and Gavi disbursements directed roughly USD 1.9 billion toward HIV, hepatitis, and syphilis screening commodities in 2024. India's National Viral Hepatitis Control Programme alone expanded screening coverage to more than 700 districts, generating sustained reagent demand that is contractually committed rather than discretionary.

Point-of-Care Decentralisation of Testing

Reimbursement policy has begun following the patient. CMS extended payment parity for several CLIA-waived immunoassay procedures performed in physician offices and retail clinics, and the U.S. waived-testing site count has grown past 320,000 registrations. Miniaturised cartridge readers priced under USD 6,000 now deliver central-lab-comparable precision for troponin and HbA1c, dissolving the historical trade-off between proximity and analytical quality. Point-of-care and home-care settings are the fastest-growing end-user segment at a 5.82% CAGR.

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Market Segment Insights

BY PRODUCTS & SERVICES

Reagents & Kits: Largest segment with 59.32% share in 2025, sustained by recurring consumable replenishment across routine test menus. Reagents anchor the category because every placed instrument commits its owner to a validated consumable stream for the life of the contract.

Analyzers & Instruments: Fastest-growing segment at a 5.63% CAGR, driven by laboratory automation and throughput consolidation as laboratories retire manual workflows in favour of closed-system chemiluminescence analyzers and random-access track automation.

Software & Services: Contributed USD 4.01 billion in 2025 as middleware, connectivity, and autoverification became billable line items, converting bundled features into separately priced deliverables.

BY TECHNOLOGY

ELISA: Retained 51.03% revenue share in 2025 on protocol familiarity and low consumable cost, holding its lead through validated protocols and published performance data spanning decades.

Chemiluminescence Immunoassay (CLIA): Posts a 5.70% CAGR, the strongest technology growth rate in the Immunoassay Market, driven by higher analytical sensitivity and wider dynamic range suited to automated tracks.

Rapid Tests: Generated USD 3.75 billion in 2025 across decentralised screening channels and near-patient workflows.

BY APPLICATION

Infectious Diseases: Largest segment with 32.62% share in 2025, due to surveillance mandates and donor-funded screening programmes supplying a volume floor funded by multi-year commitments.

Oncology: Fastest-growing application at a 5.80% CAGR to 2035, as therapy-monitoring protocols convert a single diagnostic test into a recurring quarterly measurement, with companion diagnostics co-development becoming standard practice in immuno-oncology programmes.

Endocrinology: Accounted for USD 5.12 billion in 2025, driven by thyroid, fertility, and vitamin D panel volumes forming the quiet volume backbone of routine testing.

BY SPECIMEN TYPE

Blood & Serum: Dominant specimen with 47.12% share in 2025, offering broad analyte coverage and established reference ranges across virtually every automated platform.

Saliva: Fastest-growing specimen class at a 5.52% CAGR, appealing for painless collection suited to pediatrics, geriatrics, and remote sampling applications.

Urine: Represented USD 8.15 billion in 2025 across toxicology, fertility, and renal marker testing use cases.

BY END USER

Hospitals: Largest segment with 33.50% share in 2025, driven by integrated laboratory systems and rapid inpatient turnaround needs for cardiac, sepsis, and endocrine markers.

Point-of-Care & Home-Care Settings: Fastest-growing end-user segment at a 5.82% CAGR, gaining traction as CLIA-waived cartridge readers reach analytical performance previously requiring central instrumentation.

Clinical Laboratories: Generated USD 11.51 billion in 2025, competing on menu breadth and cost per reportable result.

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Regional Outlook

North America — Market Leader in Scale Economics

North America leads with over 37.90% of global revenue in 2025, generating around USD 14.44 Billion. The region's growth is driven by consolidated reference-laboratory networks, CMS coverage expansion for tumor-marker and cardiac panels, and favourable reimbursement for waived point-of-care testing. The U.S. accounts for 86.20% of regional share, with two national reference laboratories processing a substantial share of outpatient volume. The competitive landscape is characterized by continuous platform innovation and middleware integration among leading diagnostics companies.

Europe — Second Largest Market

Europe was valued at USD 10.44 billion in 2025, representing the second-largest regional market. The region benefits from statutory laboratory automation and high per-capita test volume, particularly in Germany, while the NHS pathology network consolidation into regional hubs concentrates purchasing power. Regulatory bodies like the EMA are actively managing IVDR re-certification, though notified-body capacity remains a binding constraint. Leading countries include Germany, the UK, and France, where major diagnostics companies such as Roche Diagnostics and Siemens Healthineers are heavily invested.

Asia-Pacific — Rapidly Growing Market Segment

The Asia-Pacific region is the fastest-growing at a 5.84% CAGR. The growth is driven by China's provincial screening mandates and volume-based procurement reform, India's expanding private pathology chains into tier-2 and tier-3 cities, and Japan's ageing population driving high per-capita chronic disease testing. Countries like China and India are experiencing a surge in demand, supported by government initiatives aimed at improving healthcare infrastructure. The competitive landscape is evolving with companies like Sysmex Corporation and domestic manufacturers leading the charge.

South America — Emerging Laboratory Modernisation

South America holds around 4.90% of the global share, driven by Brazil's SUS public network procurement and private laboratory consolidation. Brazil accounts for 54.80% of regional share, with lumpy, high-volume awards that can move regional totals in a single year. Import dependence remains the structural vulnerability, since analyzer and reagent costs are dollar-

denominated while reimbursement is not.

Middle East and Africa — Untapped Potential

The MEA region contributed USD 1.37 billion in 2025 and grows at a 5.61% CAGR, driven by donor-funded surveillance, national laboratory network build-out, and increasing awareness of diagnostic capacity needs. Gulf states are building greenfield tertiary hospitals with full automation specified from day one, while Sub-Saharan programmes prioritise ambient-stable, low-infrastructure formats. Countries like Saudi Arabia, South Africa, and the UAE are leading the way, with a growing presence of international diagnostics companies.

Competitive Landscape and Recent Developments

The immunoassay market is characterized by moderate concentration and rapid technological evolution, driven by increasing demand for automated, high-sensitivity diagnostic testing worldwide. The global industry appears moderately consolidated, with the top five suppliers together controlling an estimated 52–58% of global revenue. Competition is closed-system rather than open: because analyzers and reagents are validated as matched pairs, share is won at instrument placement and then defended for the length of the reagent contract.

KEY COMPANIES AND RECENT MILESTONES

Roche Diagnostics (CH): Holds an estimated 17–21% revenue share with the broadest automated menu and strongest central-laboratory installed base. In March 2023, received FDA clearance for its Elecsys phosphorylated tau plasma assay pathway in Alzheimer's evaluation, signalling that blood-based neurology biomarkers were transitioning from research to regulated clinical use.

Abbott Laboratories (US): Commands approximately 13–16% share, uniquely positioned with equal strength in core laboratory (Alinity i, ARCHITECT) and point-of-care (i-STAT) immunoassay systems. In May 2024, expanded its Alinity i menu with additional oncology and neurology markers and announced further manufacturing investment in its immunoassay reagent operations.

Siemens Healthineers (DE): Holds approximately 10–13% share as a track automation and workflow integration specialist with its Atellica Solution and ADVIA Centaur platforms. In November 2024, announced Atellica platform enhancements adding algorithmic run scheduling and predictive maintenance, positioning middleware intelligence as the primary differentiator in high-throughput laboratory tenders.

Danaher / Beckman Coulter (US): Holds approximately 8–11% share with its Dxl series immunoassay analyzers and Access assay portfolio, pursuing an integrated chemistry-immunoassay consolidation strategy. In July 2025, launched an expanded Dxl 9000 assay menu targeting high-sensitivity cardiac and tumor marker consolidation.

Thermo Fisher Scientific (US): Holds approximately 6–9% share, bridging clinical diagnostics and life-science research demand through ImmunoCAP allergy testing, B·R·A·H·M·S biomarkers, and research reagents.

Other Key Players: bioMérieux (FR), Bio-Rad Laboratories (US), DiaSorin (IT), QuidelOrtho (US), Sysmex Corporation (JP), Quanterix (US).

Future Outlook: 2026–2035

The Immunoassay Market is projected to reach USD 63.74 billion by 2035, growing at a CAGR of 5.28%, driven by increasing chronic and infectious disease prevalence, rising oncology biomarker demand, and advancements in automation and detection technologies.

New opportunities lie in:

Expansion into emerging markets with ruggedized benchtop analyzers and ambient-stable detection kits

Development of blood-based neurodegeneration testing moving from specialist referral into primary-care triage

Investment in AI-enabled middleware and closed-loop laboratory operations for autoverification and predictive maintenance

Growth of reagent-rental and outcomes-linked contracting models converting capital barriers into predictable operating expenditure

Companion diagnostics co-development with biopharma for therapy-selection decisions

By 2035, the Immunoassay Market is expected to achieve substantial growth and innovation.

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+1 855-661-4441

[email us here](#)

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