Kalorama Information

Global Immunoassay Market: Trends, Technologies, and Growth Opportunities, 2025

SAMPLE

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Scope and Methodology

The global market for immunoassays is presented in U.S. dollars for the period from 2024 to 2029. Market analyses in this report cover worldwide immunoassay markets, ranging from high-throughput instruments used in centralized core laboratories to manual lateral flow and other point-of-care (POC) immunoassays. The report also includes immunochromatographic or lateral flow rapid tests.

There is a focus on developed regions—namely North America, Western Europe, and developed Asia-Pacific markets. Immunoassays, including lateral flow POC tests, play a critical role in expanding healthcare access to areas lacking the infrastructure for traditional, centralized diagnostics.

Market data in this report are based on manufacturer revenues, not retail pricing or reimbursement payments. The dollar value of each market segment is generally proportional to the number of tests performed, as the cost of instrumentation is typically embedded in the per-test price.

A comprehensive combination of primary and secondary research was employed to ensure accuracy, depth, and relevance in assessing current market conditions and trends. The research process involved multiple phases to gather, verify, and analyze information from a wide range of credible sources.

Information was collected through an extensive review of publicly available and proprietary databases, including industry reports, company literature, regulatory filings, investment and equity research, and medical and business journals. This helped establish context, identify market participants, and assess competitive positioning.

To validate and expand upon secondary findings, Kalorama Information conducted over 30 in-depth interviews with key industry stakeholders, including executives, product managers, marketing directors, consultants, healthcare providers, and government officials. Telephone interviews and email correspondence were the primary modes of communication, offering qualitative insights into market dynamics, customer behavior, and emerging trends.

Additional outreach to company representatives provided specific data points on revenue, market share, and product performance. These interactions were essential for corroborating financial data and understanding business strategies at both the segment and product levels. All data were cross-verified with multiple sources to ensure consistency and reliability. Where possible, estimates were triangulated using a combination of publicly disclosed information, proprietary databases, and expert interviews.

Market sizing and forecast models were built using historical data, growth trends, and assumptions informed by primary research. The base year for the data is 2024, and compound annual growth rates (CAGRs) are provided for the 2024–2029 period for each segment analyzed. Research findings support a comprehensive competitive analysis for the year 2024. Forecasts for 2025–2029 are primarily based on demographic trends, technological innovations, and global market expansion.

It is important to note that the market areas covered in this report are evolving rapidly. Some company and technology information may become outdated by the time of publication. Kalorama is aware of these developments; however, the major themes, key players, and core issues remain relevant and unchanged.

Market Overview and Market Segments

The immunoassay market is a substantial and well-established sector, with sales reaching $XX Million in 2024. It comprises two major segments:

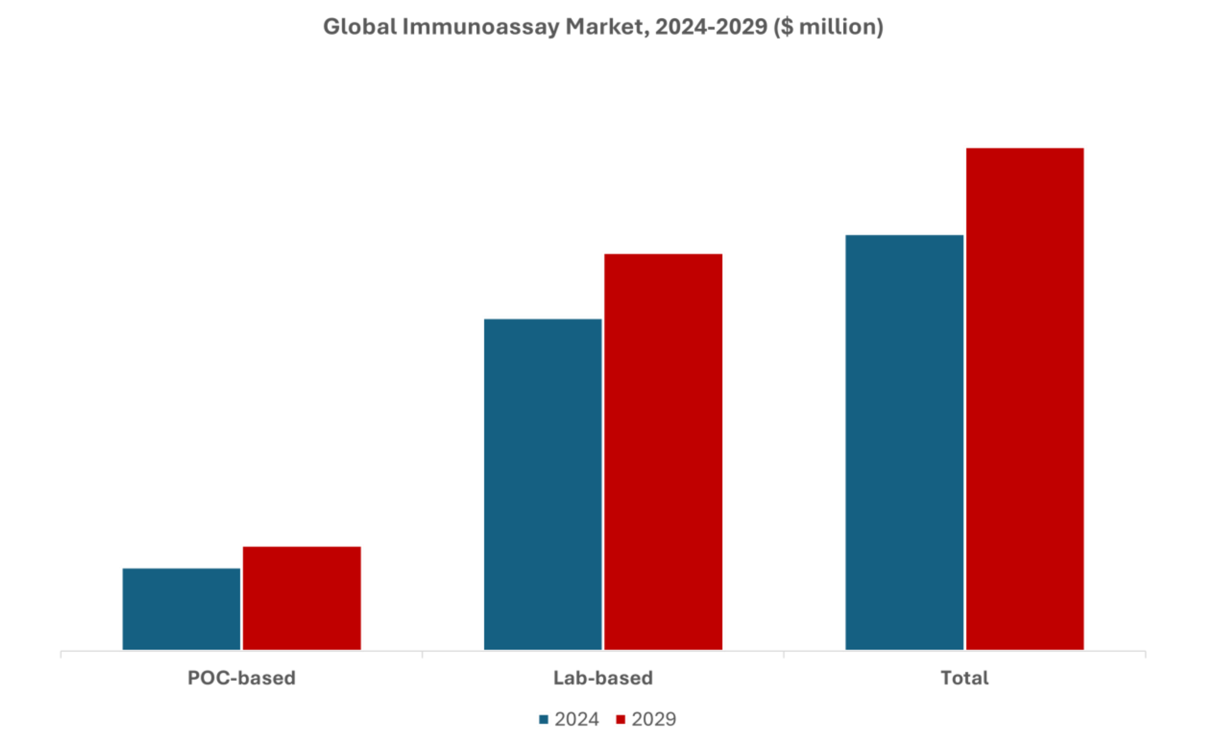
- Lab-based immunoassays, performed in centralized laboratories for clinical purposes such as screening, diagnosis, and patient monitoring.
- Point-of-care (POC) or rapid immunoassays, also used for clinical indications but designed for faster, decentralized testing.

SAMPLE: Global Immunoassay Market, by Laboratory Setting, 2024-2029 ($ million)

Laboratory Setting	2024	2029	CAGR 2024-2029
Lab-based	XX million	XX million	XX%
POC-based	XX million	XX million	XX%
Total	**XX million**	**XX million**	**XX%**

Source: Kalorama Information

SAMPLE: Global Immunoassay Market, by Laboratory Setting, 2024-2029 ($ million)



Source: Kalorama Information

Central Lab-based Immunoassay Market

Central lab-based immunoassays represent, by far, the largest segment of the immunoassay market, accounting for **XX%** of the total market in 2024. However, this segment's share is gradually shrinking due to the more rapid growth of the point-of-care (POC) or rapid test segment.

The largest subsegment within the central lab-based immunoassay market is infectious diseases, which generated **XX million** in sales in 2024—representing **XX%** of the total segment. The next two largest subsegments are metabolic disorders and other hormones, and tumor markers, accounting for **XX%** and **XX%** of the market, respectively. The metabolic disorders and other hormones category (XX% of the lab-based immunoassay market) actually comprises a group of disease indications. Other disease indications represent much smaller portions of the market. Cardiac markers, for example, captured **XX%** of the total market share in 2024.

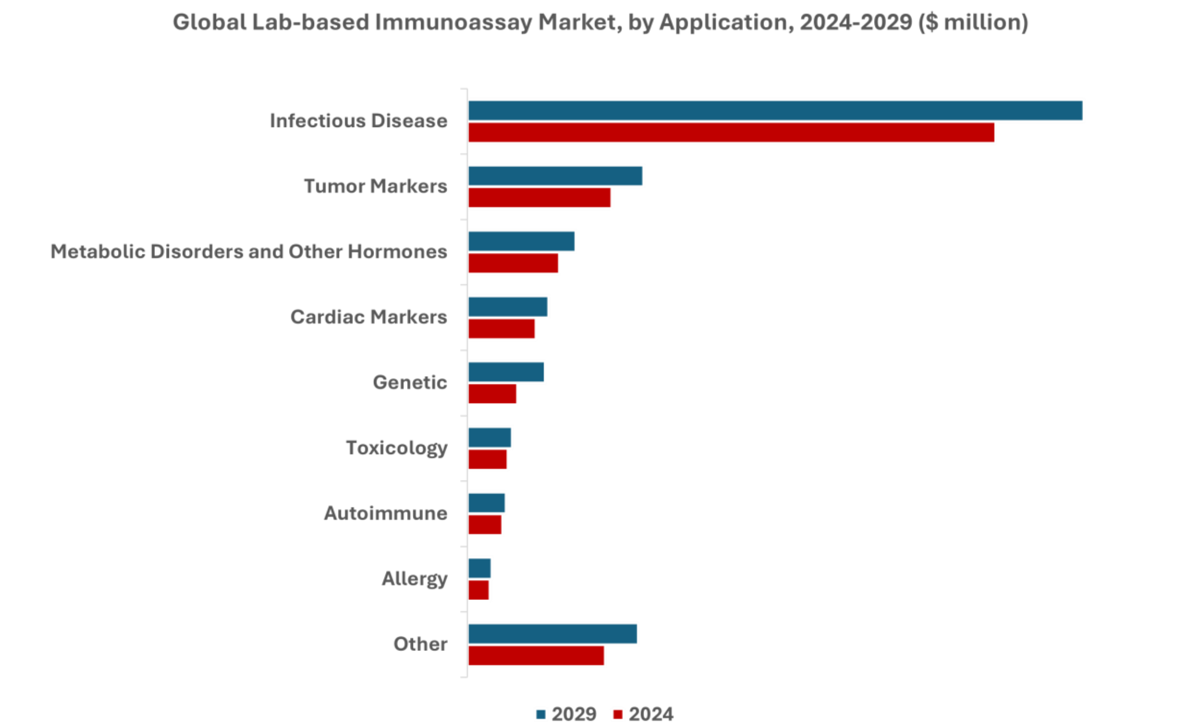
The genetic lab-based immunoassay market is the fastest-growing application area, with a projected compound annual growth rate (CAGR) of **XX%** from 2024 to 2029.

SAMPLE: Global Lab-based Immunoassay Market, by Application, 2024-2029 ($ million)

Segment	2024	2029	CAGR 2024-2029
Infectious Disease	XX million	XX million	XX%
Tumor Markers	XX million	XX million	XX%
Metabolic Disorders and Other Hormones	XX million	XX million	XX%
Cardiac Markers	XX million	XX million	XX%
Genetic	XX million	XX million	XX%
Toxicology	XX million	XX million	XX%
Autoimmune	XX million	XX million	XX%
Allergy	XX million	XX million	XX%
Other	XX million	XX million	XX%
Total	**XX million**	**XX million**	**XX%**

Source: Kalorama Information

SAMPLE: Global Lab-based Immunoassay Market, by Application, 2024-2029 ($ million)



Source: Kalorama Information

Point of Care/Rapid Test Immunoassays by Disease Category

The two largest segments of the point-of-care (POC)/rapid testing market are infectious disease tests and fertility tests, accounting for **XX%** and **XX%**, respectively, of the total POC/rapid test immunoassay market.

The goal of POC infectious disease testing is to detect pathogens in humans and determine the most appropriate course of antimicrobial treatment. While the threat of infectious diseases is often associated with developing countries, they are also a major cause of morbidity and mortality in developed regions such as Europe and the United States. Various factors—including emerging infectious diseases, mass migration, global travel, antibiotic misuse, and co-infections—underscore the need for continuous global efforts and innovative research to combat these expanding threats.

Lab-based infectious disease tests often fail to meet the urgent needs of mass screening and diagnostic programs required by public health professionals and clinicians in both developing and developed countries. As a result, there is growing demand for reliable rapid tests for infectious diseases. These tests enable earlier diagnosis and treatment, reduce healthcare costs, and help avoid unnecessary quarantines and delays. Studies have shown that many individuals seen in clinics do not return to receive their lab test results and therefore remain untreated if they test positive.

Infectious disease testing will continue to be a key driver of diagnostic testing, as new pathogen strains emerge annually—such as seasonal influenza, H1N1, Lyme disease, and West Nile virus. Additionally, hospital-acquired infections like Methicillin-resistant *Staphylococcus aureus* (MRSA) necessitate increased testing.

Hormone/fertility testing represents a market valued at **XX million** in 2024. This category includes POC tests for pregnancy, ovulation, and menopause. These tests are frequently purchased and performed by consumers, making this a significant over-the-counter (OTC)/self-test segment.

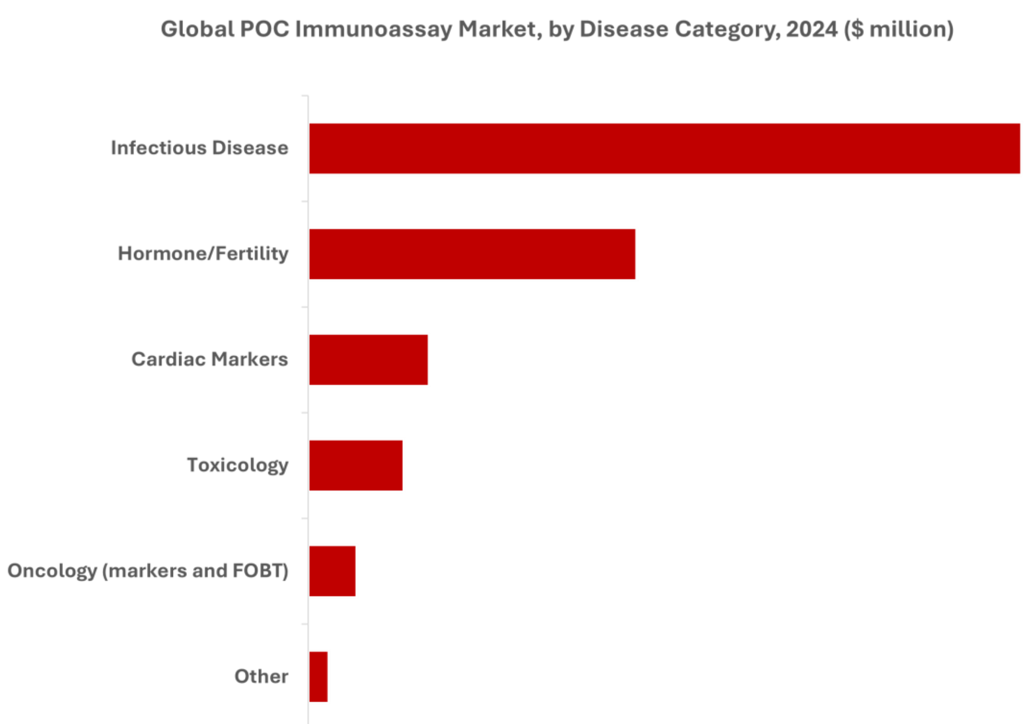
POC/rapid cardiac tests are critical in emergency settings, such as when patients present with symptoms of a potential heart attack. Available cardiac markers assist physicians in diagnosing, prognosing, and managing the risk of cardiovascular diseases such as heart failure and myocardial infarction. However, there is an ongoing effort to identify additional cardiac markers that can detect earlier stages of myocardial infarction, thereby improving treatment outcomes and saving lives. POC/rapid cardiac marker revenues totaled **XX million** in 2024.

SAMPLE: Global POC Immunoassay Market Analysis, by Disease Category, 2024 ($ million)

Product Type	Revenue Estimates	Total Market Share
Infectious Disease	XX million	XX%
Hormone/Fertility	XX million	XX%
Cardiac Markers	XX million	XX%
Toxicology	XX million	XX%
Oncology (markers and FOBT)	XX million	XX%
Other	XX million	XX%
Total	**XX million**	**XX%**

Source: Kalorama Information

SAMPLE: Global POC Immunoassay Market Analysis, by Disease Category, 2024 ($ million)



Source: Kalorama Information

Immunoassay Market by Technology Type

The immunoassay market by technology is segmented into:

- Chemiluminescent immunoassay (CLIA)
- Enzyme-linked immunosorbent assay (ELISA)
- Fluorescence immunoassay (FIA)
- Immunohistochemistry (IHC)
- Lateral flow immunoassay (LFIA)
- Radioimmunoassay (RIA)
- Others

The chemiluminescent immunoassay (CLIA) segment captured **XX%** of the global immunoassay market by technology. CLIA technology is poised for further development. In the coming years, new and more efficient analytical methods based on the principles of chemiluminescence are expected to be introduced into diagnostics at steadily decreasing costs. This transformation will align antibody diagnostics with already established biochemistry and immunoassay methods, offering noticeable advantages in both diagnostic accuracy and efficiency.

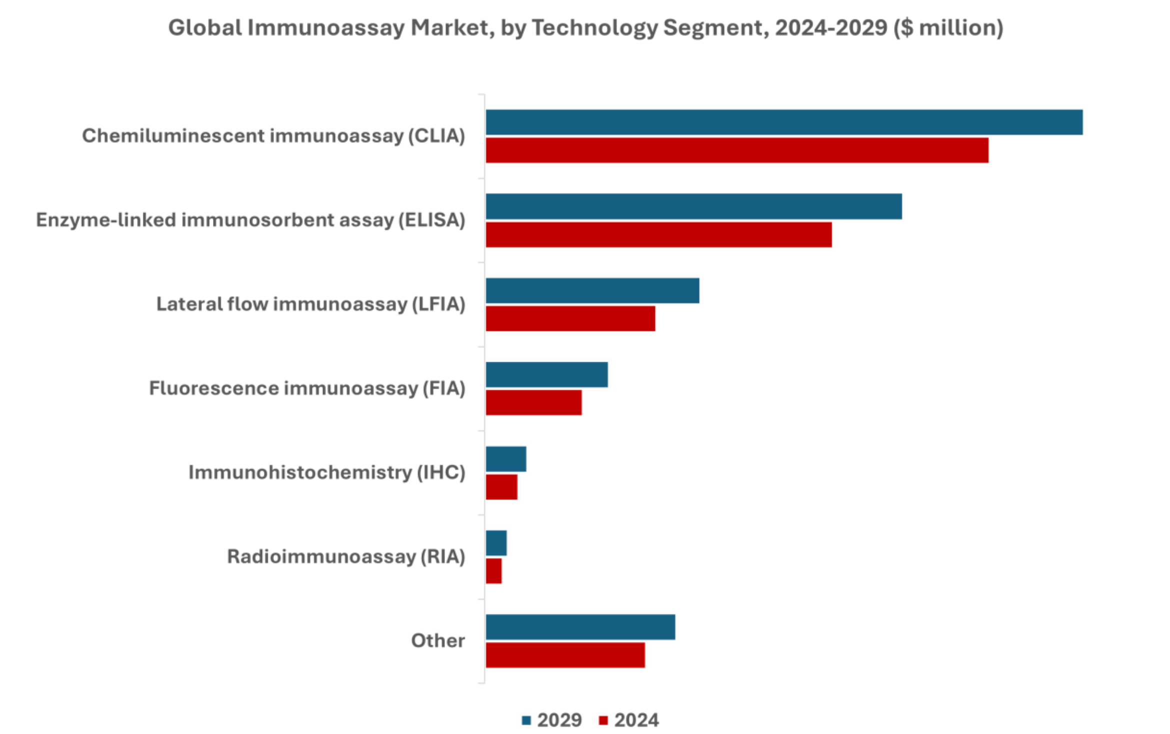
ELISA was the second most utilized technology, accounting for **XX%** in 2024. The integration of artificial intelligence (AI) is renewing interest in ELISA immunoassays. ELISA has long been a cornerstone of diagnostics, enabling the identification and quantification of biomolecules critical for disease diagnosis. However, ELISA immunoassays have faced challenges due to labor-intensive protocols and susceptibility to errors, which have impacted reliability and speed. The incorporation of AI has enhanced both speed and precision, ushering in a new era for ELISA-based diagnostics.

SAMPLE: Global Immunoassay Market, by Technology Segment, 2024-2029 ($ million)

Segment	2024	2029	CAGR 2024-2029
Chemiluminescent immunoassay (CLIA)	XX million	XX million	XX%
Enzyme-linked immunosorbent assay (ELISA)	XX million	XX million	XX%
Lateral flow immunoassay (LFIA)	XX million	XX million	XX%
Fluorescence immunoassay (FIA)	XX million	XX million	XX%
Immunohistochemistry (IHC)	XX million	XX million	XX%
Radioimmunoassay (RIA)	XX million	XX million	XX%
Other	XX million	XX million	XX%
Total	**XX million**	**XX million**	**XX%**

Source: Kalorama Information

SAMPLE: Global Immunoassay Market, by Technology Segment, 2024-2029 ($ million) [CLIA, ELISA, FIA, IHC, LFIA, RIA, Other]



Source: Kalorama Information

SAMPLE: Global Immunoassay Market Share, by Technology Segment, 2024 (%)

Segment	2024
Chemiluminescent immunoassay (CLIA)	XX%
Enzyme-linked immunosorbent assay (ELISA)	XX%
Lateral flow immunoassay (LFIA)	XX%
Fluorescence immunoassay (FIA)	XX%
Immunohistochemistry (IHC)	XX%
Radioimmunoassay (RIA)	XX%
Other	XX%
Total	**XX%**

Source: Kalorama Information

Competitive Analysis

The immunoassay market as a whole demonstrated growth in 2024. However, COVID-19 testing continued to influence certain areas of the competitive landscape. The global immunoassay market has been dominated by three leading IVD companies: Roche, Abbott Diagnostics, and Siemens Healthineers.

Roche secured the leading position, accounting for **XX%** of the global market share. Over the past few years, Roche Diagnostics has aggressively expanded its presence, displacing Abbott as the market leader. Roche has excelled in infectious disease testing, as well as in diagnostics for women's health, sepsis, vitamin D, and various cancer markers. In 2024, global immunoassay revenues reached **XX million** (or **XX billion**).

Abbott held the second-largest market share at **XX%**. Its strength lies in a broad menu of tests and assay systems, along with a dominant position in the global infectious disease testing market—capturing at least **XX%** when including its point-of-care (POC) offerings, particularly for hepatitis and HIV, outside the United States. Key emerging markets include India, Russia, Brazil, and China. Abbott has also expanded its portfolio with tests such as the Galectin-3 assay (for assessing prognosis in chronic heart failure) and the HbA1c test. The acquisition of Alere significantly strengthened Abbott's position in POC and rapid testing, building on an already substantial presence in the IVD immunoassay market.

Siemens Healthineers, the third-largest provider, captured **XX%** of the market in 2024. Its Immulite product line, a dedicated immunoanalyzer, has been automated and complemented by the ADVIA Centaur Immunoassay Systems—originally developed by Bayer Diagnostics—focusing on chemiluminescence testing.

Danaher's Beckman Coulter secured a **XX%** market share. Its Access and Synchron systems offer a wide and continuously expanding test menu. Beckman Coulter's immunoassay portfolio includes over 60 tests for cancer detection, cardiac disease, thyroid function, reproductive endocrinology, and women's health. The company continues to introduce novel and proprietary tests, including those for inhibin A, High Mobility Group Box 1 (septic shock), erythropoietin, cPAPPA (plaque instability marker), placental growth factor (PIGF), soluble fms-like tyrosine kinase 1 (sFlt-1), soluble CD40 ligand (sCD40L), preeclampsia, fertility hormones, cardiovascular disease, autoimmune and inflammatory diseases, cytokines, and prenatal screening.

bioMérieux offers an immunoassay product line with over 130 products, including rapid single-dose tests (VIKIA), high-throughput microplate processors (DAVINCI), and automated multiparametric analyzers (VIDAS, miniVIDAS, and VIDIA). The VIDAS range includes 99 tests covering bacterial, viral, and parasitic identification, antibody detection, protein markers for cardiovascular diseases and cancers, inflammatory responses, and hormonal dysfunction. In 2014, bioMérieux launched the FDA-cleared and CE-marked VIDAS C. difficile GDH assay, a fully automated and cost-effective solution for *C. difficile* diagnosis and infection control.

Thermo Fisher Scientific accounted for **XX%** of the total market. It offers a broad range of diagnostic test kits, reagents, culture media, instruments, and related products for healthcare, clinical, pharmaceutical, industrial, and food safety laboratories.

DiaSorin also held a **XX%** market share, offering a menu of over 122 assays across various areas, including bone and mineral metabolism, thyroid function, reproductive endocrinology, anemia, cardiac markers, autoimmunity, tumor markers, hypertension, adrenal function, growth, diabetes, sepsis, viral hepatitis and HIV, Treponema, EBV, ToRCH, Borrelia, VZV, Mycoplasma, measles and mumps, chlamydia, and stool diagnostics. Its LIAISON and LIAISON XL platforms are based on chemiluminescent immunoassay (CLIA) technology.

Over 100 other companies compete for the remaining **XX%** of the market. Many smaller players offer ELISA-based tests for local markets, while niche players such as Fujirebio, Bryker-CALID, QuidelOrtho, Bio-Rad, and Revvity maintain strong positions in specialized segments.

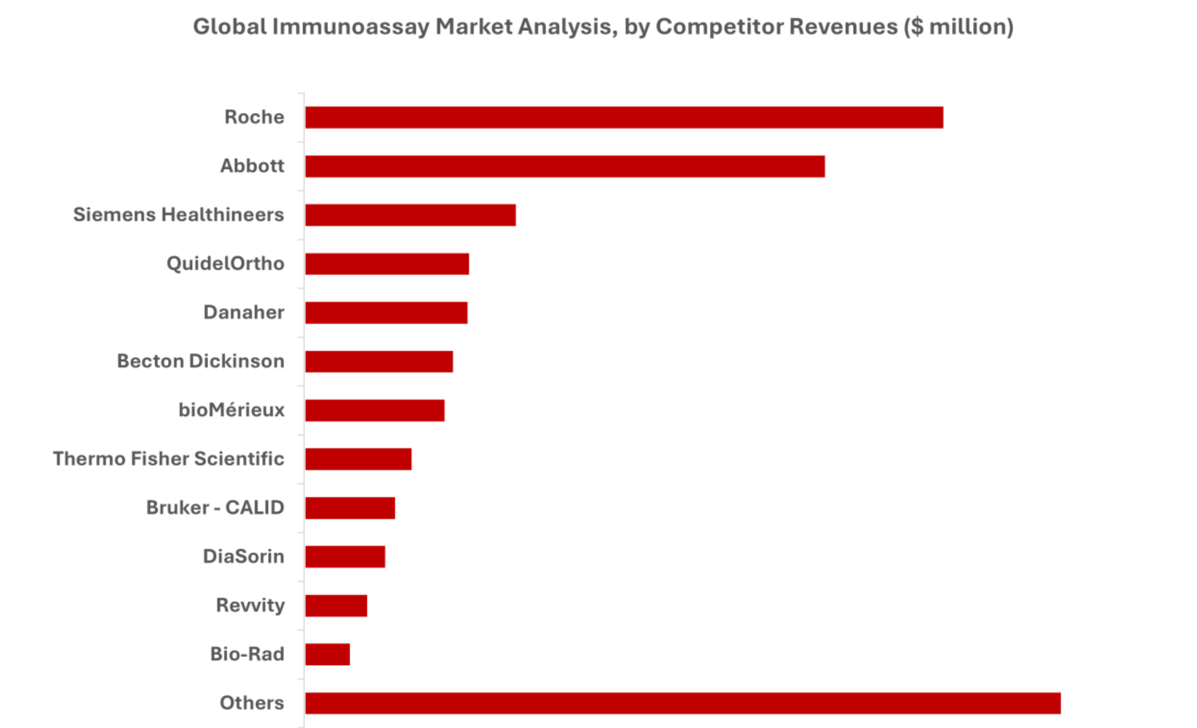
Mindray launched two new CLIA stand-alone analyzers for mid-volume laboratories: the CL-9000i for small labs and the CL-6000i for mid-sized labs, both offering high throughput. Additional systems include the SAL 6000 modular system for fast throughput and integration, and the SAL 9000 modular system, which combines the BS-2000 Chemistry Analyzer with the CL-6000i Chemiluminescence Immunoassay Analyzer for high-throughput chemistry and immunoassay testing.

SAMPLE: Global Immunoassay Market, by Competitor Revenues ($ million) and Market Share (%), 2024

Supplier	Revenue Estimates	Market Share
Roche	XX million	XX%
Abbott	XX million	XX%
Siemens Healthineers	XX million	XX%
QuidelOrtho	XX million	XX%
Danaher	XX million	XX%
Becton Dickinson	XX million	XX%
bioMérieux	XX million	XX%
Thermo Fisher Scientific	XX million	XX%
Bruker - CALID	XX million	XX%
DiaSorin	XX million	XX%
Revvity	XX million	XX%
Bio-Rad	XX million	XX%
Others	XX million	XX%
Total	**XX million**	**XX%**

Source: Kalorama Information

SAMPLE: Global Immunoassay Market Analysis, by Competitor Revenues ($ million), 2024



Source: Kalorama Information

Immunoassay Market by Geographic Regions

The global immunoassay market is divided into four geographic regions:

- North America
- Europe
- Asia Pacific
- Rest of the World

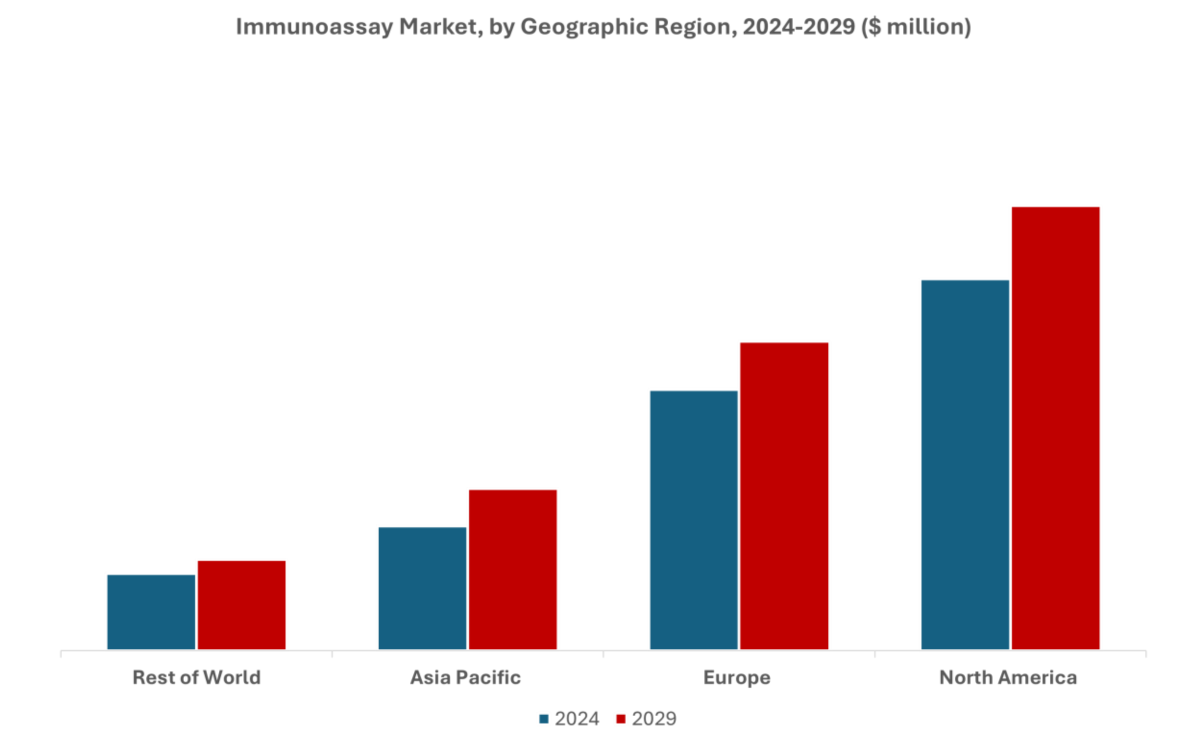
North America is the largest region in the immunoassay market, while Asia Pacific is the fastest-growing. All regions are expected to demonstrate positive growth during the forecast period from 2024 to 2029.

SAMPLE: Immunoassay Market, by Geographic Region, 2024-2029 ($ million)

Segment	2024	2029	CAGR 2024-2029
North America	XX%	XX million	XX%
Europe	XX%	XX million	XX%
Asia Pacific	XX%	XX million	XX%
Rest of World	XX%	XX million	XX%
Total	**XX%**	**XX million**	**XX%**

Source: Kalorama Information

SAMPLE: Immunoassay Market, by Geographic Region, 2024-2029 ($ million)



Source: Kalorama Information