

U.S. Biomarker-based Immunoassays Market Size, Share & Trends Analysis Report By Sample (Blood, Saliva), By Product (Reagents & Kits, Consumables), By Biomarker, By Diseases, By End Use, And Segment Forecasts, 2025 - 2033

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Abstracts

Market Size & Trends

The U.S. biomarker-based immunoassays market size was estimated at USD 2.17 billion in 2024 and is projected to reach USD 3.68 billion by 2033, growing at a CAGR of 5.9% from 2025 to 2033. The market growth is fueled by the rising U.S. burden of chronic diseases such as cancer, cardiovascular disorders, and neurological conditions, which require precise and early diagnostic tools. A major driver shaping the scope of this market is the shift toward personalized medicine. Pharmaceutical and biotechnology companies increasingly depend on biomarker-based immunoassays to support companion diagnostics and patient stratification in clinical trials. This integration ensures that targeted therapies reach the right patient groups, improving therapeutic outcomes while reducing healthcare costs. The regulatory environment in the U.S. also plays a crucial role in shaping this scope.

Alongside therapeutic uses, the market is expanding due to technological progress and digital integration. Automated immunoassay platforms combined with artificial intelligence for data analysis are supporting high-throughput and very sensitive biomarker testing. This growth is not limited to central labs but also reaches decentralized healthcare models, like point-of-care and at-home testing options. The use of saliva-based biomarker immunoassays, which are less invasive and simpler to collect, presents another major opportunity within the market's evolving landscape.

Furthermore, the U.S. biomarker-based immunoassays market extends beyond healthcare delivery into research and academic institutions, where immunoassays are vital for biomarker discovery and validation. These institutions play a key role in driving innovation and forming partnerships with industry leaders, creating a cycle that supports new product development and clinical translation. Overall, the scope of the U.S. market is broad and dynamic, covering routine diagnostics, therapeutic monitoring, drug development, and academic research. This positions biomarker-based immunoassays as a fundamental technology within the evolving landscape of precision healthcare.

The demand for minimally invasive solutions has increased as clinicians look for reliable tools to detect diseases earlier and guide treatment decisions more accurately. This trend has led leading companies to focus on innovations in plasma and serum biomarkers, especially in fields such as oncology and neurology, where early diagnosis can greatly improve patient outcomes. In this context, several product innovations highlight the growing significance of blood-based biomarker immunoassays in clinical practice. For example, in April 2024 Roche's Elecsys pTau217 plasma biomarker test, developed with Eli Lilly, received Breakthrough Device Designation from the U.S. FDA, showing its potential to transform Alzheimer's diagnosis. This test helps healthcare providers identify amyloid pathology, a key aspect of Alzheimer's disease, which can enable earlier, more accurate diagnoses. By improving access to timely diagnosis, the test not only improves patient care but also encourages patient participation in clinical trials and access to disease-modifying treatments, further increasing the demand for innovative blood-based biomarker tests in the U.S.

U.S. Biomarker-Based Immunoassays Market Report Segmentation

This report forecasts revenue growth and provides an analysis on the latest trends in each of the sub-segments from 2021 to 2033. For the purpose of this report, Grand View Research has segmented the U.S biomarker-based immunoassays market on the basis sample, product, biomarkers, diseases, end use and region.

Sample Outlook (Revenue, USD Million, 2021 - 2033)

Blood

Tissue

Urine

Saliva

Product Outlook (Revenue, USD Million, 2021 - 2033)

Consumables

Instruments/Analyzers

Reagent & Kits

Services

Biomarker Outlook (Revenue, USD Million, 2021 - 2033)

Safety & toxicity biomarkers

Efficacy & Pharmacodynamic Biomarkers

Predictive & Prognostic Biomarkers

Surrogate/Exploratory Biomarkers

Diseases Outlook (Revenue, USD Million, 2021 - 2033)

Cancer

Cardiovascular Diseases

Neurological Diseases

Immunological Diseases

Others

End Use Outlook (Revenue, USD Million, 2021 - 2033)

Hospitals & Clinics

Diagnostic Laboratories

Research & Academic Institutes

Others

This report can be delivered to the clients within 3 Business Days

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