

## **United States Biomarkers Market Report 2025-2034**

Market Report | 2025-06-20 | 250 pages | EMR Inc.

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### **Report description:**

The United States biomarkers market was valued at USD 18.10 Billion in 2024, driven by the rising inclination towards point of care testing across the region. The market is anticipated to grow at a CAGR of 8.20% during the forecast period of 2025-2034, with the values likely to reach USD 39.81 Billion by 2034. The market growth is driven by the preference for high sensitivity diagnosis and the rising application of biomarkers in diagnosis and treatment.

#### United States Biomarkers Market Overview

Biomarkers are measurable indicators of biological processes, conditions, or diseases found in blood, tissues, or other body fluids. They help in diagnosing diseases, predicting treatment responses, and monitoring therapeutic outcomes. Commonly used in oncology, cardiology, and neurology, biomarkers enable early detection and personalized medicine. Advances in genomics and proteomics are driving biomarker discovery, making them vital tools for precision healthcare and drug development. The market is anticipated to grow at a CAGR of 8.20% during the forecast period of 2025-2034.

#### United States Biomarkers Market Growth Drivers

##### Advances In Clinical Biomarkers Supporting United States Market Growth

Rising investments in neurodegenerative disease research and increasing clinical focus on protein-based biomarkers are strengthening the market. For instance, in June 2024, PTC Therapeutics reported interim Phase 2 PIVOT-HD trial results for PTC518, showing dose-dependent reductions in mutant huntingtin (mHTT) protein in blood and CSF over 12 months, alongside positive trends in motor and cognitive assessments. These findings highlight the growing clinical value of biomarkers in monitoring treatment efficacy, positioning them as essential tools in disease progression tracking and therapy development.

##### Collaborative Innovations Accelerating Biomarker Assay Development in the United States

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The demand for high-sensitivity diagnostic tools and precision medicine in neurology is driving partnerships for advanced assay platforms. For instance, in October 2024, ADx NeuroSciences and Alamar Biosciences announced a collaboration to co-develop biomarker assay solutions using Alamar's NULISA platform and ARGO HT System. This partnership is set to enhance ultra-sensitive detection capabilities for neurological biomarkers, thereby expanding the scope of biomarker-driven therapeutic development and boosting technological progress in the U.S. biomarkers market over the forecast period.

#### United States Biomarkers Market Growth Trends

Some of the notable trends include innovations empowered by latest technologies like artificial intelligence, adoption of non-invasive diagnostics and others.

#### Genetic Biomarker Discoveries Driving United States Biomarkers Market Growth

The For instance, in January 2025, UTHealth Houston researchers identified two genes with epilepsy-related somatic variants that could serve as promising diagnostic biomarkers. Published in Nature Communications, the study examined 1,386 human brain tissues, offering new insights for treating drug-resistant epilepsy.

#### AI-driven Innovations Accelerating United States Biomarkers Market Size

In October 2024, Aignostics (in collaboration with Mayo Clinic) raised USD 34 million in Series B funding to expand AI-powered computational pathology solutions in the United States. The company focuses on developing foundation models for biopharmaceutical clients to improve diagnostics. As AI enables deeper interpretation of multi-modal biomarker data, such funding and innovation will advance precision diagnostics and fuel the development of next-gen biomarker tools in the market.

#### Blood-based Biomarker Advances to Boost United States Biomarkers Market Demand

In July 2024, Biogen, Beckman Coulter, and Fujirebio collaborated to develop tau-specific blood-based biomarkers for Alzheimer's disease. These biomarkers aim to measure tau pathology non-invasively, enabling early detection and aiding in targeted drug development. This collaboration strengthens the clinical utility of biomarkers, boosts innovation in neurodegenerative disease diagnostics, and is poised to significantly contribute to market value through broader accessibility and scalable testing methods.

#### Non-invasive Diagnostics Fostering New Opportunities Bolstering United States Biomarkers Market Growth

In October 2024, ARPA-H launched the OCULAB program to develop a tear-based biomarker system for continuous health monitoring and personalized treatment. This initiative challenges traditional blood-based testing by using tear ducts for real-time diagnostics. As non-invasive, continuous monitoring becomes more feasible, this novel approach opens new commercial pathways in personalized medicine, supporting sustained growth and technological differentiation in the market.

#### United States Biomarkers Market Segmentation

The market report offers a detailed analysis of the market based on the following segments:

##### Market Breakup by Product

- Instruments and Consumables
- Assay Kits
- ??- Reagents and Chemicals

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- Services
- Software

## Market Breakup by Type

- Safety Biomarkers
- Efficacy Biomarkers
- Predictive Biomarkers
- Surrogate Biomarkers
- Pharmacodynamic Biomarkers
- Prognostics Biomarkers
- Validation Biomarkers

## Market Breakup by Application

- Clinical Diagnostics
- Drug Discovery and Development
- Personalized Medicine
- Clinical Research
- Others

## Market Breakup by Technology

- Immunoassays
- NGS
- PCR
- Mass Spectrometry
- Chromatography
- Others

## Market Breakup by Disease Indication

- Cancer
- Infectious Diseases
- Immunological Diseases
- Neurological Disorders
- Cardiovascular Disorders
- Others

## Market Breakup by End User

- Pharmaceutical and Biotechnology Companies
- Hospitals and Diagnostic Laboratories
- Academic and Research Institutes
- Others

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## Market Breakup by Region

- Mideast
- Great Lakes
- Plains
- Southeast
- Southwest
- Rocky Mountain
- Far West

## United States Biomarkers Market Share

### Immunoassays to Hold a Significant Market Share for Segmentation by Technology

Immunoassays are expected to dominate the market by technology due to their high sensitivity, specificity, and broad application in disease diagnostics, especially in oncology and infectious diseases. Widely used in clinical settings, they support rapid biomarker detection and monitoring. Although NGS and PCR are growing rapidly, immunoassays continue to hold the largest share due to scalability and proven clinical utility.

## United States Biomarkers Market Analysis by Region

The Northeast region is likely to dominate the market due to its strong presence of academic research institutions, biotech hubs, and public-private collaborations. For instance, in March 2025, Enigma Biomedical USA, Inc. began a partnership with Boston University's CTE Center and the Concussion Legacy Foundation to advance 4R Tau PET biomarkers for diagnosing chronic traumatic encephalopathy (CTE). Such initiatives reinforce the Northeast's innovation leadership, outpacing other regions like the Midwest, South, and West in biomarker discovery and validation.

## Leading Players in the United States Biomarkers Market

The key features of the market report comprise patent analysis, grants analysis, funding and investment analysis, and strategic initiatives by the leading players. The major companies in the market are as follows:

### F. Hoffmann La Roche

Roche, a global leader in diagnostics and pharmaceuticals, plays a pivotal role in the U.S. biomarkers market through innovative diagnostic solutions. In February 2025, Roche partnered exclusively with PathAI to co-develop AI-powered digital pathology algorithms for companion diagnostics. This move strengthens Roche's position in precision medicine by enhancing biomarker identification capabilities, accelerating targeted therapy development, and advancing diagnostic accuracy across disease areas.

### Merck KGaA

In March 2024, Boston Consulting Group (BCG) and Merck initiated a strategic collaboration to apply AI and GenAI for drug target discovery. Through BCG X, the partnership aims to develop algorithms that mine omics data to uncover relationships between biomarkers and disease biology. This positions Merck as a pivotal enabler of biomarker-driven drug development in the evolving U.S. biomarkers market.

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Thermo Fisher Scientific Inc.

Thermo Fisher Scientific Inc. is a global leader in life sciences, offering a wide range of laboratory products and technologies. In November 2024, it entered a collaboration with Mainz Biomed N.V. to develop and commercialize the company's next-generation colorectal cancer (CRC) screening product. Thermo Fisher will contribute its expertise in mRNA-based assays and life sciences technologies, advancing early cancer detection. This partnership positions Thermo Fisher at the forefront of innovative diagnostic solutions in the U.S. biomarkers market.

## QIAGEN

QIAGEN, a global leader in molecular diagnostics, plays a key role in the United States biomarkers market by advancing companion diagnostics (CDx). In August 2024, QIAGEN expanded its collaboration with AstraZeneca to develop CDx for chronic disease therapies. QIAGEN will leverage its QIAstat-Dx platform for genotyping assays, allowing for rapid patient evaluation, enhancing precision medicine by enabling timely treatment decisions with genomically targeted therapies.

Other key players in the market include Abbott, Agilent Technologies, Inc., Revvity, Charles River Laboratories, Bio-Rad Laboratories, Inc., and Eurofins Scientific.

## Key Questions Answered in the United States Biomarkers Market

- What was the United States biomarkers market value in 2024?
- What is the United States biomarkers market forecast outlook for 2025-2034?
- What are the major factors aiding the United States biomarkers market demand?
- How has the market performed so far, and how is it anticipated to perform in the coming years?
- What are the market's major drivers, opportunities, and restraints?
- What are the major United States biomarkers market trends?
- Which offerings will lead the market segment?
- Which type will lead the market segment?
- Which application will lead the market segment?
- Which technology will lead the market segment?
- Which disease indication will lead the market segment?
- Which end user will lead the market segment?
- Who are the key players involved in the United States biomarkers market?
- What is the patent landscape of the market?
- What are the current unmet needs and challenges in the market?
- How are partnerships, collaborations, mergers, and acquisitions among the key market players shaping the market dynamics?

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