

Predictive Biomarkers Market Size, Share and Growth Outlook 2026: By Offering Type (Consumables, Services, Software), By Class, By Technology Matrix, By Disease Indication, By Application Scope, By End-User Sector, Companies to 2034.

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Abstracts

The global Predictive Biomarkers Market size is forecast to increase from \$9.51 Billion in 2026 to \$22.52 Billion in 2034 at a CAGR of 11.38% between 2026 and 2034.

The Predictive Biomarkers market report provides detailed analysis and outlook of Predictive Biomarkers segments including By Offering Type (Consumables, Services, Software), By Class (Efficacy Biomarkers, Safety Biomarkers, Validation Biomarkers), By Technology Matrix (Polymerase Chain Reaction (PCR), Next-Generation Sequencing (NGS), Immunoassays, Mass Spectrometry and Chromatography), By Disease Indication (Oncology / Cancer, Infectious Diseases, Immunological and Autoimmune Disorders, Cardiovascular Disorders), By Application Scope (Clinical Diagnostics, Drug Discovery and Development, Personalized Medicine / Companion Diagnostics), By End-User Sector (Hospitals and Diagnostic Laboratories, Pharmaceutical and Biopharmaceutical Companies, Academic and Research Institutes) across global and regional markets. Further, analysis and outlook across 21 countries in North America, Europe, Asia Pacific, Middle East, Africa, and South America are provided in the study.

Predictive Biomarkers Industry Overview

Companion Diagnostics, Precision Oncology, and Biomarker-Driven Therapeutics Are Reshaping Predictive Biomarker Markets

The predictive biomarkers industry continues to evolve rapidly as precision medicine strategies increasingly rely on molecular diagnostics to identify patients most likely to respond to targeted therapies. Regulatory agencies, pharmaceutical developers, and diagnostic manufacturers are expanding the integration of companion diagnostics into drug development programs, transforming predictive biomarker testing into a fundamental component of modern oncology treatment pathways. Advances in next-generation sequencing, immunohistochemistry, genomic profiling, and molecular pathology are enabling more precise patient stratification while improving therapeutic outcomes and optimizing healthcare resource utilization.

Companion Diagnostic Approvals Are Accelerating Precision Oncology Adoption

Regulatory agencies are increasingly approving therapeutic agents alongside validated predictive biomarker assays, reinforcing the role of companion diagnostics in clinical decision-making. This co-development model allows healthcare providers to identify treatment-responsive patient populations with greater precision. A significant example is the approval of AstraZeneca's Truqap (capivasertib) in combination with abiraterone and prednisone for metastatic androgen pathway modulation-na^{ve} or sensitive prostate cancer. The approval was granted concurrently with an FDA-authorized companion diagnostic assay designed to identify PTEN deficiency biomarkers, enabling clinicians to select patients most likely to benefit from targeted therapeutic intervention.

Genomic Instability and Homologous Recombination Deficiency Testing Are Expanding Clinical Utility

Comprehensive genomic profiling technologies are increasingly serving as essential predictive tools for selecting targeted oncology treatments. The growing clinical importance of homologous recombination deficiency and genomic instability markers is driving broader adoption of advanced sequencing-based diagnostics. This trend is illustrated by the FDA approval of MyChoice® CDx from Myriad Genetics, Inc. as the exclusive companion diagnostic for Zejula (niraparib) in advanced ovarian cancer maintenance therapy. The assay combines BRCA1/2 mutation detection with genomic instability scoring to identify patients exhibiting homologous recombination deficiency, supporting more precise treatment selection and improved therapeutic outcomes.

Immunohistochemistry Biomarkers Continue to Drive Immunotherapy Patient Selection

Despite advances in genomic sequencing technologies, immunohistochemistry-based biomarker testing remains a cornerstone of precision oncology due to its clinical

accessibility and established predictive value. Regulatory expansion of immunotherapy indications continues to increase demand for validated biomarker assays capable of identifying eligible patient populations. This trend is reflected in the expanded FDA approval granted to Agilent Technologies, Inc. for its PD-L1 IHC 22C3 pharmDx assay in esophageal and gastroesophageal junction carcinoma. The assay enables precise evaluation of PD-L1 expression levels, allowing clinicians to identify patients who are appropriate candidates for treatment with Merck's Keytruda (pembrolizumab), further strengthening the integration of predictive biomarkers into immuno-oncology treatment pathways.

Predictive Biomarkers Market Trends, Growth Drivers, Competitive Landscape, and Future Opportunities

The global Predictive Biomarkers market is witnessing increasing investments in innovation, product development, digital transformation, artificial intelligence integration, healthcare infrastructure expansion, and strategic partnerships across developed and emerging economies. Key Companies in the industry include- Thermo Fisher Scientific Inc., Qiagen N.V., F. Hoffmann-La Roche AG, Bio-Rad Laboratories, Inc., Agilent Technologies, Inc., Illumina Inc., Merck KGaA, Bio-Techne Corporation, Siemens Healthineers AG, Danaher Corporation. The Predictive Biomarkers market is expected to remain one of the most closely watched segments in the global healthcare industry, with companies focusing on niche market segments. As healthcare systems across the US, Europe, Asia-Pacific, Latin America, and Middle East & Africa continue to prioritize efficiency, access, and innovation, the Predictive Biomarkers industry outlook remains shaped by rising healthcare expenditure, demographic change, digital transformation, and product innovation.

The report provides detailed market analysis including-

- Growth Predictive Biomarkers Market size outlook across 3 scenarios- High growth, reference, and Low growth cases

- Market Trends, Drivers, Potential Opportunities, and Challenges faced by Predictive Biomarkers companies

- Porter's Five forces analysis- Bargaining power of buyers and sellers, Threat of Substitutes and new entrants, and Intensity of competitive rivalry

- Detailed SWOT Analysis of global and regional Predictive Biomarkers markets

Competitive analysis including business description, product analysis, and financial profiles

Key country specific analysis detailing key factors shaping the short-term and long-term outlook

Recent industry developments and news including mergers, acquisitions, product launches, expansions, and company announcements

Predictive Biomarkers Market Competitive Benchmarking and Company Analysis

Leading companies in Predictive Biomarkers industry include- Thermo Fisher Scientific Inc., Qiagen N.V., F. Hoffmann-La Roche AG, Bio-Rad Laboratories, Inc., Agilent Technologies, Inc., Illumina Inc., Merck KGaA, Bio-Techne Corporation, Siemens Healthineers AG, Danaher Corporation. The Predictive Biomarkers market remains moderately to highly fragmented, with competition expected to intensify as companies accelerate investments in innovation, geographic expansion, strategic partnerships, and portfolio diversification through 2034. In developed markets such as the United States, Germany, France, the United Kingdom, and Canada, competition is increasingly centered on innovation, reimbursement positioning, and value-based healthcare solutions. Meanwhile, emerging markets including China, India, Brazil, and countries across the Middle East and Africa continue to present significant opportunities for expansion due to rising healthcare expenditure, growing patient populations, and increasing access to healthcare services.

What to expect in US Predictive Biomarkers Markets in 2026 and beyond- Market Size, Share, Growth Rate, and Forecast to 2034

The US healthcare expenditure is forecast to reach \$8.2 Trillion in 2034 from \$5.5 Trillion in 2026 based on the National Health Expenditure Accounts (NHEA) data. With an aging population, rising chronic disease burden, and increasing migration toward minimally invasive and outpatient care, the Predictive Biomarkers market remains one of the strongest-performing segments in the country.

The US Predictive Biomarkers Companies are opting new business models, optimized pricing models, industry partnerships, and AI-enabled back end transformations to enhance efficiency and cost management. The US Predictive Biomarkers market faces

successive waves of challenging trends, with strong opportunities across select segments. The CMS plan to implement Medicaid from 2027 is driving states to build eligibility verification systems throughout 2026. Looking ahead to 2034, we anticipate stronger results underpinned by opportunities exist across Predictive Biomarkers industry. On the medical device front, over 7,000 device manufacturers continue to gain from increasing demand from demand for implantable devices, surgical instruments, monitoring equipment, and diagnostic systems.

Canada- Proximity to the US and healthcare similarities to EU5 countries fuel sales of Canadian Predictive Biomarkers markets

Canada's strong Predictive Biomarkers sales performance is underpinned by an aging population and a well-developed healthcare infrastructure. Steady growth in new brand spending in rural and urban locations fuel the long-term prospects of small and medium-sized enterprises across medical, diagnostic, and therapeutic devices. The Canadian Predictive Biomarkers market presents significant opportunities for U.S. exporters of medical devices, with the U.S. being Canada's largest trading partner for this sector. Potential advantages including specialized materials, advanced manufacturing techniques, and digital technologies support the launch of new products in the country.

Germany Predictive Biomarkers Trends and Perspectives to 2034- Financial sustainability, hospital restructuring, demographic pressures, and digitization of care delivery continue to shape the German healthcare industry.

Germany continues to remain the largest Predictive Biomarkers market in Europe, driven by over €600 Billion healthcare expenditure, €12 Billion medical device R&D expenditure, statutory health insurance system covering 90% German population, nationwide rollout of the electronic patient record (ePA), and large-volume of Predictive Biomarkers population. In particular, Research and development in Germany fuels the commercialization of cutting-edge technologies. Companies across the Germany Predictive Biomarkers industry value chain are focusing on both domestic markets and exports. The country is also driving digital adoption with the Hospital Future Act driving hospitals to upgrade their information systems by 2027. Over the forecast period, aging population, rising healthcare costs, and increasing procedural volumes drive the Predictive Biomarkers market outlook.

France Market Size, Growth Rate, and Forecast Analysis to 2034- Universal healthcare system, high public healthcare expenditure, and strong government support Predictive Biomarkers sales through 2034

France Predictive Biomarkers companies are emphasizing on opportunities for rapid, at-scale innovation to boost profitability over the long-term. The country's National Health Insurance spending target (ONDAM) estimates 3.7% growth in the country's healthcare expenditure. Over the forecast period, expenditure control measures, chronic disease management initiatives, workforce reforms, and efforts to improve system efficiency drive the long-term prospects.

The biggest 2026 policy frame is the PLFSS 2026. The law sets the Maladie branch spending target at €271.4 billion for 2026 and fixes the ONDAM at €117.5 billion for city care, €112.8 billion for health establishments, and €18.3 billion for elderly-care establishments and services. France's market is also being pulled by demographics. INSEE estimates that on 1 January 2026 France had 69.1 million inhabitants, with 22% aged 65 or over. INSEE also reported that 2025 births were 645,000 and deaths were 651,000, producing a negative natural balance of about 6,000 for the first time since the end of the Second World War.

UK Predictive Biomarkers Market Size, Share, and Growth Projections to 2034- Rapid growth driven by new and existing brands across the industry value chain

Small high-need consumer segments remain key priority of Predictive Biomarkers distributors in the UK industry. Continuous launch of new products coupled with high expenditures support the market outlook. The UK Government financing remains the dominant funding source at 81.3% of total healthcare expenditure, or ?280 billion in 2025. According to the ONS, total healthcare spending grew 7.7% nominally and 3.9% in real terms from 2024 to 2025. Similarly, out-of-pocket spending was ?49 billion (14.1%) and voluntary health insurance was ?9.5 billion (2.8%). The market is driven by rapid digital adoption with NHS England's plan to give more than 500,000 staff access to new AI tools.

China Predictive Biomarkers Market Growth Drivers, Revenue Trends, and Forecast- Medical insurance coverage is rapidly expanding over the past few years

China Predictive Biomarkers market is undergoing a structural shift from hospital-centric care toward a more integrated system emphasizing primary care, outpatient services, and long-term care. Chinese local players are emerging as a strong pillar of Predictive Biomarkers industry, offering opportunities for both competition and partnership. Over the forecast period, new and innovative product launches remain key elements driving market outlook. China's healthcare industry is increasingly centered on expanding

healthcare capacity, improving access to advanced treatments, and reducing dependence on imported technologies.

The National Healthcare Security Administration reported that by end-2024, China's basic medical insurance covered 1.32662 billion people and the coverage rate was 95%. Regional disparities in consumer spending trends continue to become more pronounced in the Chinese Predictive Biomarkers industry. Over the forecast period, demand will keep shifting toward geriatrics, chronic disease management, rehabilitation, long-term care, and outpatient care, while pricing pressure will remain intense in drugs and consumables because reimbursement.

India Predictive Biomarkers Market Landscape: Current Size and Long-Term Growth Outlook - Increased pricing pressures in US market is encouraging domestic vendors to expand across India

Indian Predictive Biomarkers market is witnessing the rapid emergence of an ecosystem that brings together diverse companies across the industry value chain. Further, large-scale healthcare public and private investments and a steady growth in chronic conditions is driving sales of pharmaceuticals and medical devices. Further, non-retail channel is experiencing volume decrease and patients are migrating to the retail. Indian medical device firms are also combining precision engineering with lower labor costs to make world-class diagnostics, robotics, and critical care devices.

Brazil Predictive Biomarkers market remains price-driven, with products domestically manufactured and accessibility offering potential opportunities

Healthcare expenditure in Brazil exceeds 10% of GDP, with the country among the highest healthcare spenders in Latin America. ANS reported 53.2 million medical-plan beneficiaries in December 2025, while IBGE projects a steady rise in older-age cohorts, with people aged 60+ already representing about 23% of the population. The price sensitive market access is broad through the public system, private coverage adds a sizeable premium layer, and reimbursement, procurement, and hospital efficiency remain key buying drivers.

Middle East and Africa Predictive Biomarkers Industry Trends and Perspectives to 2034

According to the World Bank, the Middle East and North Africa population exceeds 500 million, while Sub-Saharan Africa's population exceeds 1.2 billion, making the broader MEA region one of the fastest-growing healthcare demand centers globally. The GCC

countries including Saudi Arabia, United Arab Emirates, Qatar, and Kuwait continue to account for a disproportionately large share of regional healthcare spending. Government-led programs such as Saudi Arabia's Vision 2030 are accelerating investments in hospital infrastructure, private-sector participation, medical technology adoption, and healthcare digitalization. On the other hand, South Africa, Egypt, Nigeria, and Kenya remain key healthcare markets due to their large populations, expanding private healthcare sectors, and growing investments in healthcare delivery systems.

Predictive Biomarkers Market Segmentation

By Offering Type

Consumables

Services

Software

By Class

Efficacy Biomarkers

Safety Biomarkers

Validation Biomarkers

By Technology Matrix

Polymerase Chain Reaction (PCR)

Next-Generation Sequencing (NGS)

Immunoassays

Mass Spectrometry and Chromatography

By Disease Indication

Oncology / Cancer

Infectious Diseases

Immunological and Autoimmune Disorders

Cardiovascular Disorders

By Application Scope

Clinical Diagnostics

Drug Discovery and Development

Personalized Medicine / Companion Diagnostics

By End-User Sector

Hospitals and Diagnostic Laboratories

Pharmaceutical and Biopharmaceutical Companies

Academic and Research Institutes

Leading Companies in Predictive Biomarkers Industry (2026)

Thermo Fisher Scientific Inc.

Qiagen N.V.

F. Hoffmann-La Roche AG

Bio-Rad Laboratories, Inc.

Agilent Technologies, Inc.

Illumina Inc.

Merck KGaA

Bio-Techne Corporation

Siemens Healthineers AG

Danaher Corporation

Countries Included

North America- US, Canada, Mexico

Europe- Germany, France, UK, Spain, Italy, Nordics, Others

Asia Pacific- China, India, Japan, South Korea, Australia, Southeast Asia, Others

Latin America- Brazil, Argentina, Others

Middle East and Africa- Saudi Arabia, UAE, Other Middle East, South Africa, Other Africa

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Services

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Safety Biomarkers
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By Technology Matrix
Polymerase Chain Reaction (PCR)
Next-Generation Sequencing (NGS)
Immunoassays
Mass Spectrometry and Chromatography
By Disease Indication
Oncology / Cancer
Infectious Diseases
Immunological and Autoimmune Disorders
Cardiovascular Disorders
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