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Biomarker Testing Market Forecasts to 2034 – Global Analysis By Test Type (Tumor Biomarker Testing, Genomic Testing, Proteomic Testing, Metabolomic Testing, Imaging Biomarker Testing, and Other Test Types), Biomarker Type, Technology, Disease Area, Application, End User, and By Geography

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Abstracts

According to Stratistics MRC, the Global Biomarker Testing Market is accounted for $22.4 billion in 2026 and is expected to reach $61.0 billion by 2034 growing at a CAGR of 13.3% during the forecast period. Biomarker testing involves the measurement and analysis of biological indicators such as genes, proteins, or metabolites to assess normal biological processes, disease progression, or therapeutic responses. This market is central to the evolution of precision medicine, enabling tailored treatment strategies across oncology, neurology, and autoimmune disorders. The increasing adoption of companion diagnostics and liquid biopsy techniques is expanding the clinical utility of biomarker tests, while technological advancements in next-generation sequencing and mass spectrometry are enhancing testing accuracy, throughput, and accessibility for routine patient care.

Market Dynamics:

Driver:

Rising global cancer incidence and demand for personalized oncology

The escalating burden of cancer worldwide is fueling unprecedented demand for biomarker testing to guide targeted therapies and immunotherapies. Tumor biomarker

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and genomic testing enable clinicians to identify specific mutations, such as EGFR, BRCA, or PD-L1 expression, allowing for precise drug selection that improves survival outcomes while reducing unnecessary chemotherapy exposure. As oncology drug development increasingly relies on biomarker-driven patient stratification, regulatory agencies are mandating companion diagnostic approvals alongside novel therapies. This symbiotic relationship between diagnostic advancement and therapeutic innovation ensures sustained market expansion, with biomarker testing becoming non-negotiable in modern cancer care pathways.

Restraint:

High costs and reimbursement limitations

Despite clinical benefits, significant financial barriers hinder widespread adoption of advanced biomarker testing across many healthcare systems. Comprehensive genomic profiling and multi-analyte tests can cost hundreds to thousands of dollars per patient, placing them beyond reach in resource-limited settings or for uninsured populations. Inconsistent reimbursement policies across public and private payers create uncertainty for clinical laboratories and hospitals, discouraging investment in testing infrastructure. Additionally, coverage often lags behind test innovation, leaving patients to shoulder expenses for emerging biomarkers. These economic constraints disproportionately affect lower-income regions, widening healthcare disparities and slowing the market's full potential.

Opportunity:

Expansion of liquid biopsy for early cancer detection

Minimally invasive liquid biopsy technologies are unlocking vast opportunities for screening, early diagnosis, and treatment monitoring without tissue sampling. By detecting circulating tumor DNA, exosomes, or tumor-educated platelets in blood, these tests enable serial monitoring of treatment response and early identification of resistance mutations. Emerging applications in multi-cancer early detection from a single blood draw promise to revolutionize population screening programs, catching malignancies before symptoms appear. As assay sensitivity improves and costs decrease, liquid biopsy is expected to complement—and in some cases replace—invasive tissue biopsies, dramatically expanding the addressable market for biomarker testing across preventive medicine.

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Threat:

Regulatory complexity and data interpretation challenges

Navigating fragmented global regulatory landscapes poses serious threats to market harmonization and test commercialization. Biomarker tests classified as laboratory-developed tests face different oversight compared to in vitro diagnostics, creating compliance uncertainty for developers. Simultaneously, the vast volume of genomic and proteomic data generated by high-throughput platforms strains existing bioinformatics infrastructure, leading to interpretation variability across laboratories. Inconsistent reporting standards and lack of universally accepted variant classification guidelines risk misdiagnosis or inappropriate treatment decisions. These challenges may erode clinician confidence and delay adoption, especially for novel biomarkers lacking robust clinical validation in diverse populations.

Covid-19 Impact:

The pandemic created both disruptions and unexpected accelerations for biomarker testing markets. Laboratory resources were temporarily diverted to COVID-19 testing, delaying non-urgent cancer diagnostics and elective procedure volumes. However, the crisis validated decentralized and at-home testing models, spurring innovations in remote sample collection and digital health integration for biomarker workflows. Increased awareness of infectious disease biomarkers also stimulated technology transfer to other therapeutic areas. Long-term, the pandemic reinforced the value of rapid, accurate diagnostic infrastructure, prompting government investments in genomic surveillance capabilities that are now being repurposed for oncology and rare disease testing programs worldwide.

The Tumor Biomarker Testing segment is expected to be the largest during the forecast period

The Tumor Biomarker Testing segment is expected to account for the largest market share during the forecast period, driven by the persistent dominance of oncology applications in precision medicine. Tumor biomarkers, including protein overexpression, gene mutations, and circulating tumor cells, are integral to nearly every stage of cancer management—from risk assessment and early detection to treatment selection and recurrence monitoring. The proliferation of targeted therapies and immunotherapies has created a dependency on companion diagnostic tests that identify eligible patient populations. With over 200 cancer types and thousands of associated biomarkers under

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investigation, this segment continues to attract the highest research investment and commercial activity, ensuring its leadership throughout the forecast timeline.

The Predictive Biomarkers segment is expected to have the highest CAGR during the forecast period

Over the forecast period, the Predictive Biomarkers segment is predicted to witness the highest growth rate, reflecting the accelerating shift toward pre-treatment patient stratification in drug development and clinical practice. Unlike prognostic markers that forecast disease outcome regardless of therapy, predictive biomarkers directly inform which patients are most likely to respond to a specific intervention, minimizing adverse events and healthcare waste. The rise of immunotherapies reliant on PD-L1 and MSI scoring, as well as PARP inhibitors requiring BRCA testing, exemplifies this trend. As pharmaceutical pipelines prioritize biomarker-anchored trials and regulatory bodies encourage codevelopment of drugs with companion diagnostics, predictive biomarker testing will expand faster than any other category, reshaping therapeutic paradigms across multiple disease areas.

Region with largest share:

During the forecast period, the North America region is expected to hold the largest market share, underpinned by advanced healthcare infrastructure, high per-capita healthcare spending, and strong private and public research funding. The United States leads in regulatory approvals for novel biomarker tests through the FDA's companion diagnostic pathway, while major diagnostic companies and clinical laboratories are headquartered in the region. Widespread adoption of next-generation sequencing in both academic and community oncology settings, combined with favorable reimbursement policies from Medicare and private insurers, ensures sustained market leadership. Additionally, patient advocacy groups and precision medicine initiatives drive continuous demand for cutting-edge biomarker testing services.

Region with highest CAGR:

Over the forecast period, the Asia Pacific region is anticipated to exhibit the highest CAGR, fueled by large patient populations, rising healthcare expenditures, and rapid modernization of diagnostic capabilities. Countries including China, India, Japan, and South Korea are witnessing a surge in cancer incidence alongside expanding middle-class access to advanced medical technologies. Government-led precision medicine initiatives, such as China's 'Precision Medicine Plan,' are investing heavily in genomic

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infrastructure and training. Local manufacturing of testing reagents and platforms is reducing costs, while international diagnostic companies are forming strategic partnerships with regional laboratories. As regulatory harmonization progresses and awareness of biomarker-guided therapy grows, Asia Pacific emerges as the fastest-growing market for biomarker testing.

Key players in the market

Some of the key players in Biomarker Testing Market include Thermo Fisher Scientific Inc., F Hoffmann La Roche Ltd, Abbott Laboratories, Danaher Corporation, Bio Rad Laboratories Inc., Qiagen NV, Agilent Technologies Inc., PerkinElmer Inc., Siemens Healthineers AG, Illumina Inc., Merck KGaA, Waters Corporation, Myriad Genetics Inc., Guardant Health Inc., Exact Sciences Corporation and NeoGenomics Inc.

Key Developments:

In April 2026, Abbott received the AACR Cancer Prevention Research Award for its DETECT-A study, the first large prospective interventional trial of a blood-based multi-cancer early detection test in a real-world setting.

In March 2026, Agilent showcased expanded biomarker capabilities at the USCAP Annual Meeting, featuring a new PD-L1 indication for epithelial ovarian, fallopian tube, and primary peritoneal carcinoma to guide immunotherapy.

In March 2026, Illumina expanded its collaboration with Labcorp to increase access to precision oncology, focusing on the co-commercialization of FDA-authorized liquid biopsy and solid tumor profiling kits (TruSight Oncology Comprehensive).

Test Types Covered:

- Tumor Biomarker Testing
- Genomic Testing
- Proteomic Testing
- Metabolomic Testing
- Imaging Biomarker Testing

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Other Test Types

Biomarker Types Covered:

Predictive Biomarkers

Prognostic Biomarkers

Safety Biomarkers

Pharmacodynamic Biomarkers

Surrogate Biomarkers

Technologies Covered:

Polymerase Chain Reaction (PCR)

Next-Generation Sequencing (NGS)

Immunoassays

Mass Spectrometry

Microarray Technology

Other Technologies

Disease Areas Covered:

Oncology

Cardiovascular Diseases

Neurological Disorders

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- Infectious Diseases
- Metabolic Disorders
- Other Disease Areas

Applications Covered:

- Clinical Diagnostics
- Drug Discovery & Development
- Personalized Medicine
- Clinical Research
- Other Applications

End Users Covered:

- Hospitals & Clinics
- Diagnostic Laboratories
- Pharmaceutical & Biotechnology Companies
- Academic & Research Institutes
- Other End Users

Regions Covered:

- North America
  - United States

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- Canada
- Mexico

Europe

- United Kingdom
- Germany
- France
- Italy
- Spain
- Netherlands
- Belgium
- Sweden
- Switzerland
- Poland
- Rest of Europe

Asia Pacific

- China
- Japan
- India
- South Korea

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- Australia
- Indonesia
- Thailand
- Malaysia
- Singapore
- Vietnam
- Rest of Asia Pacific

South America

- Brazil
- Argentina
- Colombia
- Chile
- Peru
- Rest of South America

Rest of the World (RoW)

- Middle East
  - Saudi Arabia
  - United Arab Emirates
  - Qatar
  - Israel

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Rest of Middle East

Africa

South Africa

Egypt

Morocco

Rest of Africa

What our report offers:
- Market share assessments for the regional and country-level segments
- Strategic recommendations for the new entrants
- Covers Market data for the years 2023, 2024, 2025, 2026, 2027, 2028, 2030, 2032 and 2034
- Market Trends (Drivers, Constraints, Opportunities, Threats, Challenges, Investment Opportunities, and recommendations)
- Strategic recommendations in key business segments based on the market estimations
- Competitive landscaping mapping the key common trends
- Company profiling with detailed strategies, financials, and recent developments
- Supply chain trends mapping the latest technological advancements

Free Customization Offerings:

All the customers of this report will be entitled to receive one of the following free customization options:

Company Profiling

Comprehensive profiling of additional market players (up to 3)

SWOT Analysis of key players (up to 3)

Regional Segmentation

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Market estimations, Forecasts and CAGR of any prominent country as per the client's interest (Note: Depends on feasibility check)

Competitive Benchmarking

Benchmarking of key players based on product portfolio, geographical presence, and strategic alliances

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Note: Tables for North America, Europe, APAC, South America, and Rest of the World (RoW) Regions are also represented in the same manner as above.

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