United States Cancer Biomarkers - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2025 - 2030)

Market Report | 2025-06-01 | 90 pages | Mordor Intelligence

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Report description:

United States Cancer Biomarkers Market Analysis

The United States cancer biomarkers market stands at USD 7.62 billion in 2025 and is on course to reach USD 11.23 billion by 2030, translating into an 8.06% CAGR. The growth trajectory reflects federal funding from the Cancer Moonshot, streamlined reimbursement through CMS's Transitional Coverage pathway, and rapid clinical uptake of liquid-biopsy platforms. Rising cancer incidence in aging cohorts, especially in Sun Belt states, sustains volume demand, while 17 state-level coverage mandates reduce out-of-pocket risk for patients . The FDA's final rule on laboratory-developed tests (LDTs) creates a clearer regulatory runway that lowers commercialization risk for novel multi-omic assays. Alongside these top-down reforms, hospital systems continue to invest in centralized genomics laboratories that cut turnaround times and ease clinician adoption.

United States Cancer Biomarkers Market Trends and Insights

Rising Cancer Prevalence and Ageing Population

Cancer incidence now tops 2 million diagnoses each year, with mortality clustering in nonmetropolitan counties where biomarker access remains sparse. Population migration toward the Sun Belt magnifies demand in Florida, Texas, and Arizona, creating a dual market dynamic: urban centers pull premium multi-omic panels, whereas rural counties present large untapped test volumes. CDC geospatial mapping shows mortality hot spots in the Midwest, confirming unmet diagnostic need. As the national median age rises, comorbidity complexity pushes providers to order broader panels, lifting average revenue per patient. Point-of-care

liquid-biopsy pilots in community hospitals cut logistic barriers, but insufficient lab infrastructure still limits reach. These demographics ensure durable revenue upside well beyond the forecast horizon.

Precision-Medicine Push and FDA Approvals for Companion Diagnostics

The FDA cleared multiple high-impact companion tests in 2024, including broader indications for FoundationOne CDx. Tissue-agnostic guidance now lets drug developers target molecular alterations rather than tumor sites, expanding testable patient pools. Parallel ctDNA draft guidance validates minimal residual disease endpoints, encouraging payers to reimburse serial monitoring. Academic flagships like Mayo Clinic report that comprehensive genomic profiling doubles trial-matching odds relative to narrow panels. The regulatory momentum cascades through hospital networks, driving enterprise-wide adoption. Standardized order sets embedded in electronic health records further normalize testing and shorten decision cycles, reinforcing the virtuous adoption loop .

High Diagnostic Costs and Fragmented Private-Payer Reimbursement

Two-thirds of oncologists cite insurance denials as the top barrier to ordering biomarkers. While 17 states mandate coverage, commercial payers apply heterogeneous criteria; UnitedHealthcare and Cigna each publish distinct medical policies that create administrative friction. Health-economic models show that broad next-generation sequencing can cut per-patient costs by more than 50% compared with sequential single-gene testing, yet payers still favor narrower panels during prior authorization. This fragmentation slows market penetration for emerging assays lacking phase-III survival data. Hospital rev-cycle teams maintain biomarker "denial management" units to appeal rejections, adding overhead that discourages smaller centers from offering advanced panels.

Other drivers and restraints analyzed in the detailed report include:

Surge in Liquid-Biopsy Adoption for Minimally Invasive Detection / Federal Cancer Moonshot and NIH Funding Uptick for Biomarker Research / Complex Multi-Agency Regulatory Pathway /

For complete list of drivers and restraints, kindly check the Table Of Contents.

Segment Analysis

Breast cancer generated 36.33% of United States cancer biomarkers market revenue in 2024 through well-established panels targeting HER2, ER, PR, and multi-gene expression. The United States cancer biomarkers market size for prostate testing is projected to expand at a 9.02% CAGR, underpinned by urine-based assays such as MyProstateScore 2.0 that remove invasive digital rectal examinations. Multi-cancer early detection (MCED) pilots also embed breast and prostate signatures, reinforcing volume demand. Rapid adoption of Decipher and Prolaris gene score tests among urologists signals further upside.

Innovators are leveraging high-risk germline markers and somatic mutations to enable risk-stratified screening in African-American men, a cohort with elevated mortality yet historically low biomarker utilization. Community outreach paired with at-home urine collection broadens reach into previously under-screened zip codes. Oncology groups in the Midwest now bundle prostate genomic scores with MRI triage to reduce unnecessary biopsies, validating the segment's cost-effectiveness story. As PSA specificity limitations become more visible, guideline committees are expected to recommend multi-omic panels, catalyzing revenue.

Protein assays retained a 50.41% revenue position in 2024 because immunoassays remain embedded in analyzer workflows across most hospital laboratories. The United States cancer biomarkers market size for genetic assays is forecast to rise at a

9.11% CAGR as sequencing prices fall and companion diagnostic labeling expands. Thermo Fisher's Proximity Extension Assay acquisition adds more than 5,000 high-specificity protein targets, blurring traditional biomolecule boundaries and enabling integrated panels.

RNA-seq and methylation signatures gain visibility as they prove earlier detection windows compared with protein markers. Yet reimbursement still favors single-analyte proteins such as CA 19-9, CEA, and PSA because of decades-long clinician familiarity. Mass-spectrometry proteomics is entering translational pipelines to overcome antibody cross-reactivity challenges, but capital-expenditure requirements slow routine adoption. Meanwhile, circulating exosomes and metabolites remain in discovery, positioning genetic and protein biomarkers as dual pillars through 2030.

The United States Cancer Biomarkers Market is Segmented by Disease (Breast Cancer, Lung Cancer, Prostate Cancer, and More), Biomolecule Type (Protein Biomarkers and More), Profiling Technology (Omics Technologies, Imaging Technologies, and More), and End User (Hospitals & Clinics, and More). The Market and Forecasts are Provided in Terms of Value (USD).

List of Companies Covered in this Report:

Abbott Laboratories / Agilent Technologies / bioMerieux / Bio-Rad Laboratories / Caris Life Sciences / Exact Sciences / Roche / Foundation Medicine / Guardant Health / GRAIL / Hologic / Illumina / Myriad Genetics / Natera / NeoGenomics / QIAGEN / Quest Diagnostics / Thermo Fisher Scientific / 23andMe / Adaptive Biotechnologies / Somalogic /

Additional Benefits:

The market estimate (ME) sheet in Excel format /
3 months of analyst support /

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