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U.S. Oncology Based Molecular Diagnostics Market Size, Share & Trends Analysis Report By Type (Breast Cancer, Lung Cancer), By Product (Instruments, Reagents), By Technology (PCR, Sequencing), By Region, And Segment Forecasts, 2025 - 2033

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Abstracts

Market Size & Trends

The U.S. oncology based molecular diagnostics market size was estimated at USD 1.49 billion in 2024 and is expected to grow at a CAGR of 5.2% from 2025 to 2033. Key market driving factors for the market include the rapid evolution of sequencing technologies (e.g., shift from Sanger to NGS, adoption of long-read platforms like Nanopore and SMRT), enabling high-throughput, comprehensive genomic profiling. Increased availability of targeted therapies and pan-cancer biomarkers (e.g., HER2, EGFR, NTRK fusions) fuels demand for companion diagnostics. Rising adoption of minimally invasive methods, such as liquid biopsy/ctDNA testing, supports real-time disease monitoring and early detection. Advances in high-sensitivity platforms like ddPCR and RNA-seq improve the detection of low-frequency mutations and fusions, while AI/ML integration enhances tumor origin prediction. The growing clinical utility across multiple tumor types-from lung adenocarcinoma to breast cancer-combined with regulatory approvals for large-panel CDx assays (e.g., FoundationOne CDx, MSK-IMPACT), further accelerates market growth.

The U.S. oncology-based molecular diagnostics (MDx) market is experiencing strong growth momentum, fueled by rapid technological advancements, increasing integration of precision medicine into routine cancer care, expanding payer coverage, and a steady rise in clinically validated biomarkers. Over the past decade, the market has evolved from single-gene, low-throughput assays such as Sanger sequencing to

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comprehensive, high-throughput next-generation sequencing (NGS) platforms capable of detecting a broad range of mutations, fusions, copy number variations, and microsatellite instability in a single workflow. This technological shift has shortened turnaround times, improved sensitivity, and allowed clinicians to make treatment decisions faster, directly impacting patient outcomes.

One of the most notable technological drivers is the adoption of rapid, fully automated platforms such as the Idylla system by Biocartis, which has steadily expanded its oncology test portfolio since its U.S. introduction in 2015. The Idylla KRAS Mutation Test (U.S. launch in 2016) and EGFR Mutation Test (U.S. launch in 2017) enabled same-day biomarker results directly from FFPE tissue without complex laboratory infrastructure. More recently, the Idylla GeneFusion Assay, launched in 2023 in the U.S., provided detection of ALK, ROS1, RET, and NTRK gene fusions as well as MET exon 14 skipping in non-small cell lung cancer (NSCLC) with a turnaround time of under 3 hours. At the USCAP 2025 Annual Meeting (March 22-27, 2025), multiple independent studies from institutions such as Memorial Sloan Kettering and MD Anderson Cancer Center confirmed high concordance between Idylla™ assays and NGS for KRAS, EGFR, and BRAF mutations, while highlighting Idylla's ability to identify additional clinically relevant mutations not detected by certain competitor panels. The platform's rapid testing of cytology supernatants and fine needle aspiration samples, which would otherwise be discarded, underscores its role in expanding testable specimen types and accelerating targeted therapy initiation.

The expansion of precision medicine and companion diagnostics is another major growth driver. Since the FDA approved the first companion diagnostic for trastuzumab in 1998, the market has seen an increasing number of targeted therapies tied to specific molecular tests. For example, in 2012, the FDA approved the cobas 4800 BRAF V600 Mutation Test to guide vemurafenib therapy in melanoma, establishing a precedent for biomarker-driven oncology treatment. Today, KRAS mutation testing in metastatic colorectal cancer-integrated into standard clinical practice since NCCN guideline updates in 2009-prevents the use of costly anti-EGFR therapies in the approximately 40% of patients who harbor KRAS mutations. Similarly, BRAF mutation testing in melanoma ensures that only patients with the V600E mutation are given vemurafenib, improving response rates and reducing unnecessary drug exposure.

Liquid biopsy is rapidly becoming a standard component of oncology diagnostics due to its non-invasive nature and ability to monitor disease dynamics in real time. DiaCarta's RadTox test, deployed statewide in Florida in 2023, is a cfDNA-based assay that measures treatment response and tumor progression between cycles of chemotherapy

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or radiotherapy. This allows oncologists to modify treatment strategies early in cases of resistance, avoiding ineffective regimens and mitigating adverse events. DiaCarta has also launched other specialized oncology assays such as Oncuria for bladder cancer recurrence monitoring and BCG therapy response prediction, addressing treatment optimization in the face of drug shortages. The company's ColoScape test, launched in 2022, detects methylation patterns and mutations specific to colorectal cancer with high sensitivity, enabling early intervention in patients with advanced adenomas.

Naveris' NavDx test, first clinically introduced in 2020 and designated an Advanced Diagnostic Laboratory Test (ADLT) by CMS in early 2024, represents another milestone in viral oncology diagnostics. NavDx detects Tumor Tissue Modified Viral (TTMV)-HPV DNA in blood, enabling earlier detection of HPV-driven cancers before clinical or imaging evidence emerges. In July 2024, Blue Shield of California began covering NavDx, expanding access to this non-invasive, highly sensitive test. The coverage decision was based on data from over 30 peer-reviewed publications demonstrating its utility in detecting molecular residual disease and informing surveillance strategies for HPV-related head and neck cancers.

The operational efficiency of modern molecular diagnostics is also transforming oncology workflows. While NGS remains the gold standard for comprehensive genomic profiling, its longer turnaround times can delay treatment initiation in aggressive cancers. Rapid PCR-based assays such as the Idylla MSI Test, launched in the U.S. in 2019, deliver same-day MSI status for colorectal and other cancers, enabling timely decisions on immunotherapy eligibility. At USCAP 2025, studies from Icahn School of Medicine at Mount Sinai and the Mayo Clinic demonstrated high concordance between Idylla™ MSI testing and traditional methods, with the added benefit of resolving classification discrepancies in rare endometrial carcinoma subtypes.

From an economic perspective, molecular diagnostics align with the U.S. healthcare system's shift toward value-based care. Studies showed that pre-treatment KRAS testing in metastatic colorectal cancer could save hundreds of millions of dollars annually by avoiding ineffective anti-EGFR therapy. Similarly, predictive tests such as Oncuria ensure that limited supplies of drugs like BCG are allocated to patients most likely to respond, reducing waste and maximizing clinical benefit.

Large-scale initiatives such as the U.S. Precision Medicine Initiative, announced in 2015, continue to drive biomarker discovery and validation, further expanding the market's testable targets. As NGS costs decline and automation improves, the integration of artificial intelligence into molecular diagnostics-particularly for tumor origin

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prediction and resistance mechanism analysis-is expected to enhance clinical utility and accelerate adoption. The combination of regulatory support for companion diagnostics, payer recognition of clinical utility, and an expanding body of evidence from real-world implementation solidifies molecular diagnostics as a central pillar in the future of oncology care in the U.S., with 2023 - 2025 marking a pivotal period of market expansion, technological maturation, and broader clinical integration.

U.S. Oncology Based Molecular Diagnostics Market Report Segmentation

This report forecasts revenue growth at country level and provides an analysis of the latest trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the U.S. oncology based molecular diagnostics market report based on product, technology, type, and region:

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

Breast Cancer

Prostate Cancer

Colorectal Cancer

Cervical Cancer

Liver Cancer

Lung Cancer

Blood Cancer

Kidney Cancer

Others

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

Instruments

Reagents

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Others

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

PCR

In situ hybridization

INAAT

Chips and microarrays

Mass spectrometry

Sequencing

TMA

Others

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