Oncology Companion Diagnostics Market Driven by Targeted Therapies & Biomarker Advances | DataM Intelligence

Oncology companion diagnostics market grows with rising demand for personalized cancer treatments, biomarker discovery, and regulatory approvals


Oncology Companion Diagnostics Market

TEXAS, TX, UNITED STATES, July 31, 2025 /EINPresswire.com/ -- Oncology companion diagnostics (CDx) are biomarker-based tests essential for selecting patients who will benefit from targeted therapies. According to DataM Intelligence, the global market stood at about USD 5.64 billion in 2024 and is forecast to grow to approximately USD 11.43 billion by 2033, at a CAGR of ~8.9%. This growth is driven by rising cancer incidence, broader adoption of precision treatments, and regulatory support for test drug pairing.

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Oncology Companion Diagnostics Market Segments

 By Product (Instrument, Consumables, Software)
 By Technology (Immunohistochemistry (IHC), Polymerase Chain Reaction (PCR), Next-Generation Sequencing (NGS), In situ hybridization (ISH)/Fluorescence in situ hybridization (FISH), Other)
 By End User (Hospital, Diagnostic Laboratory, Other)

In Product & Service segments the product offerings such as test kits and reagents held the largest share in 2023, supported by stable demand across diagnostics laboratories. Services, including CDx development collaborations, validation, and lab-based testing, are growing most quickly, rising at an estimated CAGR, as pharma increasingly outsources CDx development.

In Technology Type the IHC (immunohistochemistry) dominates in solid-tumor diagnostics, but NGS-based platforms are the fastest-growing technology, capturing traction in multi-gene profiling and rare mutations screening.

In Disease Type the non–small cell lung cancer (NSCLC) currently accounts for the largest share, thanks to EGFR, ALK, and PD-L1 biomarkers. Breast cancer CDx especially HER2 and BRCA assays is projected to grow fastest, as immunotherapy and targeted therapy use expands.

In End Use the hospitals remain the largest end users, benefitting from integrated pathology and oncology workflows. Yet pathology/diagnostic labs are the fastest-growing channel, leveraging scale and biomarker multiplexing capabilities.

Key Players & Competitive Landscape in Oncology Companion Diagnostics Market

Major players include Agilent Technologies, Illumina, QIAGEN, Thermo Fisher, Roche, bioMérieux, Abbott, Myriad Genetics, Leica Biosystems, Guardant Health, and Foundation Medicine, ARUP Laboratories, Invivoscribe, Inc., Pillar Biosciences, Inc.

• Guardant Health leads in liquid biopsy-based CDx for NSCLC and MRD monitoring.
• Foundation Medicine, via Roche, offers comprehensive genomic profiling tied to targeted therapy decisions.
• Epigenomics supports niche assays like SHOX2 for lung cancer biomarkers in Europe and Japan.

The field is evolving rapidly through collaborations linking CDx and pharma pipelines to streamline regulatory co-approvals.

Regional Market Dynamics for Oncology Companion Diagnostics Market

• North America leads the global market, supported by early integration of CDx in drug approvals, strong payer support, and high precision oncology adoption rates.
• Asia-Pacific is the fastest-growing region especially China and Japan, where CDx uptake is accelerating alongside localized test approvals and pricing support
• Europe maintains a substantial share due to robust biomarker programs in Germany, UK, and France and regulatory coordination under EMA frameworks.
• Latin America shows gradual expansion, with growth in Brazil and Mexico fueled by partnerships and oncology network improvements.
• Middle East & Africa remain nascent, yet the GCC and South Africa are expanding CDx use via private hospital and screening initiatives.

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Investment Highlights & Strategic Moves in Oncology Companion Diagnostics Market

United States
• May 2025: The U.S. FDA approved VENTANA MET (SP44) RxDx Assay as a CDx for telisotuzumab vedotin in NSCLC, enhancing precision targeting for c-MET overexpressing tumors.
• January 2025: FoundationOne CDx received FDA approval as the first CDx for pediatric tovorafenib in BRAF-altered low-grade glioma supporting expanded rare cancer access.

Japan
• In April–May 2025, Ono Pharmaceutical acquired U.S.-based Deciphera Pharmaceuticals for USD□2.4□billion, expanding its oncology therapeutics globally and signaling likely CDx development synergies in Japan and U.S. markets.

Europe
• Sophia Genetics (Switzerland) announced it has processed over 2 million genomic profiles using its AI platform, reinforcing its role in European CDx and precision oncology infrastructure.

Oncology Companion Diagnostics Market Innovation & Growth Drivers

• NGS and multi-gene panels enable simultaneous detection of actionable mutations such as EGFR, BRAF, HER2, and MSI, expanding therapeutic matching in oncology.
• Liquid biopsy platforms such as ctDNA and TMB assays are fast replacing tissue biopsies in initial diagnosis and MRD monitoring.
• AI analytics & federated learning enable scalable biomarker discovery and predictive modeling, powered by companies like Owkin, which partners with pharma to accelerate CDx co-development using federated clinical data.
• Immuno-oncology companion diagnostics like PD-L1 and TMB tests are growing in response to therapeutic uptake in checkpoint inhibitors.
Oncology Companion Diagnostics Market Challenges & Opportunities

Challenges:

• High cost and reimbursement variability across regions can limit CDx access, especially in emerging markets.
• Regulatory alignment varies FDA typically requires co-approval of drug and test, while other regions may separate approvals.
• Operational complexity of integrating CDx into clinical workflows and ensuring consistent test standardization.

Future Outlook:

With oncology companion diagnostics poised to nearly double or triple in size by 2033, strategic

CDx therapeutic linkage, multi-gene and liquid biopsy platforms, and regional adoption curves especially in Asia-Pacific and North America are powering market transformation. Adoption of AI and federated diagnostics across pharma and health systems will further unlock innovation and reimbursement economics.

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