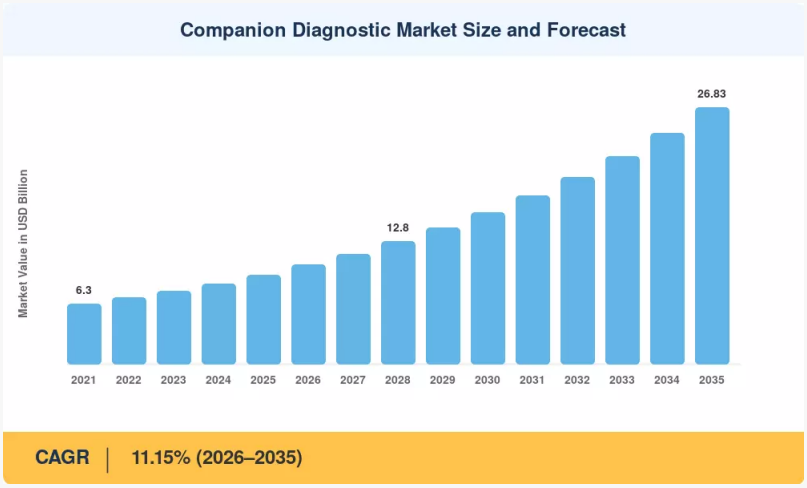
Companion Diagnostics Market to reach USD 26.83 Billion by 2035 at 11.15% CAGR

Companion Diagnostics Market to Surge from USD 9.32 Billion in 2025 to USD 26.83 Billion by 2035--- Powered by Regulatory Co-Development Requirements



Companion Diagnostic Market Size

NY, CA, UNITED STATES, August 12, 2026 /EINPresswire.com/ -- As per Market Research Future, the global Companion Diagnostics Market stood at USD 9.32 Billion in 2025, is projected to reach USD 10.36 Billion by 2026, and is forecast to climb to USD 26.83 Billion by 2035 at a CAGR of 11.15% during the forecast period 2026--2035.

The 11.15% CAGR is being supported by three converging forces: growing regulatory expectations for pairing targeted therapies with validated companion diagnostics, rapid expansion of next-generation sequencing panels, and commercialization of liquid biopsy technologies. Companion diagnostics are increasingly becoming an essential part of precision medicine by identifying patients most likely to benefit from specific therapies and helping clinicians make treatment decisions based on molecular characteristics.

Pharmaceutical and biotechnology companies are increasingly integrating companion diagnostics into drug-development programs from early clinical stages. At the same time, payer coverage for comprehensive genomic profiling is improving access to molecular testing, while AI-assisted interpretation and multi-omic platforms are expanding the value of diagnostic data. North America remains the dominant regional market, while Asia-Pacific is the fastest-growing region.

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Key Market Trends & Growth Drivers

Regulatory Mandates for Companion Diagnostic Co-Development

Regulatory agencies are increasingly emphasizing the use of validated companion diagnostics alongside targeted therapies where appropriate. This is creating a structural demand base because drug developers must increasingly consider diagnostic development as part of the therapeutic approval pathway.

The FDA's growing focus on CDx-linked oncology therapies is encouraging pharmaceutical companies to budget for parallel diagnostic development. Similar co-submission expectations from regulators in Europe and Japan are broadening the requirement internationally, strengthening demand for assays, validation services, instruments, and diagnostic partnerships.

NGS Cost Deflation and Multi-Gene Panel Expansion

Next-generation sequencing is rapidly changing companion diagnostic testing by allowing multiple biomarkers to be analyzed in a single run. Falling per-sample sequencing costs and expanding panel coverage are encouraging laboratories to move from sequential single-gene testing toward comprehensive genomic profiling.

NGS is the fastest-expanding technology segment, with a projected 14.80% CAGR from 2026 to 2035. The ability to evaluate numerous actionable biomarkers from one sample is particularly valuable in oncology, where treatment decisions increasingly depend on complex molecular profiles.

Liquid Biopsy Commercialization

Liquid biopsy is becoming one of the most important emerging technologies in the Companion Diagnostics Market. Blood-based testing can reduce dependence on invasive tissue collection and can support serial monitoring during treatment.

The liquid biopsy segment is projected to grow at a 19.65% CAGR through 2035, making it the fastest-growing sample category. Approved applications for EGFR, ALK, and other biomarkers are helping establish blood-based testing as an increasingly important complement to tissue-based diagnostics.

Market Segment Insights

BY TECHNOLOGY

Polymerase Chain Reaction (PCR): Dominant technology with 23.50% share in 2025. PCR remains

widely used for single-gene mutation testing, including EGFR and BRAF, supported by its established laboratory infrastructure.

Immunohistochemistry (IHC): Generated approximately USD 1.72 Billion in 2025. IHC remains important for protein-expression biomarkers such as HER2 and PD-L1 and continues to play a central role in oncology diagnostics.

Next-Generation Sequencing (NGS): Fastest-growing technology at a 14.80% CAGR from 2026 to 2035. Multi-gene panel approvals, falling sequencing costs, and increasing comprehensive genomic profiling are accelerating adoption.

In Situ Hybridization (ISH): Generated approximately USD 0.84 Billion in 2025 and remains relevant for detecting gene rearrangements such as ALK and ROS1.

Others: Represents approximately 8.30% share and includes emerging approaches such as digital PCR and mass spectrometry.

BY INDICATION

Lung Cancer: Dominant indication with approximately 20.40% share in 2025. EGFR, ALK, ROS1, KRAS G12C, and other actionable biomarkers create a strong structural testing requirement in non-small-cell lung cancer.

Breast Cancer: Generated approximately USD 1.68 Billion in 2025, supported by HER2, BRCA1/2, and PIK3CA testing associated with targeted and precision therapies.

Colorectal Cancer: Represents approximately 13.5% share, driven by RAS and BRAF testing required for treatment selection involving anti-EGFR therapies.

Melanoma: Fastest-growing indication at a 14.30% CAGR through 2035, supported by BRAF and NRAS mutation panels and expansion of targeted and immunotherapy combinations.

Other Indications: Projected to grow at a 12.20% CAGR as companion diagnostics expand into hematologic malignancies and rare tumors.

BY PRODUCT TYPE

Assays and Kits: Dominant product category with 70.80% share in 2025. Each new therapy carrying a CDx label can create recurring reagent demand linked to treatment eligibility and label expansion.

Instruments and Analyzers: Generated approximately USD 1.91 Billion in 2025, supported by laboratory platform upgrades and increasing molecular testing volumes.

Software and Services: Fastest-growing product category at a 16.35% CAGR through 2035. AI-driven interpretation and software-enabled analysis are increasing demand for diagnostic decision-support platforms.

BY SAMPLE TYPE

Tissue Biopsy: Dominant sample type with 72.10% share in 2025. Tissue remains the regulatory and clinical reference for histological confirmation in many treatment decisions.

Liquid Biopsy: Fastest-growing sample type at a 19.65% CAGR through 2035. Blood-based testing provides a less invasive option for selected biomarkers and can support serial monitoring.

Other Sample Types: Represents approximately 6.8% share and includes bone marrow and cytology specimens used in selected diagnostic applications.

BY END USER

Pharmaceutical & Biotechnology Companies: Dominant end-user segment with 41.20% share in 2025. These organizations fund and co-develop CDx assays linked to drug-development and clinical-trial programs.

Contract Research Organizations: Fastest-growing end-user segment at a 13.85% CAGR through 2035 as pharmaceutical companies increasingly outsource assay development, analytical validation, clinical testing, and regulatory support.

Hospitals & Reference Laboratories: Generated approximately USD 3.18 Billion in 2025, reflecting high clinical testing volumes and the increasing use of molecular diagnostics.

Academic & Research Institutions: Represents approximately 8.9% share and supports translational research, biomarker discovery, and development of emerging diagnostic technologies.

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Regional Outlook

North America --- Dominant Market (~43.15% Share, 2025)

North America led the global Companion Diagnostics Market with approximately 43.15% revenue share in 2025. The region's leadership is supported by mature payer frameworks, strong pharmaceutical R&D activity, established reference laboratories, and extensive adoption of

molecular oncology testing.

The United States accounts for approximately 82.5% of North American regional share. FDA co-development expectations and CMS coverage for comprehensive genomic profiling are supporting demand. Canada contributes through provincial genomic-testing programs, while Mexico is expanding through private oncology laboratory networks.

Europe --- Second Largest Market (~27.00% Share, 2025)

Europe held approximately 27.00% of global revenue in 2025. The market is being shaped by IVDR compliance, national genomic medicine programs, reimbursement reforms, and increasing adoption of molecular tumor profiling.

Germany is projected to grow at a 10.55% CAGR from 2026 to 2035, supported by reimbursement reforms. The UK generated approximately USD 0.48 Billion in 2025 through its NHS Genomic Medicine Service. France, Italy, Spain, and the Nordic countries are also strengthening genomic testing capacity and clinical adoption.

Asia-Pacific --- Fastest-Growing Region (13.45% CAGR, 2026--2035)

Asia-Pacific is the fastest-growing regional market, projected to expand at a 13.45% CAGR through 2035. Government genomic initiatives, expanding molecular laboratory infrastructure, increasing cancer testing, and private-sector investment are accelerating regional adoption.

China is projected to grow at a 14.65% CAGR, while India is expected to expand at 15.10% CAGR. Japan generated approximately USD 0.42 Billion in 2025, supported by PMDA companion-diagnostic requirements, while South Korea is projected to grow at 12.80% CAGR through 2035.

South America --- Growing Presence (USD 0.61 Billion, 2025)

South America generated approximately USD 0.61 Billion in 2025. Brazil represents the leading regional market, accounting for 58.5% of regional share, supported by private hospital oncology networks and advanced molecular pathology laboratories.

Argentina accounts for 22.3% of regional share, while the rest of South America represents 19.2%. Expansion of clinical-trial activity and molecular laboratory capabilities is expected to support further adoption.

Middle East & Africa --- Emerging Opportunity (~5.35% Share, 2025)

The Middle East & Africa represented approximately 5.35% of global share in 2025. Growth is concentrated in Gulf countries where government investment in genomic medicine and oncology infrastructure is accelerating.

Saudi Arabia accounts for 31.2% of regional share, followed by the UAE at 28.5%. South Africa represents 18.6% through its established reference-laboratory network, while Egypt contributes 12.4% as cancer-care infrastructure is modernized.

Competitive Landscape and Recent Developments

The Companion Diagnostics Market exhibits medium concentration, with the top five players accounting for an estimated 48--55% of global revenues. Competition is shaped by regulatory complexity, pharmaceutical co-development relationships, platform capabilities, molecular testing expertise, and the capital required to develop and validate diagnostic technologies.

The competitive landscape includes vertically integrated diagnostics companies, established IVD manufacturers, NGS specialists, and liquid-biopsy companies. Key participants include Roche Diagnostics, Abbott Laboratories, Agilent Technologies, Thermo Fisher Scientific, QIAGEN, Illumina, Guardant Health, Myriad Genetics, bioMérieux, and Exact Sciences.

KEY COMPANIES AND RECENT MILESTONES

Roche Diagnostics (October 2024): Received FDA approval for FoundationOne CDx as a companion diagnostic for a new KRAS G12C inhibitor in advanced NSCLC, expanding the panel's label to cover 17 targeted therapies.

Guardant Health (August 2024): Secured CMS Medicare coverage for the Shield blood test as a first-line colorectal cancer screening tool, representing an important milestone for liquid-biopsy reimbursement.

FDA (March 2024): Published updated guidance on using real-world data to support companion-diagnostic label expansions, potentially reducing the evidence burden for adding new indications to existing approved panels.

QIAGEN (November 2023): Partnered with a biopharma company to co-develop a therascreen CDx assay for a novel FGFR inhibitor in urothelial carcinoma, with Phase III enrollment underway.

Agilent Technologies (July 2023): Expanded the PD-L1 IHC 22C3 pharmDx assay label to include a new checkpoint-inhibitor combination in gastric cancer.

Future Outlook: 2026--2035

By 2030, AI-driven interpretation is expected to become increasingly embedded in companion diagnostic workflows. Automated variant classification, report generation, and decision-support capabilities can reduce interpretation time and improve consistency when laboratories process

complex molecular datasets.

Liquid biopsy is positioned to move from a reflex testing option toward a more prominent first-line role in selected cancers. The ability to obtain molecular information through a blood draw can support patients who lack adequate tissue samples and can enable repeated testing during treatment.

Pan-cancer and multi-omic platforms are another major opportunity. The integration of genomic, transcriptomic, and proteomic information into unified reports can provide broader biological context for treatment selection and clinical-trial matching.

Companion diagnostics are also expected to expand beyond oncology. Pharmacogenomic testing in cardiovascular, psychiatric, autoimmune, and other therapeutic areas could create additional application opportunities as drug-gene associations become more clinically actionable.

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