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Companion Diagnostics Market Size, Share & Trends Analysis Report By Product And Services (Assays, Kits, & Reagents, Instruments & Systems, Software & Services), By Indication, By Technology, By Sample Type, By End-use, By Region, And Segment Forecasts, 2025 - 2030

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Abstracts

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Companion Diagnostics Market Growth & Trends

The global companion diagnostics market size is expected treach USD 15.98 billion by 2030, registering a CAGR of 10.5% from 2025 t2030, according ta new report by Grand View Research, Inc. Companion diagnostics are specialized tests designed tensure the safe and effective use of specific therapeutic products by identifying corresponding biomarkers in patients. These tests are predominantly employed in oncology, where they guide clinicians in selecting the most appropriate targeted therapies based on a patient's unique genetic profile. For instance, Foundation Medicine's FOUNDATIONONE CDx analyzes over 300 cancer-related genes, providing critical insights that inform precision cancer treatments across various solid tumors. By identifying key mutations or genetic alterations, companion diagnostics facilitate personalized treatment regimens, thereby improving clinical outcomes and reducing the risk of adverse reactions. This individualized approach ttherapy not only enhances patient care but alssupports the broader shift towards precision medicine, where treatment strategies are tailored tthe genetic makeup of each patient.

Regulatory approvals play a pivotal role in bolstering the companion diagnostics market,

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particularly in oncology. In August 2022, the U.S. FDA approved ThermFisher Scientific Inc.'s Oncomine Dx Target Test, a companion diagnostic designed tidentify HER2 (ERBB2) activating mutations-including single nucleotide variants and exon 20 insertions—in non-small cell lung cancer tumors. Such regulatory endorsements validate the clinical utility of these tests and promote their widespread adoption. Additionally, the use of advanced techniques such as Next-Generation Sequencing (NGS) has become integral tcompanion diagnostics. NGS enables clinicians tevaluate multiple genes simultaneously, thereby providing comprehensive tumor profiling. The Centers for Disease Control and Prevention (CDC) has highlighted that NGS has successfully transitioned from a research tool ta clinically approved method within the past five years, underscoring its growing importance in diagnostic applications.

Technological innovation is a critical driver of growth in the companion diagnostics market. Key industry players are continuously advancing NGS platforms, digital ELISA, and liquid biopsy techniques timprove diagnostic precision and efficiency. Strategic partnerships are further accelerating these developments; for instance, in November 2023, QIAGEN partnered with Element Biosciences tprovide NGS workflows for the benchtop sequencer AVITI System, aiming tenhance discovery, reduce costs, and improve turnaround times in genomic research. Similarly, in January 2022, Illumina Inc. collaborated with SomaLogic Operating Co., Inc. tintegrate the SomaScan proteomics assay intits high-throughput NGS platforms. These collaborations not only expand the technological capabilities of companion diagnostics but alsfoster innovation in the development of new testing solutions, ensuring that emerging diagnostic methods keep pace with evolving clinical needs.

The rising prevalence of cancer globally has significantly spurred the adoption of companion diagnostics, as genomic testing offers a detailed insight inttumor biology that is critical for selecting effective treatment protocols. According tdata from the American Cancer Society Journal, approximately 1.9 million new cancer cases were reported in the U.S. in 2022, while the World Health Organization (WHO) noted that in the same year, there were 2.26 million new breast cancer cases and 2.21 million new lung cancer cases worldwide. In response tthese challenges, novel tests are being developed tdetect specific genetic mutations. For example, in August 2020, the U.S. FDA approved Guardant360 CDx, the first liquid biopsy companion diagnostic that employs NGS technology tdetect EGFR gene mutations in metastatic non-small cell lung cancer. In October 2023, QIAGEN further strengthened its market position by partnering with Myriad Genetics tdevelop advanced companion diagnostic solutions for oncology, thereby enhancing personalized treatment strategies and improving patient outcomes.

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Companion Diagnostics Market Report Highlights

Based on product and services segment, assays, kits, and reagents led the market with a 59.1% share in 2024, driven by increasing demand for personalized medicine and targeted therapies. These components are crucial in detecting specific biomarkers that help determine a patient's eligibility for precision treatments, particularly in oncology, cardiovascular diseases, and rare genetic disorders.

Based on indication, oncology held the dominant market share in 2024, driven by the increasing global cancer burden and the growing demand for personalized medicine. CDx plays a crucial role in identifying biomarkers that help select targeted therapies, improving treatment outcomes for cancer patients.

Based on technology, the Polymerase Chain Reaction (PCR) segment dominated the companion diagnostics market in 2024, holding a 27.7% share. Real-time PCR assays are widely used due ttheir high specificity and sensitivity, making them a preferred method for identifying cancer biomarkers

Based on sample type, tissue samples held the largest market share of 62.7% in 2024, driven by the widespread adoption of biomarker-based tissue testing for targeted therapies. Tissue samples are essential for identifying genetic mutations and protein expressions in solid tumors, guiding precision medicine in oncology.

Based on end use, the hospitals and physician laboratories segment dominated the oncology companion diagnostics market, holding a 38.6% share in 2024. Hospitals typically offer a comprehensive range of cancer diagnostic tests taddress the increasing cancer burden and aging populations.

North America dominated the global market with a market share of 40.2% in 2024. Primarily due tadvanced healthcare infrastructure, substantial healthcare expenditure, and a robust regulatory framework that expedites approvals for new diagnostic technologies

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