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Oncology Companion Diagnostic Market Opportunity, Growth Drivers, Industry Trend Analysis, and Forecast 2025 - 2034

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Abstracts

The Global Oncology Companion Diagnostic Market reached USD 4.6 billion in 2024 and is expected to grow at a CAGR of 10.8% from 2025 to 2034. Oncology companion diagnostics are essential tools that provide critical insights into the safe and effective use of corresponding drugs or biological products in cancer treatment. These diagnostics help identify specific genetic markers, mutations, and biomarkers in a patient's tumor, enabling healthcare providers to determine whether a patient is likely to respond to a targeted therapy. The increasing adoption of precision medicine has shifted the focus from traditional treatment methods to personalized approaches that tailor therapies based on a patient's unique tumor characteristics and genetic profile. This trend is a key driver fueling the demand for oncology companion diagnostics.
The market is segmented by offering, technology, disease type, and end-use. By offering, the market is divided into products and services. The product segment, which includes instruments, consumables, and software, generated USD 3 billion in revenue in 2024 and is projected to grow at a CAGR of 10.6% during the forecast period. Instruments such as polymerase chain reaction (PCR) systems and next-generation sequencers (NGS) offer high sensitivity and accuracy in detecting genetic mutations. Consumables, including reagents, assay kits, primers, and probes, ensure accurate results. Software solutions play a pivotal role in analyzing and interpreting complex genomic and clinical data, with advanced algorithms such as artificial intelligence (AI) and machine learning (ML) improving predictive accuracy and enabling streamlined data interpretation.
The market is also categorized by technology into PCR, NGS, immunohistochemistry (IHC), in situ hybridization (ISH)/fluorescence in situ hybridization (FISH), and other technologies. PCR held a 34.2% market share in 2024 and is expected to reach USD 4.5 billion by 2034. PCR systems provide high sensitivity and efficiency in detecting

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minimal amounts of DNA or RNA, delivering quick results within hours, which is essential for timely clinical decision-making. Advancements in PCR technologies, such as digital PCR (dPCR) and real-time PCR (qPCR), allow for the simultaneous detection of multiple cancer biomarkers in a single test, reducing costs and saving time.

By disease type, the market is divided into breast cancer, non-small cell lung cancer, colorectal cancer, leukemia, melanoma, prostate cancer, and others. The breast cancer segment dominated the market with a 34.7% share in 2024, primarily due to the rising prevalence of the disease. End use segmentation includes hospitals, diagnostic laboratories, academic and research institutions, and other end users. Hospitals accounted for 38.4% of the market share in 2024, attributed to their capacity to manage high volumes of cancer patients, both inpatient and outpatient. Companion diagnostics empower hospitals to manage personalized treatments, reducing side effects and improving survival rates.

The United States remains a key market due to the increasing incidence of cancer and the stringent standards established by the U.S. Food and Drug Administration (FDA) for companion diagnostics. These regulations have encouraged the development of safer, more effective diagnostic kits and instruments, enhancing the overall growth of the oncology companion diagnostic market in the region.

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