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Companion Diagnostics - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2024 - 2029)

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Abstracts

The Companion Diagnostics Market size is estimated at USD 7.74 billion in 2024, and is expected to reach USD 13.90 billion by 2029, growing at a CAGR of 12.54% during the forecast period (2024-2029).

The promotion of personalized medicine and targeted therapy as a new treatment option by key players, increasing cases of adverse drug reactions, and the development of new drug and diagnostic technology are expected to boost the market’s growth over the forecast period.

The increasing focus on personalized medicine product approvals and new technology development is propelling the market’s growth. For instance, according to an article published by Healthcare Radius in January 2023, companion diagnostics were observed to be integral to the rising focus on personalized medicine, enabling targeted treatment by identifying specific genetic markers associated with diseases. Their role in co-developing drug and diagnostic technologies ensures a synergistic approach to treatment, maximizing efficacy and minimizing adverse effects. Thus, the benefits offered by companion diagnostics are expected to increase their adoption for treating cancer patients globally.

The increasing cases of adverse drug reactions due to medication inefficacy also drive the need for companion diagnostics in the market, thus aligning therapeutic approaches with patients' genetic profiles to optimize treatment outcomes. For instance, according to an article published by Healthcare Radius in January 2023, companion diagnostics offer a strategic approach to mitigate the potential risks associated with drug treatments and help effectively identify patients predisposed to experiencing adverse effects during

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therapy. This targeted identification enhances patient safety and optimizes treatment outcomes, thus aligning with medical and business objectives within the healthcare industry. Companion diagnostics can help physicians adjust the dosage or switch to a different treatment option, thus improving patients' overall quality of life.

The rising burden of cancer increases the demand and awareness for personalized medicines among the population globally. For instance, according to the report published by the American Cancer Society in January 2024, about 2 million new cancer cases are projected to be diagnosed in the United States in 2024, compared to 1.9 million cases in 2023. Additionally, according to the report by Red Espa?ola de Registros de C?ncer published in January 2023, the incidence rate of cancer cases estimated in Spain for 2023 was 279,260. Clinical diagnostics are integral to implementing personalized medicine, thus leveraging individuals' genetic profiles to enhance precision and efficacy in cancer treatment. This approach ensures tailored strategies that align with specific patient needs, fostering optimal outcomes within oncology care.

Companies are strategically enhancing collaborations to advance biomarkers and diagnostic technologies, particularly focusing on cost efficiency and regulatory compliance. This trend has generated numerous opportunities for diagnostic applications in critical medical indications such as cancer, cardiovascular diseases, and neurological disorders. For instance, in January 2024, Agilent Technologies Inc. signed an agreement with Incyte, bringing together Agilent’s expertise in developing companion diagnostics (CDx) to support the development and commercialization of Incyte’s hematology and oncology portfolio. This agreement allows Agilent to expand its companion diagnostics portfolio with novel biomarkers.

Major companies are actively advancing innovative technologies and formulating strategic growth plans to tackle a broader range of unmet needs in cancer care. For instance, in October 2023, Foundation Medicine Inc. received approval from the US Food and Drug Administration for FoundationOneCDx and FoundationOneLiquid CDx to be used as companion diagnostics for Pfizer’s BRAFTOVI (encorafenib) in combination with MEKTOVI (binimetinib) for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation.

In February 2023, Roche signed a collaboration with Janssen Biotech Inc. (Janssen) to create companion diagnostics for targeted therapies, further strengthening research and innovation activities.

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Thus, the increasing promotion of personalized medicine and targeted therapy by key players, rising cases of adverse drug reactions, and the development of new drug and diagnostic technologies are impacting the companion diagnostics market's growth. However, the high cost of drug development and associated clinical trials and reimbursement issues among many countries are expected to restrain the market over the forecast period.

Companion Diagnostics Market Trends

The Lung Cancer Segment is Expected to Witness Significant Growth Over the Forecast Period

Companion diagnostic tests (CDXs) are considered mandatory in decision-making for treatment with targeted therapies in lung cancer. Patients with lung cancer who receive companion diagnostics as part of their initial treatment have more survival benefits, such as targeted therapy selection, which helps in providing personalized treatment to the target patient.

The high incidence rate of lung cancer and novel innovations in companion diagnostics by major players are likely to boost the segment's growth over the forecast period.

Globally, the high incidence rate of non-small cell lung cancer (NSCLC), coupled with the growing development of oncology companion diagnostic tests for the disease, is expected to boost the segment's growth. For instance, according to a report published by the American Cancer Society in January 2024, about 10-15% of all lung cancers were observed to be small cell lung cancer (SCLC), and about 80-85% were non-small cell lung cancer (NSCLC). The same source reported an estimated 234,580 new cases of lung cancer in 2024 in the United States, leading to more demand for lung cancer companion diagnostics. Similarly, according to a report published by the American Cancer Society in 2023, about 238,340 people were diagnosed with lung cancer. Such prevalence is expected to fuel the growth of the lung cancer segment in the companion diagnostic market over the forecast period.

The segment is also growing due to the rising number of product approvals and launches. In June 2023, ARUP Laboratories received approval from the US Food and Drug Administration for AAV5 DetectCDx as a companion diagnostic to aid in the selection of adult patients eligible for treatment with ROCTAVIAN (valoctocogene roxaparvovec-rvox).

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Companies are also focusing on adopting key collaborative strategies to expand their product portfolios in the market. In July 2023, Tempus collaborated with TScan Therapeutics to develop a companion diagnostic (CDx) test to treat cancer patients. The collaboration supports TScan’s screening protocol for its Phase 1 solid tumor, including non-small cell lung cancer, a clinical trial designed to enable customized mixtures of TCR-Ts to be administered to patients based on tumor antigen positivity and intact HLA expression.

Therefore, the high incidence rate of lung cancer, novel innovations in companion diagnostics by major players, and strategic activities are expected to drive the segment’s growth during the forecast period.

North America is Expected to Hold a Significant Market Share Over the Forecast Period

North America is expected to witness significant growth in the overall companion diagnostics market, with the United States emerging as a key contributor. Companion diagnostics are recognized as pivotal tools for making treatment decisions related to various oncology drugs, as evidenced by the FDA's classification of these assays based on associated risks. This acknowledgment underscores the strategic importance of companion diagnostics in oncology, emphasizing their role as critical elements in informed and risk-assessed treatment decisions.

The increasing burden of cancer in the United States is also expected to drive the market. For instance, according to a report published by the Cancer Journal for Clinicians1 in January 2024, about 313,510 breast cancer cases, 152,810 colorectal cancer cases, and 66,440 pancreatic cancer cases were estimated in the United States in 2024. The incidence of cancer has also been rising in Canada, which is expected to boost the demand for companion diagnostics tests in the market. For instance, according to a report published by Canadian Cancer Statistics in November 2023, about 239,100 new cancer cases were estimated to be diagnosed in Canada in 2023, compared to 233,900 new cancer cases in 2022. This data shows the increasing burden of cancer in the region, which is expected to boost the demand for companion diagnostics.

Product launches, strategic collaborations, partnerships, and product approvals by the government are expected to drive the North American companion diagnostics market over the forecast period. In June 2023, the US FDA initiated a new voluntary pilot

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program for certain oncology drug products used with certain corresponding in vitro diagnostic tests to help clinicians select appropriate cancer treatments for patients. Similarly, in June 2022, GRAIL LLC, a healthcare company, signed a strategic collaboration with AstraZeneca to develop and commercialize companion diagnostic (CDx) assays for use with AstraZeneca's therapies. The company focuses on developing companion diagnostic tests to identify patients with high-risk, early-stage disease. Such developments are expected to positively impact the regional market's growth.

The increasing burden of cancer, rising product launches, and growth strategies by major players are expected to significantly boost the region's share in the global companion diagnostics market.

Companion Diagnostics Industry Overview

The companion diagnostics market is highly fragmented and competitive, with several major players. The rising focus of companies on personalized medicine, co-development activities, and increased cases of adverse drug reactions are expected to boost the market's competitive nature. Some of the key players in the market are Abbott, Agilent Technologies Inc., F Hoffmann-La Roche Ltd, Biomerieux, Qiagen NV, and Siemens Healthineers AG.

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