Companion Diagnostics Market - Growth, Trends, Covid-19 Impact, and Forecasts (2023 - 2028)

Market Report | 2023-01-23 | 120 pages | Mordor Intelligence

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Report description:

The companion diagnostics market is expected to register a CAGR of 3.5% over the forecast period.

Early diagnosis of COVID-19 became essential in the market, as it could help find the proper treatment for patients affected by the disease. The most commonly used and reliable test for the diagnosis of COVID-19 was the polymerase chain reaction (PCR) test performed using nasopharyngeal swabs or other upper respiratory tract specimens, including throat swabs. Thus, diagnosis using polymerase chain reaction (PCR) emerged as a major focus for managing the disease. For instance, According to an article published by Systematic Reviews in Pharmacy, in 2022, SARS-CoV-2 vaccination companion diagnostics to improve COVID-19 vaccination schedules involved serological antibody tests. SARS-CoV-2 vaccine companion diagnostics offered significant benefits at that stage of research, including permanent, reliable immune protection by its monitoring with a specific test combination and, consequently, medical security against COVID-19. Thus, boosting the market growth.

Moreover, the companion diagnostics market is expected to experience substantial growth due to the rise in product launches, the development of new biomarkers for various diseases, a surge in research and development of targeted therapies, an increase in demand for customized medicine with increased recognition in the developing markets, and a higher number of unmet cancer care needs. For instance, in January 2022, Amoy Diagnostics Co. Ltd and PREMIA Holdings (HK) Limited launched the AmoyDx Pan Lung Cancer PCR Panel (the "PLC Panel") in Japan as a reimbursed companion diagnostic for multiple anti-cancer agents. Furthermore, the growth of the global companion diagnostics market can be attributed to the rising focus on personalized medicine and the co-development of drug and diagnostic technologies. Moreover, the increasing cases of adverse drug reactions related to medications due to the lack of efficacy drive the need for companion diagnostics. Globally, the rising burden of cancer increases the demand and awareness for personalized medicines among the population. For instance, as per the data published by the Australian Institute of Health and Welfare, in December 2021, it was estimated that about 151,000 Australians were

diagnosed with cancer (413 per day), and 49,000 died (135 per day). With companies expanding their collaborations for better biomarkers and diagnostics to focus on cost regulations, there have been many opportunities for applications in indications like cancer, cardiovascular, and neurological disorders.

Thus, the abovementioned factors are impacting the market growth of the companion diagnostics market. However, the high cost of drug development and associated clinical trials and reimbursement issues among many countries are expected to restrain the market growth.

Companion Diagnostics Market Trends

The Lung Cancer Segment is Expected to Hold a Significant Share in the Market 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 than those who are not tested. Globally, the high incidence rate of non-small cell lung cancer (NSCLC), coupled with the rise in the development of oncology companion diagnostic tests for the disease, is expected to boost the segment's growth. For instance, in August 2022, The U.S. FDA granted premarket approval to Thermo Fisher Scientific's Oncomine Dx Target Test as a companion diagnostic (CDx) to identify patients whose tumors have a HER2 (ERBB2) activating mutations (SNVs & Exon 20 Insertion) in non-small cell lung cancer (NSCLC), who may be candidates for ENHERTU (fam-trastuzumab deruxtecan-nxki). ENTER is a precisely engineered HER2-directed antibody-drug conjugate (ADC) jointly developed and commercialized by Daiichi Sankyo and AstraZeneca. In addition, in July 2021, Labcorp launched Therascreen KRAS PCR Mutation Analysis, a companion diagnostic to identify patients with non-small cell lung cancer (NSCLC) who are eligible for therapy with LUMAKRAS (sotorasib). This was a novel therapeutic option developed by Amgen.

Moreover, lung cancer is the most common form of cancer. As per Lung Cancer Research Foundation 2022, an estimated 236,740 people were diagnosed with lung cancer in 2022 in the United States, leading to more demand for lung cancer companion diagnostics. This is expected to help the market growth over the forecast period.

Therefore, the factors mentioned above are expected to drive segmental growth in the market during the forecast period.

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

North America dominated the overall companion diagnostics market, with the United States emerging as a major contributor. The use of companion diagnostics is considered an important treatment decision tool for various oncology drugs, which is also reflected in how the FDA classifies these assays concerning risk. Companion diagnostics clinical trials have come to the forefront in the pharmaceutical industry, despite the COVID-19 pandemic, as it helps to boost the chances of clinical success. The testing kit was in high demand for identifying those infected with SARS-CoV-2. COVID-19 remained the primary focus for diagnostic test makers in terms of research & development. In May 2020, MiraDx set up its lab to provide COVID-19-based test services in the United States. The company claimed that the lab could analyze more than 9,000 tests accurately.

The increasing burden of cancer in the United States is also expected to drive market growth. According to the American Cancer Society, in January 2022, a total of 1.9 million new cancer cases from cancer are expected to occur in the United States by the end of 2022. Moreover, people with chronic conditions are the most frequent users of companion diagnostics in the United States; they drive the market's growth.

Product launches and government clearance by key players are driving the companion diagnostics market growth. For instance, in October 2021, the United States Food and Drug Administration approved Agilent's Ki-67 IHC MIB-1 pharmDx (Dako Omnis), which

aids in identifying patients with early breast cancer (EBC) at high risk of disease recurrence. This will further drive the market growth over the forecast period in North America.

Due to the abovementioned factors, North America is expected to hold a significant share of the global companion diagnostics market.

Companion Diagnostics Market Competitor Analysis

The companion diagnostics market is moderately fragmented and highly 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 competitive rivalry in the market studied. The major market players, such as Abbott Laboratories Inc., Agilent Technologies Inc., F Hoffmann-La Roche Ltd, Biomerieux SA, and Qiagen NV, are increasing the overall competitive rivalry of the market studied.

Additional Benefits:

The market estimate (ME) sheet in Excel format
3 months of analyst support

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