Companion Diagnostic Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Product and Services (Kits and Reagents, Assays, Software, and Services), By Technology (PCR, NGS, In-Situ Hybridization, Immunohistochemistry, and Others), By Disease Indication (Oncology, Neurology, Cardiology, Infectious Diseases, and Others), By Application (In-Vitro Diagnostics, Drug Discovery, and Others), By End User (Pharmaceutical & Biotechnology Companies, Research Laboratories, Contract Research Organization, and Others), By Region and Competition

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Abstracts

Global Companion Diagnostic Market has valued at USD 5.85 Billion in 2022 and is anticipated to project impressive growth in the forecast period with a CAGR of 12.29% through 2028. Companion diagnostics are medical devices used in conjunction with therapeutic drugs to assess the impact and suitability of drugs for specific individuals. These diagnostics are developed alongside drugs to identify patient groups that respond to or are not suitable for the therapy based on their characteristics. Healthcare professionals utilize this device to evaluate the effectiveness of a particular treatment for a patient.

In 2020, Roche obtained FDA approval for the Cobas EGFR Mutation Test v2

companion diagnostic, which assists in determining the appropriate use of EGFR tyrosine kinase inhibitors for lung cancer treatment. Companion Diagnostic (CDx) is a clinical test co-developed with a therapeutic drug to identify patients who will respond or not respond to the drug. It enables the identification of patient groups that can or cannot be treated with the corresponding drug. CDx helps practitioners evaluate the benefits, side effects, and associated risks of therapeutic drugs, ensuring patient safety.

The global Companion Diagnostics Market is driven by factors such as increasing patient demand for tailored therapy, expanded applications of personalized medications, higher prevalence of chronic diseases, and growing incidence of medication-related allergies. These factors contribute to the development of customized CDx, promoting market growth. Additionally, CDx tests offer advantages such as cost-effectiveness, high sensitivity, and rapid and accurate results within shorter time frames, further fueling the growth of the Companion Diagnostics Market.

Key Market Drivers

Increasing Demand for NGS-Based Technology

The growing demand for next-generation sequencing (NGS) technology, with its exceptional capability to identify rare variants, plays a critical role in the continued success and wider distribution of companion diagnostics solutions in the companion diagnostics market. By utilizing NGS panels, a single test has the potential to aid in the treatment of numerous types of cancers, offering a more comprehensive approach to personalized medicine.

For instance, in July 2022, Almac Diagnostic forged a strategic partnership with AstraZeneca, a leading pharmaceutical company, to collaboratively develop and commercialize multiple companion diagnostic (CDx) products. These innovative CDx solutions will be based on cutting-edge NGS (next-generation sequencing) and qPCR-based (quantitative polymerase chain reaction) technologies, further advancing the field of precision medicine and enhancing patient care. Through this collaboration, Almac Diagnostic and AstraZeneca aim to improve the accuracy and effectiveness of diagnostics, enabling targeted therapies and personalized treatment plans for patients. This partnership demonstrates the commitment of both companies to drive innovation in the field of companion diagnostics and contribute to the advancement of precision medicine.

By leveraging the power of NGS and qPCR technologies, Almac Diagnostic and AstraZeneca envision a future where companion diagnostics play a pivotal role in guiding treatment decisions and improving patient outcomes across various therapeutic areas. This collaboration represents a significant step forward in the development of advanced diagnostic solutions that will revolutionize the way diseases are diagnosed and treated. With the combination of cutting-edge technologies and strategic partnerships, the field of precision medicine is poised to make significant strides in improving patient care and transforming healthcare on a global scale.

Companion Diagnostics for the Targeted Cancer Drugs

Clinical studies have shown that a significant percentage, up to 75%, of cancer patients do not respond favorably to the same prescribed cancer drug. This highlights the pressing need for companion diagnostic tests, which play a crucial role in identifying the presence of a molecular target and also uncovering any off-target effects of a therapeutic. By doing so, these tests can predict toxicities and adverse effects associated with a drug, ultimately aiding in personalized treatment approaches.

It is worth noting that over 90% of globally approved companion diagnostic (CDx) tests are specifically associated with targeted cancer therapeutics. This CDx approach to cancer genomic characterization not only helps physicians identify the specific alterations driving the growth of a patient’s cancer but also enables them to explore targeted treatment options that may not have been previously considered. This comprehensive and tailored approach to cancer treatment holds immense potential in improving patient outcomes and revolutionizing the field of oncology.

Advancements in The Latest Technologies

Next-generation sequencing (NGS) based companion indicative tests aim to unlock nuclear information from the genome of each individual to guide treatment decisions for various diseases. By utilizing advanced sequencing techniques, NGS can identify multiple biomarkers in a shorter timeframe compared to other sequencing methods. This comprehensive approach allows for the assessment of biomarkers in a single test, potentially benefiting the treatment of a wide range of illnesses. Furthermore, the continuous advancements in NGS technology provide market players with a competitive edge over those offering alternative technologies such as PCR, ICH, and ISH. As a result, key industry players are actively engaged in the development of companion diagnostic products based on NGS, capitalizing on the opportunities presented by this innovative field.

Rising Use of Personalized Medicine

The increasing utilization of personalized medicine is a key driver behind the growth of the companion diagnostic market. Personalized medicine encompasses a multifaceted approach to patient care, enhancing not only the ability to diagnose and treat diseases but also enabling the identification of diseases at earlier stages, facilitating more effective treatment. The growing popularity of personalized medical care stems from its targeted approach based on individuals' genetic characteristics. In the United States, a considerable number of individuals seeking medical care experience misdiagnosis, which can result in delayed and inaccurate diagnoses.

Furthermore, companion diagnostics are gaining prominence in the development of personalized medicines for early disease detection and the selection of precise treatment methods, ultimately contributing to reduced mortality rates. Accurate assessment of an individual's genetic composition plays a vital role in determining their health status and susceptibility to severe diseases. Increasing awareness about genetic diseases will further facilitate the development and commercialization of personalized medicines, specifically tailored to address these conditions. Moreover, the demand for companion diagnostic tests is anticipated to rise throughout the forecast period, driven by the need for accurate patient diagnosis and the advancement of personalized medicine.

Key Market Challenges

Lack of Awareness and High Cost of Companion Diagnostics Techniques

While immunotherapy has shown significant promise in the treatment of cancer, its high cost has limited widespread patient access. As a result, physicians may opt to combine treatments, which can extend the duration of treatment from five months to over three years. With longer treatment duration comes a greater financial burden, as the cost of personalized immunotherapies is also substantial. In fact, the cost of cancer immunotherapies can far exceed that of other treatment options such as chemotherapy or radiation therapy. Consequently, the high cost of immuno-oncology treatments is believed to impede the growth of the companion diagnostics market. This financial barrier highlights the need for continued research and innovation to develop more affordable and accessible immunotherapies for cancer patients.

Lack of Resources in Underdeveloped Nations

Companion diagnostic tests require meticulous attention at every step to ensure successful execution and reproducible results. One of the significant challenges in these scientific fields is the scarcity of technically skilled and trained personnel. The complexity of companion diagnostic tests often demands sophisticated techniques and instruments, such as image processing, in certain analytical procedures. The presence of proficient and experienced staff with strong technical capabilities is paramount for biopharma companies, academic institutions, R&D laboratories, and organizations.

However, there is a decline in comprehensive training programs for laboratory professionals as they face undue pressure to deliver faster turnaround times. Consequently, the focus on training laboratory managers or preparing them to become experts is insufficient. Moreover, the compensation package offered is not competitive, leading to a high turnover rate. These factors, combined with the lack of recognition and understanding of the importance of laboratory professionals, contribute to the diminishing number of professionals in this field. This trend is expected to continue during the forecast period, potentially offsetting the market growth in focus.

Key Market Trends

Growing Importance of Promotional Activities

The increasing significance of promotional activities represents a key trend in the companion diagnostics market. Companion diagnostics, due to their specificity in being applicable only to particular drugs, are not as extensively marketed as other available test kits and devices in the market. Therefore, it is crucial to give greater attention to improving the distribution network and enhancing the availability of products to end users. In terms of advertising sources, internet channels and search engines are among the most vital, considering their higher visibility and the limited return on investment and visibility of other media.

Furthermore, besides boosting sales, emphasis is placed on product functionality, accuracy, and vendors' after-sales services, while marketing communication takes a back seat. Limited promotion activities pose challenges in reaching the target market and understanding a company's competitive position. To attract customers to a company website, the publication of multiple blogs and newsletters can be beneficial. This approach allows businesses to sustain their marketing campaigns over an extended period and attract repeat visitors. As the market continues to witness product enhancements, vendors are increasingly recognizing the importance of promotional activities, and this trend is expected to gain momentum, thereby supporting the growth of the global companion diagnostics market throughout the forecast period.

Growing advancements in biologics

The companion diagnostics market is highly consolidated, with key players such as F. Hoffmann-La Roche Ltd. (Switzerland), Agilent Technologies, Inc. (the US), Qiagen N.V. (Germany), Thermo Fisher Scientific, Inc. (the US), and Abbott Laboratories, Inc. (the US) collectively holding a significant market share in 2020. Intense competition exists among market players, and only major corporations can afford the substantial investment in capital, research and development, and manufacturing. Consequently, this market poses significant barriers to entry for new competitors.

Segmental Insights

Technology Insights

The Polymerase Chain Reaction (PCR) segment is currently dominating the market share and is expected to experience significant growth throughout the forecast period. This can be attributed to its cost-effectiveness, high sensitivity, and specificity, which are crucial factors driving the expansion of the market. Moreover, PCR can be employed on simple automated platforms, further enhancing its appeal. Furthermore, PCR plays a vital role in determining the sequencing of unknown etiologies for various diseases, making it an indispensable driver of this segment. Its ability to accurately identify the genetic makeup of pathogens contributes to better understanding and diagnosis of diseases.

On the other hand, the next-generation sequencing segment is projected to grow rapidly in the forecast period. This is primarily due to its key advantages, such as higher sensitivity in detecting low-frequency variants, shorter turnaround time for analyzing large sample volumes, and the ability to simultaneously sequence hundreds to thousands of genes or gene regions. These advantages make next generation sequencing a promising technology with immense potential for various applications in the field of genomics and personalized medicine.

End User Insights

The companion diagnostics market is fragmented into various segments, including Pharmaceutical & Biotechnology Companies, Research Laboratories, Contract

Research Organizations, and Others. Among these, the Pharmaceutical & Biotechnology Companies segment holds the largest market share. This can be attributed to the growing utilization of companion diagnostics in drug development and the increasing significance of companion diagnostic biomarkers. Companion diagnostics play a crucial role in personalized medicine, helping to identify patients who are most likely to benefit from a specific treatment. This not only improves patient outcomes but also enhances the efficiency and effectiveness of the drug development process. With advancements in technology and the increasing focus on precision medicine, the demand for companion diagnostics is expected to further rise in the coming years.

Regional Insights

In terms of revenue share, North America is projected to dominate the market during the forecast period. This can be attributed to several factors, including the high prevalence of chronic diseases, the presence of well-established clinical laboratories and companion diagnostic vendors, and the availability of advanced instruments and devices. Moreover, the region benefits from a growing geriatric population, high disposable income, increasing awareness about companion diagnostics, and a rising number of research and development activities. These additional factors are expected to further fuel the revenue growth of the North America market in the coming years. North America accounted for the largest share of the companion diagnostics market. The growth of the companion diagnostics market in North America can be attributed to the presence of numerous leading companion diagnostics vendors and public clinical research centers, the easy availability of technologically advanced devices and instruments, and the highly developed healthcare system in the US and Canada.

The utilization of companion diagnostics is considered a significant treatment option tool for various oncology drugs, a classification reflected in the FDA's assessment of these tests in terms of risk.

Key Market Players

Abbott Laboratories Inc.

Agilent Technologies Inc.

F.Hoffmann-La Roche Ltd

Biomerieux SA

+44 20 8123 2220
info@marketpublishers.com

Qiagen NV

Siemens Healthcare

Thermo Fisher Scientific Inc.

Danaher Corporation (Beckman Coulter Inc.)

Myriad Genetics Inc.

Illumina Inc.

Report Scope:

In this report, the Global Companion Diagnostic Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Companion Diagnostic Market, By Product and Services:

Kits and Reagents

Assays

Software

Services

Companion Diagnostic Market, By Technology:

PCR

NGS

In-Situ Hybridization

Immunohistochemistry

Others

Companion Diagnostic Market, By Disease Indication:

Oncology

Neurology

Cardiology

Infectious Diseases

Others

Companion Diagnostic Market, By Application:

In-Vitro Diagnostics

Drug Discovery

Others

Companion Diagnostic Market, By End User:

Pharmaceutical & Biotechnology Companies

Research Laboratories

Contract Research Organization Others

Companion Diagnostic Market, By Region:

North America

United States

Canada

Mexico

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Europe

France

United Kingdom

Italy

Germany

Spain

Asia-Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

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UAE

Kuwait

Turkey

Egypt

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Companion Diagnostic Market.

Available Customizations:

Global Companion Diagnostic market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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