Oncology Companion Diagnostic Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Product & Service (Product (Instrument, Consumables, Software), Service), By Technology (Polymerase chain reaction (PCR), Next-generation sequencing (NGS), Immunohistochemistry (IHC), In situ hybridization (ISH)/Fluorescence in situ hybridization (FISH), Others), By Disease Type (Breast cancer, Non-small cell lung cancer, Colorectal cancer, Leukemia, Melanoma, Prostate cancer, Others), By End Use (Hospitals, Pathology/Diagnostic laboratory, Academic medical center), By Region, and By Competition

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Report description:

Global Oncology Companion Diagnostic Market has valued at USD 2.97 billion in 2022 and is anticipated to project impressive growth in the forecast period with a CAGR of 7.93% through 2028. The global oncology companion diagnostic market is a rapidly evolving sector within the broader field of healthcare and diagnostics. Companion diagnostics are tests or tools used to identify specific biomarkers or genetic mutations that are associated with a patient's cancer, and they are crucial for personalized cancer treatment.

Key Market Drivers

Advancements in Precision Medicine

Precision medicine, a groundbreaking approach to healthcare that tailors treatments to individual patients, is transforming the

way we combat cancer. At the heart of this medical revolution is the global oncology companion diagnostic market, which is experiencing unprecedented growth. Advancements in precision medicine are playing a pivotal role in driving this growth, enhancing our ability to diagnose and treat cancer in a highly individualized and effective manner.

Advancements in precision medicine have paved the way for more effective and personalized treatment plans for cancer patients. Companion diagnostics are instrumental in this process, as they allow healthcare providers to identify specific biomarkers or genetic mutations that are driving a patient's cancer. With this information, clinicians can recommend treatments that are more likely to succeed, minimizing trial-and-error approaches and the potential for harmful side effects.

By tailoring treatments to an individual's unique genetic and molecular profile, precision medicine has the potential to significantly improve therapeutic outcomes. Patients can receive the right treatment at the right time, increasing the chances of remission or prolonged survival. This not only benefits patients but also reduces the burden on healthcare systems and decreases the overall cost of care.

Pharmaceutical companies are increasingly collaborating with diagnostic firms to develop companion diagnostics alongside targeted cancer therapies. These partnerships have led to more efficient drug development processes. With a companion diagnostic in place, clinical trials can be more precise, as only patients with the specific biomarkers are included, which accelerates the testing and approval of novel drugs.

Regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have recognized the importance of companion diagnostics in precision medicine. They have established guidelines and regulatory pathways to ensure the safety and efficacy of these tests, thereby providing a level of assurance for healthcare professionals and patients. This regulatory support encourages further investment in diagnostic research and development.

Precision medicine and companion diagnostics empower patients to actively participate in their treatment decisions. Patients are more informed about their condition, the treatment options available, and the potential outcomes. This collaborative approach between patients and healthcare providers fosters better communication, patient compliance, and overall satisfaction.

Pharmaceutical Partnerships

The global oncology companion diagnostic market is undergoing a remarkable expansion, with the potential to redefine cancer diagnosis and treatment. Central to this growth is the strategic collaboration between pharmaceutical companies and diagnostic firms. These partnerships are driving innovation, improving patient care, and playing a crucial role in the evolution of precision medicine in the field of oncology.

Companion diagnostics are tests that identify specific biomarkers, genetic mutations, or other molecular characteristics associated with a patient's cancer. These diagnostics play a pivotal role in personalized or precision medicine, ensuring that the right treatment is administered to the right patient at the right time. The success of this approach depends on the identification of relevant biomarkers, which is where pharmaceutical partnerships come into play.

Pharmaceutical companies are increasingly recognizing the value of companion diagnostics in the development and commercialization of their cancer therapies. Partnerships with diagnostic firms allow them to develop companion diagnostic tests in tandem with their targeted drugs. This collaboration ensures that patients who can benefit from a specific drug are accurately identified, ultimately improving the success rate of clinical trials.

The synergy between pharmaceutical and diagnostic companies accelerates the drug development process. By identifying suitable companion diagnostics early in the development pipeline, pharmaceutical firms can design more targeted and efficient clinical trials. These trials are more likely to yield positive results because patients with specific biomarkers are selected, reducing variability and improving the prospects of new drug approvals.

Pharmaceutical partnerships expand the market reach of companion diagnostics. When a new cancer drug with an associated diagnostic test receives regulatory approval, it becomes available to a global patient population. This can substantially increase the market potential for both the drug and its companion diagnostic test.

The use of companion diagnostics leads to improved patient outcomes. It allows physicians to tailor treatment plans based on the patient's unique genetic and molecular profile. This not only increases the effectiveness of treatment but also minimizes potential side effects. Patients experience more targeted care and an increased likelihood of positive therapeutic outcomes.

Pharmaceutical partnerships contribute to cost-efficiency in the healthcare system. Companion diagnostics, when used in combination with specific therapies, reduces the need for trial-and-error treatments, unnecessary drug administration, and the

associated costs. This not only benefits healthcare systems but also enhances the patient's experience.

Biomarker Discovery and Technological Advances

The global oncology companion diagnostic market is on the cusp of a transformative era, largely due to the intersection of two key factors: biomarker discovery and advances in technology. These elements are redefining the landscape of cancer diagnosis and treatment, making personalized and precise medicine a reality for cancer patients worldwide.

Biomarkers are specific biological molecules or characteristics that indicate the presence of a disease, the course of the disease, or a patient's response to treatment. In oncology, biomarkers play a pivotal role in identifying the genetic mutations, protein expressions, and other molecular features unique to an individual's tumor. Advances in biomarker discovery are instrumental in boosting the growth of the oncology companion diagnostic market.

Advancements in diagnostic technology have facilitated more accurate and efficient identification of these biomarkers, empowering clinicians to tailor cancer care plans to each patient's unique genetic makeup. Here's how the synergy between biomarker discovery and technological innovation is propelling the growth of the global oncology companion diagnostic market.

Biomarker discovery, facilitated by state-of-the-art technologies, enables oncologists to make precise diagnoses. By identifying specific genetic mutations, such as EGFR in lung cancer or HER2 in breast cancer, and other biomarkers, clinicians can select the most appropriate and effective targeted therapies. This personalization of treatment improves therapeutic outcomes and reduces the potential for harmful side effects, driving demand for companion diagnostics.

The discovery of relevant biomarkers is essential for the development of targeted cancer therapies. Pharmaceutical companies collaborate with diagnostic firms to identify and validate these biomarkers early in the drug development process. This ensures that clinical trials are more precise, as only patients with the specific biomarkers are included, expediting drug development and regulatory approvals.

Advances in technology have led to the development of faster and more accurate diagnostic tests. High-throughput sequencing, next-generation sequencing (NGS), and other advanced techniques allow for the simultaneous analysis of multiple biomarkers in a patient's tumor sample. This technology ensures timely and comprehensive assessments, aiding clinicians in making critical treatment decisions swiftly.

Liquid biopsies, a cutting-edge technology, are revolutionizing cancer diagnosis. These tests analyze circulating tumor DNA (ctDNA) or tumor-derived biomarkers in bodily fluids, offering a non-invasive and real-time approach to monitoring a patient's response to treatment and detecting disease recurrence. Liquid biopsies reduce the need for invasive tissue biopsies and provide a wealth of diagnostic information.

Expanding Range of Cancer Types

The global oncology companion diagnostic market is experiencing a remarkable transformation, largely driven by the expanding range of cancer types for which companion diagnostics are being developed. These powerful tools are redefining how we diagnose and treat a growing variety of malignancies, ushering in an era of personalized medicine that is making a difference for patients worldwide.

Companion diagnostics are tests designed to identify specific genetic mutations, biomarkers, or molecular characteristics unique to an individual's tumor. These tests are indispensable in oncology because they enable clinicians to deliver precisely tailored treatments. The growth of the global oncology companion diagnostic market is intrinsically linked to its ability to expand its reach to a broader array of cancer types.

Traditionally, companion diagnostics have been associated with well-known cancer types like breast, lung, and colorectal cancers. However, advances in biomarker discovery, driven by genomic and proteomic research, have allowed for the identification of specific molecular targets in rare and less common cancer types. This expansion of targetable cancers has broadened the market's scope.

The growth of companion diagnostics has led to a focus on rare cancers, such as certain pediatric cancers or cancers driven by specific genetic mutations. In the past, these cancers had limited treatment options. Now, companion diagnostics help identify the unique genetic alterations in these cases, enabling physicians to offer more effective treatments and ultimately improving outcomes for patients with rare cancers.

Companion diagnostics are making significant inroads into hematological malignancies like leukemia, lymphoma, and myeloma. These blood-related cancers present their own unique challenges, but the development of companion diagnostics allows for more

precise diagnosis and treatment decisions, enhancing therapeutic outcomes and reducing the need for aggressive chemotherapy.
Expanding the range of cancer types that can be addressed with companion diagnostics is inherently patient-centered. Patients with less common cancers no longer have to settle for generic treatment approaches. With companion diagnostics, they can receive individualized care based on their unique genetic and molecular profiles, leading to more effective and less toxic therapies.
As companion diagnostics become available for a wider spectrum of cancer types, the global oncology companion diagnostic market is experiencing significant growth. The potential patient population benefiting from these tests continues to increase, resulting in a more substantial market reach and revenue potential.
Key Market Challenges
Biomarker Identification and Validation
One of the primary challenges in the oncology companion diagnostic market is the identification and validation of relevant biomarkers. Biomarkers are the cornerstone of companion diagnostics, as they help match patients with the most suitable treatment. However, the discovery and validation of new biomarkers are time-consuming and costly processes, often requiring extensive clinical research and validation studies.
Intellectual Property and Licensing
Many biomarkers and diagnostic technologies are protected by intellectual property rights, leading to challenges in licensing and collaboration among different diagnostic and pharmaceutical companies. These complexities can sometimes hinder the development and commercialization of companion diagnostics.
Adoption Barriers
Physician adoption and utilization of companion diagnostics can be a hurdle. Some healthcare professionals may lack awareness or experience in using these tests, leading to underutilization. Proper education and training are needed to overcome this challenge.
Key Market Trends
Liquid Biopsies Revolutionizing Diagnostics
Liquid biopsies are poised to revolutionize the field of oncology companion diagnostics. These non-invasive tests analyze circulating tumor DNA (ctDNA), circulating tumor cells (CTCs), or exosomes in blood or other bodily fluids. They offer a real-time and minimally invasive way to monitor a patient's response to treatment, detect disease recurrence, and identify potential resistance to therapy. Liquid biopsies are expected to become more mainstream, reducing the reliance on traditional tissue biopsies.
Genomic and Proteomic Advancements
Advancements in genomic and proteomic research are accelerating the discovery and validation of new biomarkers. These scientific breakthroughs enable the development of more precise and efficient diagnostic tests. In the near future, companion diagnostics will be better equipped to identify specific genetic mutations, protein expressions, and other molecular features, enhancing their effectiveness.
International Collaboration and Standardization
As the global oncology companion diagnostic market expands, international collaboration and standardization efforts will become more critical. These efforts will ensure that companion diagnostics are accessible and consistent in quality across different regions, benefiting both patients and healthcare providers worldwide.
Segmental Insights
Product and Service Insights
In 2022, the product segment of the market saw the most substantial increase in revenue share, primarily due to the emergence of advanced technologies like Next-Generation Sequencing (NGS) for cancer diagnosis. Leading companies such as Illumina, Roche, and ThermoFisher Scientific are poised for significant growth in the foreseeable future. This growth is attributed to the rising utilization of cancer companion diagnostic equipment and the increasing global disease burden. For example, in October 2022, the FDA approved Roche's first companion diagnostic, designed to assist doctors in determining the eligibility of patients with HER2 low metastatic breast cancer for treatment with Enhertu, which is jointly developed and commercialized by AstraZeneca and Daiichi Sankyo as an antibody-drug conjugate (ADC).

Consumables and reagents play a vital role in ensuring the reliability of cancer testing across various technologies. Therefore, major players are actively involved in the development of consumables for oncology companion diagnostics. For instance, in February 2020, Biocare Medical introduced seven new IVD IHC antibody markers. These initiatives are expected to boost the growth of the consumables segment within the oncology companion diagnostics market. Key companies like Fujifilm Wako Diagnostics, Thermo Fisher Scientific, Sysmex Corporation, Abbott Diagnostics, and Roche Diagnostics are significant players offering reagents for cancer diagnosis and a variety of cancer research products.

The service segment is projected to experience the highest CAGR during the forecast period. The presence of service providers like Covance, Q2 Solutions, and LabCorp, offering CDx development services, is expected to drive the growth of the services segment in the oncology companion diagnostics market. In June 2023, the FDA initiated a pilot program aimed at reducing the risks associated with using laboratory tests for identifying cancer biomarkers. This program is designed to assist clinicians in selecting appropriate cancer treatments for their patients.

Technology Insights

Immunohistochemistry (IHC) dominated the revenue landscape in 2022, primarily due to the widespread availability of IHC-based companion diagnostic solutions within the oncology market. Major industry players are consistently involved in securing product approvals and introducing new offerings, driving growth in this segment. IHC-based companion diagnostics play a crucial role in expediting the drug development process, significantly increasing the likelihood of successful regulatory approvals.

The adoption of IHC-based oncology companion diagnostic assays offers valuable support at every stage of the development process. A broad spectrum of antibody therapies, including Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC), Antibody Drug Conjugates (ADC), immune checkpoint blockade, and signal transduction blockade, harness the advantageous attributes of IHC technology as a companion diagnostic. This, in turn, accelerates clinical trials and streamlines marketing procedures, facilitating a more efficient drug development and approval process.

Regional Insights

In 2022, North America asserted its dominance in the field of oncology companion diagnostics. This was largely due to the significant impact of funding and grants from organizations like the National Cancer Institute (NCI), which aimed to expedite the development of precision therapies. Notably, the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) initiatives, administered by NCI, were instrumental in promoting the advancement of cutting-edge technologies and products for cancer prevention, detection, and treatment. Additionally, a series of conferences held in Canada to raise awareness about the latest trends and innovations in companion diagnostics further contributed to this growth.

In July 2021, Labcorp, a global life sciences company based in the United States, introduced the therascreen KRAS PCR Mutation Analysis, a diagnostic tool designed for identifying NSCLC patients eligible for LUMAKRAS treatment, a product developed by Amgen.

Looking ahead, the Asia Pacific region is poised to experience the most rapid CAGR during the forecast period spanning from 2023 to 2030. This growth is anticipated to be driven by effective regulations governing the approval of oncology companion diagnostic tests for cancer and the accelerated research and development efforts in the United States focused on integrated and personalized medicine.

Key Market Players

Agilent Technologies Inc
Illumina Inc
QIAGEN NV
Thermo Fisher Scientific Inc
F Hoffmann-La Roche AG
ARUP Laboratories Inc
Abbott Laboratories Inc
Myriad Genetics Inc
bioMerieux SA
Invivoscribe Inc

Report Scope:

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

- Oncology Companion Diagnostic Market, By Product & Service:
  - Product
    - Instrument,
    - Consumables
    - Software
  - Service
- Oncology Companion Diagnostic Market, By Technology:
  - Polymerase chain reaction (PCR)
  - Next-generation sequencing (NGS)
  - Immunohistochemistry (IHC)
  - In situ hybridization (ISH)/Fluorescence in situ hybridization (FISH)
  - Others
- Oncology Companion Diagnostic Market, By Disease Type:
  - Breast cancer
  - Non-small cell lung cancer
  - Colorectal cancer
  - Leukemia
  - Melanoma
  - Prostate cancer
  - Others
- Oncology Companion Diagnostic Market, By End Use:
  - Hospitals
  - Pathology/Diagnostic laboratory
  - Academic medical center
- Oncology Companion Diagnostic Market, By Region:
  - North America
    - United States
    - Canada
    - Mexico
  - Europe
    - Germany
    - United Kingdom
    - France
    - Italy
    - Spain
  - Asia-Pacific
    - China
    - Japan
    - India
    - Australia
    - South Korea
  - South America
    - Brazil
    - Argentina
    - Colombia

o Middle East & Africa
? South Africa
? Saudi Arabia
? UAE
? Kuwait
Competitive Landscape
Company Profiles: Detailed analysis of the major companies present in the Global Oncology Companion Diagnostic Market.
Available Customizations:
Global Oncology 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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