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Oncology Companion Diagnostic Market Forecasts to 2034 – Global Analysis By Product (Instrument, Consumables and Software), Technology, Indication, End User and By Geography

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Abstracts

According to Stratistics MRC, the Global Oncology Companion Diagnostic Market is accounted for $5.3 billion in 2026 and is expected to reach $16.1 billion by 2034 growing at a CAGR of 14.9% during the forecast period. Companion diagnostics in oncology refers to diagnostic methods or tests that are intended specially to help cancer patients choose the best therapy or course of treatment. By identifying certain biomarkers, genetic mutations, or molecular features in a patient's tumour, these tests assist medical professionals in customizing treatment plans for individual patients. These diagnostics find biomarkers that predict a patient's potential response to a certain treatment.

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.

Market Dynamics:

Driver:

Growing emphasis on targeted therapies and immunotherapies

For the best patient selection, targeted treatments and immunotherapies frequently need for certain biomarkers or genetic fingerprints. In order to match patients with the

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most appropriate medicines based on their molecular profile, companion diagnostics are essential in the identification of these predictive biomarkers. Complementary diagnostics help effective targeted treatments and immunotherapies reach the market more quickly. The availability of validated diagnostics helps these therapies succeed commercially by boosting the trust of regulators and healthcare professionals in their effectiveness.

Restraint:

High development costs and limited reimbursement

Diagnostic firms may choose not to engage in research and development due to the high development costs involved with companion diagnostics. This can result in a lack of creativity and slow development of fresh, enhanced oncology diagnostic tests. Healthcare systems or payers may be reluctant to fund companion diagnostics owing to cost concerns, which might result in a delayed uptake of the tests. Their incorporation into clinical practice may be delayed as a result and further hamper the growth of the market.

Opportunity:

Its ability to reduce clinical trial timelines

Clinical trials can be streamlined by oncology companion diagnostics that effectively identify patient populations likely to react to a certain drug. Trials can prove efficacy faster by including patients with certain biomarkers or genetic profiles, which might shorten the time it takes to create new drugs. Complementary diagnostics enable clinical trials to more accurately identify and enlist people who will most likely benefit from the investigated treatment. Thus, the time and resources required to complete the experiment are decreased as a result of the focused patient recruiting, which speeds up enrolment further creating wide range of opportunities for the growth of the market during the forecast period.

Threat:

Regulatory challenges and stringent approval processes

Complying with strict regulatory criteria frequently results in longer development times and higher development costs for companion diagnostics. The necessity of conducting

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extensive preclinical and clinical validation studies in order to obtain regulatory clearance results in longer development times and higher costs. The presence of variability in biomarker expression among distinct tumour types or patient groups might provide challenges to the validation and interpretation process, which may result in regulatory approvals being denied.

Covid-19 Impact

Hospitals and other healthcare institutions reallocated personnel and equipment in order to handle the increase in COVID-19 patients. A backlog of non-urgent patients and accompanying diagnostic tests resulted from priorities shifting in oncology departments, which were centered on urgent or critical cancer cases. Cancer screenings, diagnoses, and treatments have gradually improved as healthcare systems have adjusted to the obstacles presented by the epidemic. Ongoing initiatives to clear the backlog of postponed cases and diagnostic testing have contributed to the market recovery for cancer companion diagnostics.

The next-generation sequencing (NGS) segment is expected to be the largest during the forecast period

The next-generation sequencing (NGS) segment is estimated to have a lucrative growth, because of comprehensive study of a patient's tumor DNA, RNA, and other genetic data which is made possible by next-generation sequencing. Comparing it to conventional single-gene testing, it allows for the simultaneous identification of several genetic mutations, changes, and biomarkers linked to cancer, yielding a more complete picture. When it comes to selecting patients who are qualified for clinical trials evaluating new targeted treatments or immunotherapies, next-generation sequencing -based companion diagnostics are essential thus propelling the market.

The leukemia segment is expected to have the highest CAGR during the forecast period

The leukemia segment is anticipated to witness the highest CAGR growth during the forecast period, as leukemia is a malignancy that affects the bone marrow and blood. It is one of the major segments of the oncology companion diagnostic market. As soon as it comes to finding qualified individuals for clinical trials testing novel immunotherapies, targeted therapies, or combination treatments for leukemia, companion diagnostics play a crucial role. They aid in the creation and assessment of innovative therapies and therapeutic approaches.

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Region with largest share:

North America is projected to hold the largest market share during the forecast period owing funding from organizations like the National Cancer Institute (NCI) would hasten the development of precision therapies and have a favorable impact on the regional market. The NCI's Small Business Technology Transfer (STTR) and Small Business Innovation Research (SBIR) programs work to enhance and create cutting-edge tools and solutions for cancer diagnosis, prevention, and treatment. Furthermore, a number of conferences held in Canada to raise awareness of the developments and trends in CDx serve as an additional boost to this expansion.

Region with highest CAGR:

Asia-Pacific is projected to have the highest CAGR over the forecast period, owing to growing incidence of different malignancies has increased need for accurate and customized diagnostic instruments. The identification of biomarkers using companion diagnostics facilitates the customization of treatment plans for specific patients. Adoption has expanded as a result of patients' and healthcare professionals' growing understanding of the advantages of companion diagnostics and tailored treatment. Furthermore, access to sophisticated diagnostic technologies has been made easier by the growing cost of healthcare in a number of Asia Pacific nations.

Key players in the market

Some of the key players profiled in the Oncology Companion Diagnostic Market include Roche Ltd., F. Hoffmann-La Roche Ltd., Thermo Fisher Scientific, Inc., Illumina, Inc., Agilent Technologies, Inc., Abbott, Invivoscribe, Inc., bioM?rieux SA, Myriad Genetics, Inc., ARUP Laboratories, QIAGEN N.V., Agendia N.V, Biogenex Laboratories, Inc., GE Healthcare, Life Technologies Corporation, Ventana Medical Systems, Inc., Labcorp Drug Development, Leica Biosystems, MolecularMD Corporation and Dako, Inc.

Key Developments:

In December 2023, Roche enters into a definitive merger agreement to acquire Carmot Therapeutics, including three clinical stage assets with best-in-class potential in obesity and diabetes.

In November 2023, Roche launches automated serology hepatitis E virus tests, including a test to detect acute HEV infections, recommended in the new WHO 2023

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Essential Diagnostics List. The tests complete Roche’s panel used for the differential diagnosis of acute viral hepatitis caused by the hepatitis A, B, C and E viruses.

In November 2023, Thermo Fisher Scientific & Flagship Pioneering Expand Ongoing Strategic Partnership to Jointly Create New Platform Companies with First-in-Class Enabling Technologies for Life Sciences.

Products Covered:

- Instrument
- Consumables
- Software

Technologies Covered:

- Next-Generation Sequencing (NGS)
- Polymerase Chain Reaction (PCR)
- In Situ Hybridization (ISH)
- Fluorescence In Situ Hybridization (FISH)
- Immunohistochemistry (IHC)
- Protein Expression Analysis
- Genetic Mutation Analysis
- Microarray-Based Assays
- Methylation Analysis
- Other Technologies

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Indications Covered:

- Leukemia
- Melanoma
- Prostate Cancer
- Breast Cancer
- Colorectal Cancer
- Non-Small Cell Lung Cancer
- Ovarian Cancer
- Brain Tumors
- Lymphoma
- Other Indications

End Users Covered:

- Academic Medical Center
- Hospital
- Pathology/Diagnostic Laboratory

Regions Covered:

- North America
  - US
  - Canada

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- Mexico

Europe

- Germany
- UK
- Italy
- France
- Spain
- Rest of Europe

Asia Pacific

- Japan
- China
- India
- Australia
- New Zealand
- South Korea
- Rest of Asia Pacific

South America

- Argentina
- Brazil

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Chile

Rest of South America

Middle East & Africa

Saudi Arabia

UAE

Qatar

South Africa

Rest of Middle East & Africa

What our report offers:
- Market share assessments for the regional and country-level segments
- Strategic recommendations for the new entrants
- Covers Market data for the years 2023, 2024, 2025, 2026, 2027, 2028, 2030, 2032 and 2034
- Market Trends (Drivers, Constraints, Opportunities, Threats, Challenges, Investment Opportunities, and recommendations)
- Strategic recommendations in key business segments based on the market estimations
- Competitive landscaping mapping the key common trends
- Company profiling with detailed strategies, financials, and recent developments
- Supply chain trends mapping the latest technological advancements

Free Customization Offerings:

All the customers of this report will be entitled to receive one of the following free customization options:

Company Profiling

Comprehensive profiling of additional market players (up to 3)

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SWOT Analysis of key players (up to 3)

Regional Segmentation

Market estimations, Forecasts and CAGR of any prominent country as per the client's interest (Note: Depends on feasibility check)

Competitive Benchmarking

Benchmarking of key players based on product portfolio, geographical presence, and strategic alliances

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Contents

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9 GLOBAL ONCOLOGY COMPANION DIAGNOSTIC MARKET, BY GEOGRAPHY

10 KEY DEVELOPMENTS

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11 COMPANY PROFILING

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List Of Tables

LIST OF TABLES

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Note: Tables for North America, Europe, APAC, South America, and Middle East & Africa Regions are also represented in the same manner as above.

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