

Companion Diagnostics Market Size, Share & Trends Analysis Report By Product And Services (Assays, Kits, & Reagents, Instruments & Systems, Software & Services), By Indication, By Technology, By Sample Type, By End-use, By Region, And Segment Forecasts, 2025 - 2030

<https://marketpublishers.com/r/CF4B47566CF1EN.html>

Date: March 2025

Pages: 100

Price: US\$ 5,950.00 (Single User License)

ID: CF4B47566CF1EN

Abstracts

This report can be delivered to the clients within 3 Business Days

Companion Diagnostics Market Growth & Trends

The global companion diagnostics market size is expected to reach USD 15.98 billion by 2030, registering a CAGR of 10.5% from 2025 to 2030, according to a new report by Grand View Research, Inc. Companion diagnostics are specialized tests designed to ensure the safe and effective use of specific therapeutic products by identifying corresponding biomarkers in patients. These tests are predominantly employed in oncology, where they guide clinicians in selecting the most appropriate targeted therapies based on a patient's unique genetic profile. For instance, Foundation Medicine's FOUNDATIONONE CDx analyzes over 300 cancer-related genes, providing critical insights that inform precision cancer treatments across various solid tumors. By identifying key mutations or genetic alterations, companion diagnostics facilitate personalized treatment regimens, thereby improving clinical outcomes and reducing the risk of adverse reactions. This individualized approach to therapy not only enhances patient care but also supports the broader shift towards precision medicine, where treatment strategies are tailored to the genetic makeup of each patient.

Regulatory approvals play a pivotal role in bolstering the companion diagnostics market,

particularly in oncology. In August 2022, the U.S. FDA approved ThermoFisher Scientific Inc.'s OncoPrint Dx Target Test, a companion diagnostic designed to identify HER2 (ERBB2) activating mutations—including single nucleotide variants and exon 20 insertions—in non-small cell lung cancer tumors. Such regulatory endorsements validate the clinical utility of these tests and promote their widespread adoption. Additionally, the use of advanced techniques such as Next-Generation Sequencing (NGS) has become integral to companion diagnostics. NGS enables clinicians to evaluate multiple genes simultaneously, thereby providing comprehensive tumor profiling. The Centers for Disease Control and Prevention (CDC) has highlighted that NGS has successfully transitioned from a research tool to a clinically approved method within the past five years, underscoring its growing importance in diagnostic applications.

Technological innovation is a critical driver of growth in the companion diagnostics market. Key industry players are continuously advancing NGS platforms, digital ELISA, and liquid biopsy techniques to improve diagnostic precision and efficiency. Strategic partnerships are further accelerating these developments; for instance, in November 2023, QIAGEN partnered with Element Biosciences to provide NGS workflows for the benchtop sequencer AVITI System, aiming to enhance discovery, reduce costs, and improve turnaround times in genomic research. Similarly, in January 2022, Illumina Inc. collaborated with SomaLogic Operating Co., Inc. to integrate the SomaScan proteomics assay into its high-throughput NGS platforms. These collaborations not only expand the technological capabilities of companion diagnostics but also foster innovation in the development of new testing solutions, ensuring that emerging diagnostic methods keep pace with evolving clinical needs.

The rising prevalence of cancer globally has significantly spurred the adoption of companion diagnostics, as genomic testing offers a detailed insight into tumor biology that is critical for selecting effective treatment protocols. According to data from the American Cancer Society Journal, approximately 1.9 million new cancer cases were reported in the U.S. in 2022, while the World Health Organization (WHO) noted that in the same year, there were 2.26 million new breast cancer cases and 2.21 million new lung cancer cases worldwide. In response to these challenges, novel tests are being developed to detect specific genetic mutations. For example, in August 2020, the U.S. FDA approved Guardant360 CDx, the first liquid biopsy companion diagnostic that employs NGS technology to detect EGFR gene mutations in metastatic non-small cell lung cancer. In October 2023, QIAGEN further strengthened its market position by partnering with Myriad Genetics to develop advanced companion diagnostic solutions for oncology, thereby enhancing personalized treatment strategies and improving patient outcomes.

Companion Diagnostics Market Report Highlights

Based on product and services segment, assays, kits, and reagents led the market with a 59.1% share in 2024, driven by increasing demand for personalized medicine and targeted therapies. These components are crucial in detecting specific biomarkers that help determine a patient's eligibility for precision treatments, particularly in oncology, cardiovascular diseases, and rare genetic disorders.

Based on indication, oncology held the dominant market share in 2024, driven by the increasing global cancer burden and the growing demand for personalized medicine. CDx plays a crucial role in identifying biomarkers that help select targeted therapies, improving treatment outcomes for cancer patients.

Based on technology, the Polymerase Chain Reaction (PCR) segment dominated the companion diagnostics market in 2024, holding a 27.7% share. Real-time PCR assays are widely used due to their high specificity and sensitivity, making them a preferred method for identifying cancer biomarkers.

Based on sample type, tissue samples held the largest market share of 62.7% in 2024, driven by the widespread adoption of biomarker-based tissue testing for targeted therapies. Tissue samples are essential for identifying genetic mutations and protein expressions in solid tumors, guiding precision medicine in oncology.

Based on end use, the hospitals and physician laboratories segment dominated the oncology companion diagnostics market, holding a 38.6% share in 2024. Hospitals typically offer a comprehensive range of cancer diagnostic tests to address the increasing cancer burden and aging populations.

North America dominated the global market with a market share of 40.2% in 2024. Primarily due to advanced healthcare infrastructure, substantial healthcare expenditure, and a robust regulatory framework that expedites approvals for new diagnostic technologies.

Contents

CHAPTER 1. METHODOLOGY AND SCOPE

- 1.1. Market Segmentation and Scope
- 1.2. Market Definitions
- 1.3. Research Methodology
 - 1.3.1. Information Procurement
 - 1.3.2. Information or Data Analysis
 - 1.3.3. Market Formulation & Data Visualization
 - 1.3.4. Data Validation & Publishing
- 1.4. Research Scope and Assumptions
 - 1.4.1. List of Data Sources

CHAPTER 2. EXECUTIVE SUMMARY

- 2.1. Market Outlook
- 2.2. Segment Outlook
- 2.3. Competitive Insights

CHAPTER 3. COMPANION DIAGNOSTICS MARKET VARIABLES, TRENDS, & SCOPE

- 3.1. Market Introduction/Lineage Outlook
- 3.2. Market Size and Growth Prospects (USD Million)
- 3.3. Market Dynamics
 - 3.3.1. Market Drivers Analysis
 - 3.3.2. Market Restraints Analysis
- 3.4. Companion Diagnostics Market Analysis Tools
 - 3.4.1. Porter's Analysis
 - 3.4.1.1. Bargaining power of the suppliers
 - 3.4.1.2. Bargaining power of the buyers
 - 3.4.1.3. Threats of substitution
 - 3.4.1.4. Threats from new entrants
 - 3.4.1.5. Competitive rivalry
 - 3.4.2. PESTEL Analysis
 - 3.4.2.1. Political landscape
 - 3.4.2.2. Economic and Social landscape
 - 3.4.2.3. Technological landscape

- 3.4.2.4. Environmental landscape
- 3.4.2.5. Legal landscape
- 3.4.3. Pipeline
- 3.4.4. Case Study

CHAPTER 4. COMPANION DIAGNOSTICS MARKET: PRODUCT AND SERVICES ESTIMATES & TREND ANALYSIS

- 4.1. Segment Dashboard
- 4.2. Companion Diagnostics Market: Product and Services Movement Analysis, 2024 & 2030 (USD Million)
- 4.3. Assays, Kits, and Reagents
 - 4.3.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)
- 4.4. Instruments and Systems
 - 4.4.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)
- 4.5. Software and Services
 - 4.5.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

CHAPTER 5. COMPANION DIAGNOSTICS MARKET: INDICATION ESTIMATES & TREND ANALYSIS

- 5.1. Segment Dashboard
- 5.2. Companion Diagnostics Market: Indication Movement Analysis, 2024 & 2030 (USD Million)
- 5.3. Oncology
 - 5.3.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)
- 5.4. Infectious Diseases
 - 5.4.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)
- 5.5. Cardiovascular Diseases
 - 5.5.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)
- 5.6. Neurological Disorders
 - 5.6.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)
- 5.7. Other Indications
 - 5.7.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

CHAPTER 6. COMPANION DIAGNOSTICS MARKET: TECHNOLOGY ESTIMATES & TREND ANALYSIS

- 6.1. Segment Dashboard

6.2. Companion Diagnostics Market: Sample Type Movement Analysis, 2024 & 2030 (USD Million)

6.3. Polymerase Chain Reaction (PCR)

6.3.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

6.4. Next-generation Sequencing (NGS)

6.4.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

6.5. In-situ Hybridisation (ISH)

6.5.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

6.6. Immunohistochemistry (IHC)

6.6.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

6.7. Magnetic Resonance Imaging (MRI)

6.7.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

6.8. Other Technology

6.8.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

CHAPTER 7. COMPANION DIAGNOSTICS MARKET: SAMPLE TYPE ESTIMATES & TREND ANALYSIS

7.1. Segment Dashboard

7.2. Companion Diagnostics Market: Sample Type Movement Analysis, 2024 & 2030 (USD Million)

7.3. Tissue Samples

7.3.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

7.4. Blood Samples

7.4.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

7.5. Other Sample Types

7.5.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

CHAPTER 8. COMPANION DIAGNOSTICS MARKET: END USE ESTIMATES & TREND ANALYSIS

8.1. Segment Dashboard

8.2. Companion Diagnostics Market: End Use Movement Analysis, 2024 & 2030 (USD Million)

8.3. Academic and Research Centers

8.3.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

8.4. Hospitals and Physician Laboratories

8.4.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

8.5. CROs

- 8.5.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)
- 8.6. Reference Laboratories
 - 8.6.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)
- 8.7. Pharmaceutical and Biotechnology Companies
 - 8.7.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)
- 8.8. Other End-use
 - 8.8.1. Market Revenue Estimates and Forecasts, 2018 - 2030 (USD Million)

CHAPTER 9. COMPANION DIAGNOSTICS MARKET: REGIONAL ESTIMATES & TREND ANALYSIS

- 9.1. Companion Diagnostics Market Share, By Region, 2024 & 2030 (USD Million)
- 9.2. North America
 - 9.2.1. North America Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)
 - 9.2.2. U.S.
 - 9.2.2.1. U.S. Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)
 - 9.2.3. Canada
 - 9.2.3.1. Canada Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)
 - 9.2.4. Mexico
 - 9.2.4.1. Mexico Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)
- 9.3. Europe
 - 9.3.1. Europe Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)
 - 9.3.2. UK
 - 9.3.2.1. UK Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)
 - 9.3.3. Germany
 - 9.3.3.1. Germany Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)
 - 9.3.4. France
 - 9.3.4.1. France Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)
 - 9.3.5. Italy
 - 9.3.5.1. Italy Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.3.6. Spain

9.3.6.1. Spain Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.3.7. Denmark

9.3.7.1. Denmark Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.3.8. Sweden

9.3.8.1. Sweden Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.3.9. Norway

9.3.9.1. Norway Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.4. Asia Pacific

9.4.1. Asia Pacific Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.4.2. Japan

9.4.2.1. Japan Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.4.3. China

9.4.3.1. China Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.4.4. India

9.4.4.1. India Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.4.5. Australia

9.4.5.1. Australia Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.4.6. South Korea

9.4.6.1. South Korea Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.4.7. Thailand

9.4.7.1. Thailand Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.5. Latin America

9.5.1. Latin America Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.5.2. Brazil

9.5.2.1. Brazil Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.5.3. Argentina

9.5.3.1. Argentina Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.6. Middle East and Africa

9.6.1. Middle East and Africa Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.6.2. South Africa

9.6.2.1. South Africa Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.6.3. Saudi Arabia

9.6.3.1. South Africa Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.6.4. UAE

9.6.4.1. UAE Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

9.6.5. Kuwait

9.6.5.1. Kuwait Companion Diagnostics Market Estimates and Forecasts, 2018 - 2030 (USD Million)

CHAPTER 10. COMPETITIVE LANDSCAPE

10.1. Recent Developments & Impact Analysis by Key Market Participants

10.2. Company Categorization

10.3. Company Heat Map Analysis

10.4. Company Profiles

10.4.1. QIAGEN

10.4.1.1. Participant's Overview

10.4.1.2. Financial Performance

10.4.1.3. Product and Services Benchmarking

10.4.1.4. Recent Developments/ Strategic Initiatives

10.4.2. Agilent Technologies, Inc.

10.4.2.1. Participant's Overview

10.4.2.2. Financial Performance

10.4.2.3. Product and Services Benchmarking

10.4.2.4. Recent Developments/ Strategic Initiatives

10.4.3. Abbott

10.4.3.1. Participant's Overview

10.4.3.2. Financial Performance

10.4.3.3. Product and Services Benchmarking

- 10.4.3.4. Recent Developments/ Strategic Initiatives
- 10.4.4. Thermo Fisher Scientific, Inc.
 - 10.4.4.1. Participant's Overview
 - 10.4.4.2. Financial Performance
 - 10.4.4.3. Product and Services Benchmarking
 - 10.4.4.4. Recent Developments/ Strategic Initiatives
- 10.4.5. F. Hoffmann La Roche Ltd
 - 10.4.5.1. Participant's Overview
 - 10.4.5.2. Financial Performance
 - 10.4.5.3. Product and Services Benchmarking
 - 10.4.5.4. Recent Developments/ Strategic Initiatives
- 10.4.6. Foundation Medicine
 - 10.4.6.1. Participant's Overview
 - 10.4.6.2. Financial Performance
 - 10.4.6.3. Product and Services Benchmarking
 - 10.4.6.4. Recent Developments/ Strategic Initiatives
- 10.4.7. Myriad Genetics
 - 10.4.7.1. Participant's Overview
 - 10.4.7.2. Financial Performance
 - 10.4.7.3. Product and Services Benchmarking
 - 10.4.7.4. Recent Developments/ Strategic Initiatives
- 10.4.8. Illumina, Inc.
 - 10.4.8.1. Participant's Overview
 - 10.4.8.2. Financial Performance
 - 10.4.8.3. Product and Services Benchmarking
 - 10.4.8.4. Recent Developments/ Strategic Initiatives

I would like to order

Product name: Companion Diagnostics Market Size, Share & Trends Analysis Report By Product And Services (Assays, Kits, & Reagents, Instruments & Systems, Software & Services), By Indication, By Technology, By Sample Type, By End-use, By Region, And Segment Forecasts, 2025 - 2030

Product link: <https://marketpublishers.com/r/CF4B47566CF1EN.html>

Price: US\$ 5,950.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/CF4B47566CF1EN.html>