Developments in Companion Diagnostics

Landscape Overview And Drivers

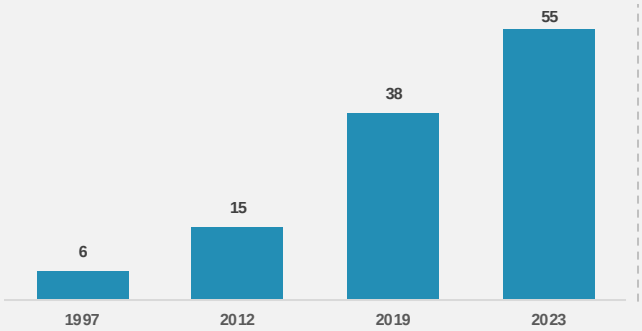
Companion diagnostics (CDx) have been rapidly advancing, with 55 assays approved by the FDA as of July 2023. The demand for CDx is driven by various factors such as the need for personalized medicine, increasing adoption of next-generation sequencing (NGS) and others. Ability of CDx to identify patients likely to benefit from therapy through specific biomarkers has spurred collaborations between pharmaceutical and diagnostic companies, leading to the development and launch of combination products.

CURRENT LANDSCAPE

As of July 2023, the number of CDx assays approved by the FDA had reached 55. The majority of companion diagnostics is currently in oncological indications.

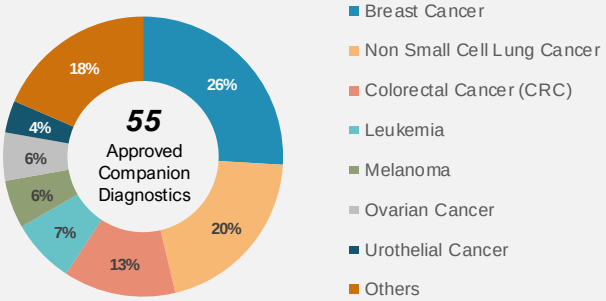
FDA-approved CDx

1997-2023



FDA-approved CDx by indication

2023

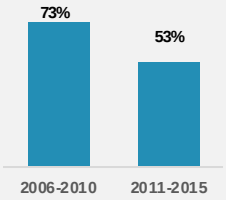


MARKET DRIVERS

Growing need for personalized medicine, rising demand for next-generation sequencing (NGS), cost reduction of genetics-based CDx tests, heightened number of deal signings, and regulatory developments drive CDx demand.

Rising Significance of Personalized Medicine

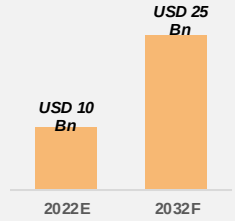
Investment growth in personalized medicine in the US



- CDx is a key driver enabling choices in personalized treatment and precision medicine.
- Rising significance of personalized medicine has been observed through growth of ~73% in investments in the US.

Increasing Demand for NGS-Based Technology

Market Size of NGS Technology in US



- Forecasted growth of NGS to ~USD 25 Bn indicates increasing demand, particularly for identifying rare variants within candidate genes
- This demand is crucial for the successful and widespread adoption of CDx

Decreasing Cost of Genetic Testing

Cost of sequencing a **single** genome in 2001

USD 100

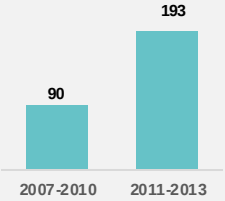
NGS claims to sequence **whole** genomes

USD 1,000

- The cost of DNA sequencing has steadily decreased since the introduction of NGS.
- The reduced costs of genetic-based CDx tests allows broader market access, which drives market growth.

Rise in CDx Deals

CDx Deals Signed



- Owing to incentives for drug developers to have CDx for their products, there has been a recent increase in deals.
- Nearly half of the deals are for discovery-stage efforts.

Regulatory Developments

- On April 13, 2020, the FDA released the final guidance titled "Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products." This guidance aims to enable class labeling on diagnostic tests for oncology therapeutic products when scientifically appropriate.
- Recently, in June 2023, the US FDA introduced a voluntary pilot program for specific oncology drug products used with corresponding in-vitro diagnostic tests. The program helps clinicians select suitable cancer treatments for patients.
- Both the guidance and the pilot program represent crucial steps in addressing safety risks associated with poorly performing laboratory-developed tests.

KEY DEVELOPMENTS

The expanding field of CDx is witnessing numerous launches and collaborations. These launches and collaborations collectively contribute to the dynamic and evolving landscape of CDx, allowing for improved patient care through targeted therapies and precision medicine approaches.

Product Launches

- In 2022, Roche received approval from the FDA for the first CDx to identify patients with HER2-low metastatic breast cancer.
- US officials first authorized the test in 2000. Now, Roche has added a scoring algorithm to help pathologists identify patients with breast cancers that express low levels of the HER2 receptor protein.

- In May 2020, MBL announced the release of an IVD kit for the hereditary disorder Spinal Muscular Atrophy (SMA).
- The MEBCDX AAV9 test kit, licensed from Quest Diagnostics, was approved by the Ministry of Health, Labour, and Welfare (MHLW) on April 27 as a CDx assay for Novartis International AG's SMA gene therapy Zolgensma™.

Partnerships

- In 2022, GRAIL announced a strategic collaboration with AstraZeneca to develop CDx to enable the treatment of early-stage cancer.
- The collaboration will begin by developing CDx tests to identify high-risk, early-stage patients. They also have plans for multiple studies across various indications in the upcoming years.

- In 2021, INOVIO and QIAGEN announced their collaboration to develop liquid biopsy-based CDx products based on NGS technology to complement INOVIO's therapies.
- The collaboration's first project aims to jointly develop a diagnostic test and will identify women best suited to receive clinical treatment with VGX-3100, which is INOVIO's immunotherapy designed to treat advanced cervical dysplasia linked to human papillomavirus (HPV).

Right from understanding key issues to advising you through the right set of insights and recommendations, Aranca Research, consolidation, and insightful analysis will aid in-depth understanding of therapy and effective decision-making

HOW CAN ARANCA HELP?

01 **Market Assessment:** Disease burden/disease landscape, diagnosis and treatment paradigm, humanistic and economic burden

02 **Current and Future Landscape:** Current treatments and latest pipeline landscape assessment for a particular therapy area

03 **Strategic Initiative Analysis:** Understanding key market trends in terms of M&As, funding, deals and other pertinent strategic initiatives

04 **Health Technology Assessment (HTA):** Analysis of various HTA decisions published by various countries

Connect with us

info@aranca.com

www.aranca.com/contact-us.php

www.linkedin.com/company/aranca