

CDx Development Market (2nd Edition): Distribution by Type of Service Offered (Feasibility Studies, Assay Development, Analytical Validation, Clinical Validation and Manufacturing), Analytical Technique Used (Next Generation Sequencing (NGS), Polymerase Chain Reaction (PCR), Immunohistochemistry / in situ Hybridization (IHC / ISH), Liquid Biopsy and Others), Therapeutic Areas (Oncological and Non-oncological) and Key Geographies (North America, Europe, Asia-Pacific and Rest of the World): Industry Trends and Global Forecasts, 2022-2035

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Abstracts

As of 2022, the CDx development market boasts a valuation of approximately \$664 million, with a projected Compounded Annual Growth Rate (CAGR) of 10.7% anticipated throughout the forecast period. Recent years have witnessed a substantial enhancement in comprehending the molecular mechanisms underpinning disease pathogenesis, paving the way for the creation of targeted therapies meticulously designed to address disease-related molecular signatures. The integral role of Companion Diagnostics (CDx diagnostics) has emerged as indispensable in informing physicians about patients' unique genetic profiles, facilitating well-informed treatment decisions tailored to individual needs.

Typically developed in tandem with investigational drugs, these diagnostic tests play a crucial role in evaluating the safety, efficacy, and therapeutic impact of the drugs on the intended targets. The pivotal approval of trastuzumab and HercepTest™ by the USFDA

in 1998 marked a milestone, triggering a trend where numerous novel targeted cancer drugs, guided by diagnostic assays, have progressed through clinical stages or gained approval for commercial use. In the period since 2020, the USFDA has greenlit 44 CDx diagnostics, with three CDx targeted therapies securing approval for advanced ovarian cancer, breast cancer, and non-small cell lung cancer.

An extensive study encompassing nearly 200 distinct pharmacological interventions across over 670 clinical trials has indicated that the probability of a lead compound successfully navigating clinical development phases and achieving approval is a mere 11%. Leveraging disease-specific biomarker information for patient recruitment not only elevates the success rates of studies but also slashes trial costs by nearly 60%.

Recognizing the multifaceted advantages, the healthcare industry is gradually shifting from the conventional one-size-fits-all drug approach to customized pharmacological interventions. This transition is poised to intensify the demand for CDx diagnostics. However, the intricacies inherent in co-developing drugs and companion diagnostic tests have prompted drug developers to prefer outsourcing CDx diagnostics operations. Remarkably, approximately 80% of companies opt for third-party service providers or CDx development companies due to a lack of in-house expertise in test development. Consequently, many CDx development companies have made substantial investments in cutting-edge tools and technologies, including polymerase chain reaction (PCR), immunohistochemistry (IHC), in situ hybridization (ISH), and next-generation sequencing (NGS), to provide comprehensive end-to-end services to sponsor companies in the CDx development market.

Beyond conventional analytical techniques, several innovators have diversified their portfolios by incorporating state-of-the-art solutions, such as digital PCR (dPCR) and digital immunoassays, to meet the evolving needs of their clientele. With the burgeoning demand for personalized therapies and ongoing technological advancements, it is anticipated that the CDx development industry will sustain significant market growth throughout the forecast period.

Key Market Segments

Type of Service Offered

Feasibility Studies

Assay Development

Analytical Validation

Clinical Validation

Manufacturing

Analytical Technique Used

Next Generation Sequencing (NGS)

Polymerase Chain Reaction (PCR)

Immunohistochemistry / in situ Hybridization (IHC / ISH)

Liquid Biopsy

Others

Therapeutic Areas

Oncological

Non-oncological

Geographical Regions

North America

Europe

Asia-Pacific

Rest of the World

Research Coverage:

The report studies the CDx development market by type of service offered, analytical technique used, therapeutic areas and key geographies.

The report analyzes factors (such as drivers, restraints, opportunities, and challenges) affecting the market growth.

The report assesses the potential advantages and obstacles within the market for those involved and offers information on the competitive environment for top players in the market.

The report forecasts the revenue of market segments with respect to major regions.

A comprehensive overview of the CDx diagnostics market, including profiles of industry players, year of establishment, company size, ownership, headquarters location, services offered, analytical techniques used, therapeutic areas assessed, and regulatory certifications/accreditations.

A regional competitiveness analysis of CDx development companies, considering factors like supplier power (experience and company size) and portfolio specifications (services offered, analytical techniques used, therapeutic areas assessed, and precision medicine-related deals signed since 2017).

Detailed profiles of prominent CDx development service providers, including company overviews, financial information (if available), service portfolios, recent developments, and future outlook.

An assessment of the current landscape of CDx diagnostics, covering marketed and in-development products, assay techniques, target disease indications, biomarker details, sample types, regulatory authorities involved, expedited review designations, and developer profiles.

Analysis of partnerships and collaborations for CDx diagnostics services from 2017-2021, categorized by partnership type, year, therapeutic areas, company locations, and active players.

An analysis of companies likely to enter collaborations with CDx development

companies, listing drug developers sponsoring biomarker-focused clinical trials, based on the number of trials and time to market.

Examination of mergers and acquisitions in the CDx development market from 2017-2021, including trends in terms of the number of companies acquired, with details on year, deal type, headquarters location, company size, value drivers, and acquisition deal multiples.

A qualitative assessment of the needs of stakeholders in CDx development, addressing concerns and potential industry responses based on past and current trends.

Value chain analysis of companion diagnostic development, covering R&D, clinical assessment, manufacturing, payer negotiation, and marketing activities, along with cost requirements.

Assessment of completed, ongoing, and planned biomarker-driven oncology clinical trials sponsored by major pharmaceutical companies over the last five years, examining key trends across various trial parameters.

Case studies on therapies using CDx diagnostics, highlighting their availability, molecule type, route of administration, and corresponding CDx diagnostics products/programs. It also provides information on drug developers, establishment year, company size, ownership, and headquarters location.

A case study on the current market landscape of precision medicine software solutions that offer intelligent insights for CDx development, patients, and healthcare experts, including the platform used, purpose, data type, therapeutic area, end users, and developer information.

Key Benefits of Buying this Report

The report offers market leaders and newcomers valuable insights into revenue estimations for both the overall market and its sub-segments.

Stakeholders can utilize the report to enhance their understanding of the competitive landscape, allowing for improved business positioning and more effective go-to-market strategies.

The report provides stakeholders with a pulse on the container closure integrity testing market, furnishing them with essential information on significant market drivers, barriers, opportunities, and challenges.

You will get access to complimentary PPT insights and excel data packs / dynamic dashboards to easily navigate through complex analyses / charts.

Key Market Companies

Almac Diagnostic Services

Biocartis

BGI Genomics

Cerba Research

Eurofins

Geneuity Clinical Research Services

Interpace Biosciences

Labcorp (formerly known as Covance)

MEDx (Suzhou) Translational Medicine

MEDICAL & BIOLOGICAL LABORATORIES (MBL)

MLM Medical Labs

Novogene

QIAGEN

Quest Diagnostics

Q? Solutions

ResearchDx

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