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Global Companion Diagnostic IHC Assay Kits Market 2026 by Manufacturers, Regions, Type and Application, Forecast to 2032

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Abstracts

According to our (Global Info Research) latest study, the global Companion Diagnostic IHC Assay Kits market size was valued at US$ 661 million in 2025 and is forecast to a readjusted size of US$ 1210 million by 2032 with a CAGR of 9.0% during review period.

Companion diagnostic IHC assay kits are regulated in vitro diagnostic products used to detect specific protein biomarkers in formalin-fixed, paraffin-embedded tissue and other pathology specimens, with the result directly linked to patient selection for a corresponding targeted therapy, immunotherapy, or antibody-drug conjugate. A commercial assay commonly combines a clinically validated primary antibody with positive and negative controls, chromogenic or other detection reagents, and a defined interpretation procedure. Testing may be performed on fully automated, semi-automated, or manual immunohistochemistry workflows, with treatment-related results derived from staining intensity, the percentage of positive cells, composite scoring algorithms, or protein-loss patterns. Key performance requirements include analytical specificity, lot-to-lot consistency, platform compatibility, stability of clinical cutoffs, and inter-laboratory reproducibility. The principal customers are hospital pathology laboratories, independent reference laboratories, pharmaceutical developers, and diagnostic co-development programs. The average gross margin is approximately 60%.

The continued expansion of precision oncology is creating mandatory demand for tissue-based protein biomarker testing. Broader use of immune checkpoint inhibitors, HER2-directed therapies, and drugs targeting emerging markers such as CLDN18.2, FOLR1, and PTEN is extending companion diagnostic IHC beyond its traditional concentration in breast and lung cancer. Hospital pathology departments and central laboratories increasingly prioritize alignment with drug labels, validated clinical cutoffs,

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and interpretation manuals, creating a clear commercial boundary between regulated companion diagnostic kits and general-purpose IHC antibodies.

Product development is focused on ready-to-use reagents, standardized controls, automated staining workflows, and digital pathology-assisted interpretation. Leading suppliers typically co-develop assays with pharmaceutical companies and use installed staining platforms to standardize antibody clones, detection chemistry, and scoring algorithms across laboratories. The expansion of multiprotein panels and newer membrane-protein targets is also increasing requirements for tissue controls, cutoff validation, pathologist training, and multi-region regulatory submissions, shifting competition from individual reagent sales toward integrated platforms, assays, interpretation standards, and drug-development partnerships.

North America and Europe remain the leading markets because of concentrated regulatory approvals, strong linkage with innovative oncology drugs, and high penetration of automated pathology platforms. China and Japan are expanding through local drug indications, domestic assay approvals, and investment in pathology testing capacity. Opportunities are emerging from new antibody-drug conjugates, tumor-agnostic immunotherapy, and regional companion diagnostic development, while platform lock-in, inter-clone concordance, specimen pre-analytics, reimbursement, and frequent drug-label updates can slow commercialization. Suppliers able to support pharmaceutical development, regulatory validation, and routine laboratory implementation are positioned more favorably.

Report Scope

This report is a detailed and comprehensive analysis for global Companion Diagnostic IHC Assay Kits market. Both quantitative and qualitative analyses are presented by manufacturers, by region & country, by Type and by Application. As the market is constantly changing, this report explores the competition, supply and demand trends, as well as key factors that contribute to its changing demands across many markets. Company profiles and product examples of selected competitors, along with market share estimates of some of the selected leaders for the year 2025, are provided.

Key Features:

Global Companion Diagnostic IHC Assay Kits market size and forecasts, in

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consumption value ($ Million), sales quantity (Units), and average selling prices (US$/Unit), 2021-2032

Global Companion Diagnostic IHC Assay Kits market size and forecasts by region and country, in consumption value ($ Million), sales quantity (Units), and average selling prices (US$/Unit), 2021-2032

Global Companion Diagnostic IHC Assay Kits market size and forecasts, by Type and by Application, in consumption value ($ Million), sales quantity (Units), and average selling prices (US$/Unit), 2021-2032

Global Companion Diagnostic IHC Assay Kits market shares of main players, shipments in revenue ($ Million), sales quantity (Units), and ASP (US$/Unit), 2021-2026

The Primary Objectives in This Report Are:

To determine the size of the total market opportunity of global and key countries

To assess the growth potential for Companion Diagnostic IHC Assay Kits

To forecast future growth in each product and end-use market

To assess competitive factors affecting the marketplace

This report profiles key players in the global Companion Diagnostic IHC Assay Kits market based on the following parameters - company overview, sales quantity, revenue, price, gross margin, product portfolio, geographical presence, and key developments. Key companies covered as a part of this study include Agilent Technologies, Roche, Leica Biosystems, Amoy Diagnostics, Nichirei Biosciences, etc.

This report also provides key insights about market drivers, restraints, opportunities, new product launches or approvals.

Companion Diagnostic IHC Assay Kits market is split by Type and by Application. For the period 2021-2032, the growth among segments provides accurate calculations and forecasts for consumption value by Type, and by Application in terms of volume and value. This analysis can help you expand your business by targeting qualified niche

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markets.

Market Segmentation

Market segment by Type

Primary Antibody-Only Kits

Single-Marker Complete Assay Kits

Multiprotein Panel Kits

Other Kit Configurations

Market segment by Detection Format

Single-Target Chromogenic IHC Assays

Multiprotein Panel IHC Assays

Dual-Stain or Multiplex IHC Assays

Other Detection Formats

Market segment by Staining Platform Type

Closed Automated Platforms

Open Automated Platforms

Manual or Semi-Automated Workflows

Other Platform Types

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Market segment by Application

Hospital Pathology Laboratories

Independent Reference Laboratories

Pharmaceutical and Biotechnology Companies

Academic and Research Institutions

Others

Major players covered

Agilent Technologies

Roche

Leica Biosystems

Amoy Diagnostics

Nichirei Biosciences

Market segment by region, regional analysis covers

North America (United States, Canada, and Mexico)

Europe (Germany, France, United Kingdom, Russia, Italy, and Rest of Europe)

Asia-Pacific (China, Japan, Korea, India, Southeast Asia, and Australia)

South America (Brazil, Argentina, Colombia, and Rest of South America)

Middle East & Africa (Saudi Arabia, UAE, Egypt, South Africa, and Rest of Middle East & Africa)

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Chapter Outline

Chapter 1, to describe Companion Diagnostic IHC Assay Kits product scope, market overview, market estimation caveats and base year.
Chapter 2, to profile the top manufacturers of Companion Diagnostic IHC Assay Kits, with price, sales quantity, revenue, and global market share of Companion Diagnostic IHC Assay Kits from 2021 to 2026.
Chapter 3, the Companion Diagnostic IHC Assay Kits competitive situation, sales quantity, revenue, and global market share of top manufacturers are analyzed emphatically by landscape contrast.
Chapter 4, the Companion Diagnostic IHC Assay Kits breakdown data are shown at the regional level, to show the sales quantity, consumption value, and growth by regions, from 2021 to 2032.
Chapter 5 and 6, to segment the sales by Type and by Application, with sales market share and growth rate by Type, by Application, from 2021 to 2032.
Chapter 7, 8, 9, 10 and 11, to break the sales data at the country level, with sales quantity, consumption value, and market share for key countries in the world, from 2021 to 2026.and Companion Diagnostic IHC Assay Kits market forecast, by regions, by Type, and by Application, with sales and revenue, from 2027 to 2032.
Chapter 12, market dynamics, drivers, restraints, trends, and Porters Five Forces analysis.
Chapter 13, the key raw materials and key suppliers, and industry chain of Companion Diagnostic IHC Assay Kits.
Chapter 14 and 15, to describe Companion Diagnostic IHC Assay Kits sales channel, distributors, customers, research findings and conclusion.

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