

Global HER2 ELISA Kits Market Growth 2026-2032

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Abstracts

The global HER2 ELISA Kits market size is predicted to grow from US\$ 72.78 million in 2025 to US\$ 111 million in 2032; it is expected to grow at a CAGR of 6.2% from 2026 to 2032.

HER2 testing kits primarily determine HER2 status by detecting the overexpression of HER2 protein or the amplification of the HER2 gene within tumor tissue. Specifically, the IHC (Immunohistochemistry) method utilizes anti-HER2 antibodies to bind with HER2 proteins in tissue sections; following a chromogenic visualization process, results are categorized as 0, 1+, 2+, or 3+ based on staining intensity. Conversely, ISH/FISH (In Situ Hybridization/Fluorescence In Situ Hybridization) methods employ HER2 gene probes alongside reference probes such as CEP17 to perform hybridization, assessing gene amplification status based on signal counts and ratios. These products are primarily utilized in the pathological classification, prognostic assessment, and companion diagnostics for breast cancer, gastric cancer, and gastroesophageal junction cancer. Their objective is to assist in identifying patients suitable for HER2-targeted therapies, such as trastuzumab, pertuzumab, and trastuzumab deruxtecan.

The upstream supply chain encompasses fluorescent/chromogenic probes, buffers, enzymatic reagents, microscope slides, quality control materials, anti-fading agents, and pathological testing equipment; the downstream market targets hospital pathology departments, third-party laboratories, and oncology centers. Globally, the average unit price for HER2 testing kits stands at approximately \$80 per kit, with global sales reaching approximately 930,000 kits. The industry boasts an annual production capacity of 1.5 million to 2 million kits and maintains a profit margin of approximately 50%.

The global market for human HER2 gene amplification testing kits is poised for growth, driven by advancements in precision medicine, companion diagnostics, and the expanding scope of HER2-targeted therapies. Consequently, market demand is

continuously trending toward greater standardization, automation, and high sensitivity. As the demand for HER2 testing rises across breast cancer, gastric cancer, and various other cancer types, technologies such as FISH, CISH, and Dual ISH will increasingly prioritize interpretive consistency, testing efficiency, and compatibility with automated pathology platforms. Future market competition will center on probe stability, result accuracy, reagent compatibility, regulatory compliance, and endorsement by clinical guidelines; concurrently, emerging therapeutic stratification concepts such as 'HER2-low' and 'HER2-ultralow' are expected to drive further refinement and segmentation of clinical testing scenarios.

LP Information, Inc. (LPI)'s newest research report, the 'HER2 ELISA Kits Industry Forecast' looks at past sales and reviews total world HER2 ELISA Kits sales in 2025, providing a comprehensive analysis by region and market sector of projected HER2 ELISA Kits sales for 2026 through 2032. With HER2 ELISA Kits sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world HER2 ELISA Kits industry.

This Insight Report provides a comprehensive analysis of the global HER2 ELISA Kits landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyzes the strategies of leading global companies with a focus on HER2 ELISA Kits portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global HER2 ELISA Kits market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for HER2 ELISA Kits and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global HER2 ELISA Kits.

This report presents a comprehensive overview, market shares, and growth opportunities of HER2 ELISA Kits market by product type, application, key manufacturers and key regions and countries.

Segmentation by Type:

Fluorescence In Situ Hybridization Kit

Chromogenic In Situ Hybridization Kit

Segmentation by Probe Type:

HER-2 Single-Color Probe Kit

HER-2 Dual-Color Probe Kit

HER-2/CEP17 Dual-Probe Kit

HER-2 Locus-Specific Probe Kit

HER-2 Copy Number Probe Kit

Segmentation by Fluorescent Signal:

Single-Color FISH Kit

Dual-Color FISH Kit

Multi-Color FISH Kit

Segmentation by Application:

Hospital

Clinic

Laboratory

Others

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analysing the company's coverage, product portfolio, its market penetration.

Thermo Fisher Scientific

Agilent Technologies

Leica Biosystems

BD Bioscience

Roche Diagnostics

LSBio

Abcam

Abbott Molecular

Nichirei Biosciences

Dakewe Biotech

Sysmex

ZytoVision

Biolynx

AmoyDx

LBP Medicine

CELNOVTE

Maixin Biotech

Key Questions Addressed in this Report

What is the 10-year outlook for the global HER2 ELISA Kits market?

What factors are driving HER2 ELISA Kits market growth, globally and by region?

Which technologies are poised for the fastest growth by market and region?

How do HER2 ELISA Kits market opportunities vary by end market size?

How does HER2 ELISA Kits break out by Type, by Application?

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