

Global HER2 Assay Kit Supply, Demand and Key Producers, 2026-2032

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Abstracts

The global HER2 Assay Kit market size is expected to reach \$ 114 million by 2032, rising at a market growth of 5.9% CAGR during the forecast period (2026-2032).

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.

This report studies the global HER2 Assay Kit production, demand, key manufacturers, and key regions.

This report is a detailed and comprehensive analysis of the world market for HER2 Assay Kit and provides market size (US\$ million) and Year-over-Year (YoY) Growth, considering 2025 as the base year. This report explores demand trends and competition, as well as details the characteristics of HER2 Assay Kit that contribute to its increasing demand across many markets.

Highlights and key features of the study

Global HER2 Assay Kit total production and demand, 2021-2032, (K Boxes)

Global HER2 Assay Kit total production value, 2021-2032, (USD Million)

Global HER2 Assay Kit production by region & country, production, value, CAGR, 2021-2032, (USD Million) & (K Boxes), (based on production site)

Global HER2 Assay Kit consumption by region & country, CAGR, 2021-2032 & (K Boxes)

U.S. VS China: HER2 Assay Kit domestic production, consumption, key domestic manufacturers and share

Global HER2 Assay Kit production by manufacturer, production, price, value and market share 2021-2026, (USD Million) & (K Boxes)

Global HER2 Assay Kit production by Type, production, value, CAGR, 2021-2032, (USD Million) & (K Boxes)

Global HER2 Assay Kit production by Application, production, value, CAGR, 2021-2032, (USD Million) & (K Boxes)

This report profiles key players in the global HER2 Assay Kit market based on the following parameters - company overview, production, value, price, gross margin,

product portfolio, geographical presence, and key developments. Key companies covered as a part of this study include Thermo Fisher Scientific, Agilent Technologies, Leica Biosystems, BD Bioscience, Roche Diagnostics, LSBio, Abcam, Abbott Molecular, Nichirei Biosciences, Dakewe Biotech, etc.

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

Stakeholders would have ease in decision-making through various strategy matrices used in analyzing the World HER2 Assay Kit market

Detailed Segmentation:

Each section contains quantitative market data including market by value (US\$ Millions), volume (production, consumption) & (K Boxes) and average price (US\$/Box) by manufacturer, by Type, and by Application. Data is given for the years 2021-2032 by year with 2025 as the base year, 2026 as the estimate year, and 2027-2032 as the forecast year.

Global HER2 Assay Kit Market, By Region:

United States

China

Europe

Japan

South Korea

ASEAN

India

Rest of World

Global HER2 Assay Kit Market, Segmentation by Type:

Fluorescence In Situ Hybridization Kit

Chromogenic In Situ Hybridization Kit

Global HER2 Assay Kit Market, 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

Global HER2 Assay Kit Market, Segmentation by Fluorescent Signal:

Single-Color FISH Kit

Dual-Color FISH Kit

Multi-Color FISH Kit

Global HER2 Assay Kit Market, Segmentation by Application:

Hospital

Clinic

Laboratory

Others

Companies Profiled:

Global HER2 Assay Kit Supply, Demand and Key Producers, 2026-2032

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 Answered:

1. How big is the global HER2 Assay Kit market?
2. What is the demand of the global HER2 Assay Kit market?
3. What is the year over year growth of the global HER2 Assay Kit market?

4. What is the production and production value of the global HER2 Assay Kit market?
5. Who are the key producers in the global HER2 Assay Kit market?
6. What are the growth factors driving the market demand?

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