

HER2 Testing Market Assessment, By Cancer Type [Breast cancer, Gastric cancer and Others], By Technique [Immunohistochemistry, In situ hybridization, Differential polymerase chain reaction (PCR) and Others], By End-user [Hospitals, Diagnostic labs and Others], By Region, Opportunities and Forecast, 2017-2031F

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Report description:

Global HER2 testing market is projected to witness a CAGR of 7.23% during the forecast period 2024-2031F, growing from USD 202.4 million in 2023 to USD 353.65 million in 2031. Several factors drive the growth of global HER2 testing market, such as the rising prevalence of breast cancer and gastric cancer, technological advancements, the use of AI, increased healthcare expenditure, government initiatives, policies, and programs. An increase in private and public sector investments in the diagnostics market, the presence of several top players, and developmental strategies like mergers, acquisitions, collaborations, and new product launches accelerate the global HER2 testing market growth.

The global HER2 testing market is further undergoing robust growth due to the rise in the prevalence of breast cancer at the global level. Women are more prone to get affected by this deadly disease. Genetic mutations, family history of breast cancer, and obesity are some of the risk factors for breast cancer. To combat the disease, HER2 tests play a crucial role as a prognostic and predictive marker in breast cancer specimens. HER2 testing is a highly reliable tool to detect whether a breast cancer is HER2-positive or HER2-negative, through which a clinician can choose an appropriate treatment strategy for the patient. Other factors, such as improvement in healthcare facilities by adopting HER2 testing in the healthcare sector and technological advancements in the market, such as integrating AI in HER2 testing for quick and accurate analysis, are further accelerating growth in the global HER2 testing market.

Governmental support to combat breast cancer worldwide, by initiating policies and programs at national and international level, to increase awareness regarding screening, early diagnosis, and proper management of the disease, further encourage increased use of cancer detecting techniques such as HER2 testing among the population. These governmental initiatives attract public and private companies to join and invest in further innovations, new launches, research, and development of more efficient and

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effective HER2 testing techniques to provide quality medical treatment and improve healthcare facilities in the market. Moreover, continuous mergers and acquisitions, partnerships and collaborations between the healthcare industries and increased FDA approvals for HER2 testing further propel the global HER2 testing market.

For instance, in January 2023, Guardant Health announced that it has received FDA approval for Guardant360 CDx, which is a blood diagnostic test, that detects ESR1 mutations and HER2-positive and HER2-negative breast cancer.

Rise in Prevalence of Breast Cancer

The increasing occurrence of breast cancer is a major driving factor for the global HER2 testing market. Breast cancer has become a public health problem at a global level due to its increasing prevalence in developing as well as developed countries. It affects both men and women; however, most commonly affecting women of older age. WHO states that, in 2020, worldwide, 2.3 million women were diagnosed with breast cancer leading to 6,85,000 deaths globally. It is estimated that breast cancer is the most common cancer worldwide. Family history of breast cancer, increasing age, excessive tobacco and alcohol consumption, and history of radiation exposure are the leading risk factors for the rising prevalence of breast cancer around the world. Early diagnosis is the best treatment for breast cancer, and diagnostic tools such as HER2 tests play a crucial role in it. HER2 test is a highly efficient testing technique in detecting HER2-positive and HER2-negative breast cancer, due to which its demand among the healthcare providers is increasing. With growing breast cancer awareness programs regarding various screening and diagnostic tools and techniques, popularity of HER2 testing is increasing, escalating growth of the global HER2 testing market.

Technological Advancement in HER2 Testing

In today's world, digitalization and AI have revolutionized advancement in the healthcare industry. AI has a huge potential in medical tools and appliances such as HER2 testing. In recent years, there has been a surge in innovative technologies aimed at overcoming the limitations of traditional testing techniques for more quality analysis. These technological advancements efficiently increase the accuracy and timeliness of cancer detection in a large population. Many key market players are launching AI-based HER2 testing options to improve their product portfolio and provide better health outcomes to the patients.

For instance, in July 2023, PathAI, a pioneer in providing AI-integrated pathology tools and appliances to advance precision medicine, announced the availability of AIM-HER2 Breast Cancer for research use by biopharma researchers and clinical research lab pathologists. In addition to providing automatic digital HER2 scoring, AIM-HER2 Breast Cancer is the first algorithm in the market to show the slide features that influence the system's predicted score using additive multiple instance learning (aMIL) heatmaps. Integrating AI in the HER2 testing can further provide a boost to the global HER2 testing market.

Increased Demand for In Situ Hybridization (ISH)

Among the technique segment, in situ hybridization is expected to show the fastest growth in the global HER2 testing market. Extensive research and development activities and increased investments by key market players in the segment have led to huge demand in the HER2 testing market. Moreover, its potential to provide information about the location of the target nucleic acids within cells or complex tissues is the main reason behind its increasing demand in the industry. Due to this, many key market players are launching the technique in their product portfolio.

For instance, in December 2023, Cytelabs, which is a leader in providing diagnostics products and services for cancer treatment and management, announced that it has launched Dual in situ hybridization (DISH) test for breast cancer detection. The launch is expected to improve accuracy in HER2 testing and will assist in providing the right and best treatment plan for breast cancer patients. A supportive regulatory system is enabling pharmaceutical companies to invest and launch drugs for these growing heart diseases, which further propels the global HER2 testing market.

Hospitals Hold Dominant Share in Global HER2 Testing Market

Among the end-user segment, hospitals hold a significant market share in the global HER2 testing market. The increasing global population and rising number of hospitals are the main reasons for the segment's dominance in the market. With growing healthcare expenditure, increased healthcare infrastructure, and increased prevalence of chronic diseases, the market is growing with increasing hospital facilities providing proper diagnosis and treatment facilities. For instance, according to the American Hospital Association, in 2023, there were 6,129 hospitals in the United States, and more hospitals are under construction. Increased availability of various types of diagnostic tools and appliances, along with increased trust among the population regarding the reliability and quality of healthcare facilities provided in the hospitals, further propelled the growth of this segment. Hospitals offer a broader range of services compared to diagnostic laboratories, such as inpatient care, surgeries, and specialized

testing such as HER2 tests for cancer detection and quality treatment, leading to better growth opportunities in the segment.

North America Holds the Largest Share in HER2 Testing Market

North America holds the maximum share of the global HER2 testing market. The robust healthcare infrastructure of the region, along with increased healthcare expenditure and investments in providing improved healthcare facilities to the population involving drug discoveries and manufacturing, research, and development in manufacturing innovative, efficient diagnostics such as HER2 testing, leads to an enhanced HER2 testing market in the region. Moreover, the growing prevalence of breast cancer in the United States has been a prominent factor in the huge demand for HER2 testing in the region.

Breast cancer is the most common cancer among women in the United States, as per the American Cancer Society. It states that in the year 2023, about 297,790 new cases of invasive breast cancer and approximately 55,720 new cases of ductal carcinoma in situ (DCIS) were diagnosed among women in the United States. It states that breast cancer will lead to about 43,700 women deaths in the country. The increasing number of breast cancer cases in the United States has led to an increased demand for potential diagnostic measures such as HER2 testing in healthcare facilities. Due to this, the HER2 testing market holds a significant regional share. Moreover, increased investments, constant governmental support, and research and development further accelerate growth in the market.

Future Market Scenario (2024 – 2031F)

The global HER2 testing market is expected to grow in the future due to multiple factors. Primarily, the increasing prevalence of breast cancer and gastric cancer worldwide has increased the adoption of HER2 testing in the healthcare industry. Increase in healthcare expenditure, governmental support, policies, and programs, reimbursement policies, increased research and development, and innovative launches by the public and private companies along with technological advancements such as AI-based HER2 testing techniques are further accelerating the growth of global HER2 testing market. Moreover, collaborative ventures involving diagnostics industry, biomedical companies, and other pharmaceutical companies have spurred innovation and growth in global HER2 testing market.

Key Players Landscape and Outlook

In HER2 testing market, public and private companies are progressively establishing initiatives, strategic partnerships, and distribution agreements, which are pivotal in propelling the global HER2 testing market's expansion. These alliances empower firms to adapt to each other's strengths, gain access to new markets and technologies, and pool resources for research and development endeavors. Distribution agreements enable companies to broaden their market presence at an international level. These collaborative initiatives promote innovation, expedite product development, and improve disease treatment and, in the end, contribute to the enduring and robust growth of the healthcare industry.

For instance, in December 2023, AstraZeneca India signed a partnership with Roche Diagnostics India to improve diagnostic testing for breast cancer patients by streamlining HER2 diagnostic tests in its diagnostics segment's product portfolio. The strategic acquisition will enable the company to help in improving standards of care for breast cancer patients and improve its product portfolio for management of the disease. Along with improving medical treatment, the partnership aims to enhance in-depth knowledge, research and development activities, and innovative product launches that will further expand the company's global footprint in the market.

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