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Next-Generation Breast Cancer Diagnostic and Screening Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented by Technology (Real-Time PCR, Immunohistochemistry (IHC), Next-Generation Sequencing (NGS), Fluorescence In-Situ Hybridization (FISH), others), by Biomarker (BRCA1/2, ER/PR Receptors, HER-2, Others), by Cancer Sub-Type (Luminal A, Luminal B, Triple Negative/Basal Like, Human Epidermal Growth Factor Receptor 2 (HER-2) Enriched), by Offering (Products, Services), by End User (Hospitals and Clinics, Diagnostic Centers and Reference Labs, Academic and Research Institutes), by region, and Competition

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Abstracts

Global Next-Generation Breast Cancer Diagnostic and Screening Market has valued at USD 2.90 billion in 2022 and is anticipated to witness an impressive growth in the forecast period with a CAGR of 10.51% through 2028. Next-generation breast cancer diagnostic and screening methods refer to advanced and innovative approaches to detecting and diagnosing breast cancer. These methods incorporate cutting-edge technologies, molecular insights, and personalized approaches to improve the accuracy and effectiveness of breast cancer detection, diagnosis, and risk assessment. Next-generation methods enable the molecular subtyping of breast cancer based on specific

genetic markers. This subtyping provides insights into the tumor's behavior and helps determine the most appropriate treatment strategy. Common subtypes include hormone receptor-positive, HER2-positive, and triple-negative breast cancer. The increasing incidence of breast cancer worldwide has been a significant driver. As breast cancer rates continue to rise, the demand for advanced diagnostic and screening methods to detect the disease at an early stage has also increased.

Ongoing technological advancements in breast imaging, genetic testing, and molecular diagnostics have improved the accuracy and early detection of breast cancer, driving demand for these technologies. The shift toward personalized medicine has led to an increased demand for diagnostic tests that provide individualized information about a patient's breast cancer subtype and genetic profile. This information guides treatment decisions. Breast cancer awareness campaigns and initiatives promoting early detection have encouraged more women to undergo regular breast cancer screening, contributing to market growth. Next-generation sequencing (NGS) and genomic profiling have expanded their applications in breast cancer diagnosis, allowing for a more comprehensive assessment of the disease's genetic characteristics. Growing awareness of hereditary factors contributing to breast cancer risk has led to an increased demand for genetic testing, including BRCA1/2 mutation testing, among individuals with a family history of the disease.

Key Market Drivers

Advancements in Technology

Digital mammography has largely replaced traditional film mammography. It offers improved image quality, easier storage and retrieval of images, and the ability to enhance and manipulate images for better visualization of breast tissue. 3D Mammography (Tomosynthesis) also known as breast tomosynthesis, this technology captures multiple X-ray images of the breast from different angles and creates a 3D image. It reduces false positives and improves the detection of breast cancer, particularly in women with dense breast tissue. Breast Magnetic Resonance Imaging (MRI) uses powerful magnets and radio waves to create detailed images of breast tissue. It is especially useful for assessing the extent of disease and detecting tumors in women at high risk. Advanced ultrasound technology, including elastography and contrast-enhanced ultrasound, provides additional information about breast lesions and can help distinguish between benign and malignant tumors. Genetic testing for breast cancer risk has advanced significantly. Next-generation sequencing allows for the analysis of multiple genes simultaneously, providing a comprehensive assessment of

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genetic mutations associated with breast cancer.

Liquid biopsy techniques involve analyzing biomarkers, such as circulating tumor DNA (ctDNA), circulating tumor cells (CTCs), and microRNAs, in a blood sample. These tests can provide real-time information about cancer status and treatment response. AI algorithms are being developed to analyze mammograms and other medical images for signs of breast cancer. AI can improve accuracy and efficiency in breast cancer diagnosis, reducing false positives and false negatives. Technologies like gene expression profiling and proteomics are used to characterize breast cancer at the molecular level. This information helps determine the best treatment options and predict patient outcomes. The integration of telemedicine and remote monitoring solutions allows for breast cancer screening and follow-up care without the need for in-person visits, enhancing access to diagnostic services. Digital pathology enables pathologists to view and analyze tissue samples remotely, improving efficiency and enabling collaboration among experts for more accurate diagnosis. Advanced computational models and algorithms have been developed to assess an individual's breast cancer risk based on a combination of factors, including genetics, family history, and lifestyle. Emerging techniques like positron emission tomography (PET) and single-photon emission computed tomography (SPECT) are being explored for their potential in breast cancer diagnosis and staging. Immunohistochemistry (IHC) techniques have been refined to provide more accurate characterization of breast cancer subtypes and biomarkers, guiding treatment decisions. This factor will help in the development of Global Next-Generation Breast Cancer Diagnostic and Screening Market.

Expanding Applications of Genomic Sequencing

Genomic sequencing, the process of determining the complete DNA sequence of an organism's genome, has expanded its applications across various fields of science and medicine. One of the most notable areas of expansion is in healthcare and genetics. Genomic sequencing is used to characterize the genetic mutations in cancer cells. This information helps oncologists determine the most appropriate targeted therapies and treatment strategies for individual cancer patients. Liquid biopsies, which involve sequencing cell-free DNA in the blood, are gaining prominence for monitoring tumor dynamics and treatment responses. Genomic sequencing enables the identification of genetic variations that can affect an individual's response to medications. Pharmacogenomics helps healthcare providers select the most effective and safe drugs and dosages for patients, minimizing adverse effects. Genomic sequencing is crucial for diagnosing rare genetic diseases, especially when traditional diagnostic methods fail. Whole exome sequencing (WES) and whole genome sequencing (WGS) are used to

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identify disease-causing genetic mutations. Genomic sequencing can be applied in prenatal testing to screen for genetic abnormalities and chromosomal disorders in fetuses. Non-invasive prenatal testing (NIPT) analyzes cell-free fetal DNA in the mother's bloodstream. Genomic sequencing is used to track the spread of infectious diseases, such as viruses and bacteria. It helps identify outbreak sources, understand transmission patterns, and guide public health interventions. Sequencing the genomes of microorganisms, including bacteria and viruses, aids in understanding their biology, evolution, and mechanisms of infection. This is crucial for vaccine development and antibiotic resistance monitoring.

Genomic sequencing is applied in agriculture to improve crop breeding, increase crop yield, and develop disease-resistant plant varieties. It also helps trace the origin of foodborne outbreaks and ensure food safety. Environmental DNA (eDNA) sequencing is used to study biodiversity and ecosystems. It helps identify species in environmental samples, monitor invasive species, and assess the impact of environmental changes. Genomic sequencing is used in forensic science for human identification, paternity testing, and solving criminal cases. It provides a powerful tool for identifying suspects and victims based on DNA evidence. Genomic sequencing allows scientists to study the evolutionary history and relationships between species. Comparative genomics helps uncover genetic adaptations and the genetic basis of evolutionary traits. With the expansion of genomic data, bioinformatics tools and data analysis techniques are essential for managing, analyzing, and interpreting large-scale genomic datasets. This field continues to evolve alongside genomic sequencing technologies. Genomic sequencing is increasingly used for health and wellness purposes, such as identifying genetic predispositions to certain conditions, optimizing nutrition and fitness plans, and providing insights into ancestry and genealogy. This factor will pace up the demand of Global Next-Generation Breast Cancer Diagnostic and Screening Market.

Rising Awareness and Early Detection Campaigns

Awareness campaigns provide essential information about breast cancer risk factors, signs, symptoms, and the benefits of early detection. This education empowers individuals to make informed decisions about their health and screening options. Awareness initiatives often promote adherence to recommended breast cancer screening guidelines, which may include mammography, genetic testing, clinical breast exams, and self-breast exams. Encouraging adherence to these guidelines drives demand for screening services. Breast cancer awareness campaigns help reduce the stigma associated with cancer and dispel fears related to screening procedures. When individuals are more informed and less fearful, they are more likely to undergo

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recommended screenings. Early detection of breast cancer is associated with better treatment outcomes and improved survival rates. Awareness campaigns emphasize the importance of detecting cancer at an early, more treatable stage, motivating individuals to seek screening services. Many awareness campaigns target specific populations, including women of certain age groups, ethnic backgrounds, or those with known risk factors. Targeted outreach efforts increase awareness and screening rates within these populations.

Awareness campaigns often include information about where and how to access breast cancer screening services. This information makes it easier for individuals to schedule screenings and seek care. Awareness campaigns often advocate for funding and support for breast cancer research. This research leads to advancements in screening technologies and diagnostic methods, increasing the availability of next-generation tools. These campaigns emphasize the importance of individual agency in healthcare decisions. Empowered patients are more likely to engage in preventive healthcare measures like screening. Many breast cancer awareness campaigns involve local communities, healthcare providers, and advocacy organizations. These collaborations foster a sense of community support and encourage individuals to prioritize their health. Sharing the stories of breast cancer survivors who benefited from early detection and treatment can inspire others to prioritize screening and early intervention. Awareness campaigns have a global impact by raising awareness about breast cancer in regions with limited access to healthcare. These campaigns contribute to international efforts to combat breast cancer. Awareness campaigns can influence healthcare policies and regulations, advocating for improved access to screening services, insurance coverage, and research funding. This factor will accelerate the demand of Global Next-Generation Breast Cancer Diagnostic and Screening Market.

Key Market Challenges

Ethical and Legal Issues

As next-generation diagnostic and screening methods generate large volumes of sensitive patient data, ensuring privacy and data security becomes paramount. Ethical concerns arise regarding the storage, sharing, and protection of patient genetic and medical information. Patients must provide informed consent before undergoing genetic testing or other screening procedures. Ensuring that patients fully understand the implications of the tests, including potential psychological and medical consequences, is an ethical imperative. Concerns about genetic discrimination in employment, insurance, and other areas may deter individuals from undergoing genetic testing. Legal

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protections against such discrimination are essential to address these concerns. Ethical and legal questions arise about who owns the genetic and medical data generated through screening. This includes issues related to data access, sharing, and commercialization. Next-generation screening technologies must adhere to regulatory standards to ensure safety, accuracy, and efficacy. Navigating the complex regulatory landscape can be a challenge for companies and healthcare providers. Ethical issues related to healthcare equity and access arise when next-generation screening technologies are not equally available to all populations. Disparities in access can lead to unequal health outcomes.

Cost and Accessibility

Many next-generation breast cancer screening and diagnostic methods, such as genetic testing, molecular profiling, and advanced imaging techniques, can be expensive. The cost of equipment, laboratory testing, and data analysis can be a barrier to access for both patients and healthcare providers. Socioeconomic disparities can affect access to advanced breast cancer screening. Low-income individuals and underserved populations may face difficulties in accessing these services due to financial constraints and limited healthcare resources. The availability and extent of insurance coverage for next-generation breast cancer screening and diagnostics vary by region and healthcare system. Lack of adequate insurance coverage can limit access for many patients, making these services financially out of reach. Access to advanced diagnostic centers, specialized expertise, and next-generation technologies may be limited in rural or remote areas. Geographic barriers can hinder individuals from undergoing timely screenings and diagnostics. In some regions, a lack of healthcare infrastructure and resources can limit access to advanced screening and diagnostic services. This includes the availability of trained healthcare professionals and specialized facilities. The high cost of next-generation technologies can be particularly challenging for healthcare systems in developing countries, where resources are limited. This can result in disparities in breast cancer detection and care on a global scale.

Key Market Trends

Integration of Multi-Omics Data

Multi-omics approaches enable healthcare providers to obtain a detailed profile of breast cancer at the molecular level. This includes information on genetic mutations, gene expression patterns, protein activity, metabolite levels, and epigenetic modifications. Integration of multi-omics data allows for precise molecular subtyping of

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breast cancer, which helps tailor treatment strategies based on the unique characteristics of each patient's tumor. This approach enhances the effectiveness of targeted therapies and minimizes unnecessary treatments. Multi-omics data analysis can identify biomarkers associated with early-stage breast cancer and risk prediction. This aids in early detection and risk assessment, enabling healthcare providers to intervene at an earlier, more treatable stage. Multi-omics analysis identifies specific molecular targets within breast cancer cells that can be exploited for treatment. This leads to the development of targeted therapies and more effective treatment options. Multi-omics data can be used to monitor a patient's response to treatment over time. Changes in gene expression, protein activity, or metabolite levels can indicate treatment efficacy or the need for therapeutic adjustments.

Segmental Insights

Technology Insights

In 2022, the Global Next-Generation Breast Cancer Diagnostic and Screening Market dominated by immunohistochemistry (IHC) segment and is predicted to continue expanding over the coming years. Immunohistochemistry (IHC) is a widely used laboratory technique in pathology for the detection of specific proteins or antigens in breast tissue samples. In the context of breast cancer, IHC is employed to identify the presence or absence of certain biomarkers, such as hormone receptors (estrogen receptor, progesterone receptor) and human epidermal growth factor receptor 2 (HER2). IHC is crucial in determining the molecular subtype of breast cancer. For example, the presence of hormone receptors (ER/PR) helps classify breast cancer as hormone receptor-positive, which has implications for treatment decisions. Similarly, HER2 status is assessed by IHC, which influences the choice of targeted therapies. The IHC results can provide prognostic information, helping healthcare providers and patients understand the likely course of the disease and make informed treatment decisions.

Biomarker Insights

In 2022, the Global Next-Generation Breast Cancer Diagnostic and Screening Market dominated by BRCA1/2 segment and is predicted to continue expanding over the coming years. BRCA1 and BRCA2 are genes that play a critical role in repairing damaged DNA and maintaining genomic stability. Mutations in these genes, specifically pathogenic mutations, are associated with an increased risk of developing breast and ovarian cancers, among others. Individuals who inherit pathogenic mutations in BRCA1

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or BRCA2 have a significantly higher risk of developing breast cancer. These mutations are among the most well-established genetic risk factors for breast cancer. The detection of BRCA1/2 mutations is an important aspect of breast cancer risk assessment. Individuals with a strong family history of breast or ovarian cancer or certain ethnic backgrounds may be candidates for genetic testing to identify these mutations.

Cancer Sub-Type Insights

In 2022, the Global Next-Generation Breast Cancer Diagnostic and Screening Market dominated by luminal A segment and is predicted to continue expanding over the coming years. Luminal A is one of the molecular subtypes of breast cancer. It is characterized by the presence of hormone receptors, particularly estrogen receptor (ER) and/or progesterone receptor (PR), on the surface of cancer cells. Luminal A tumours tend to be less aggressive and have a relatively better prognosis compared to other subtypes. The presence of hormone receptors, such as ER and PR, in luminal A breast cancer makes it susceptible to hormonal therapies, such as tamoxifen or aromatase inhibitors. This subtype's specific characteristics can influence treatment decisions, and hormone receptor testing is a crucial part of breast cancer diagnosis.

Offering Insights

In 2022, the Global Next-Generation Breast Cancer Diagnostic and Screening Market dominated by services segment and is predicted to continue expanding over the coming years. Some companies or healthcare providers may offer comprehensive breast cancer care packages that include screening, diagnostics, counselling, and follow-up services. These packages may encompass a range of services, making the services segment appear dominant in terms of revenue. Services related to genetic counselling, risk assessment, and patient education may be an integral part of breast cancer diagnostics and screening programs. Patients often require counselling to understand their test results and make informed decisions, which can contribute to the prominence of services.

End User Insights

In 2022, the Global Next-Generation Breast Cancer Diagnostic and Screening Market was dominated by hospitals and clinics segment in the forecast period and is predicted to continue expanding over the coming years. Hospitals and clinics are primary points of access to healthcare services for patients. Women often visit these facilities for routine

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check-ups, screenings, and medical consultations. This direct access to patients makes hospitals and clinics well-positioned for breast cancer diagnostic and screening services. Hospitals, especially large tertiary care centres, offer comprehensive healthcare services, including diagnostic imaging, pathology, and oncology departments. This allows for a seamless integration of breast cancer screening and diagnostics into the patient care pathway. In many healthcare systems, hospitals and clinics have established relationships with insurance providers, facilitating the reimbursement of breast cancer diagnostic and screening procedures. This can make these services more affordable for patients.

Regional Insights

The North America region dominates the Global Next-Generation Breast Cancer Diagnostic and Screening Market in 2022. North America, particularly the United States and Canada, boasts a well-developed healthcare infrastructure with a high level of investment in medical technology and research. This infrastructure supports the adoption of advanced diagnostic and screening technologies. Next-generation sequencing (NGS) technologies, a key component of breast cancer diagnostics, were rapidly adopted in North America. The region's research institutions and clinical laboratories have been early adopters of NGS for genetic testing, including cancer genomics. North America is home to numerous leading research institutions, academic medical centers, and biotechnology companies. These entities drive innovation in breast cancer diagnostics and screening, leading to the development of cutting-edge technologies and tests.

Key Market Players

Abbott Laboratories

Agendia Inc.

Agilent Technologies, Inc.

Bio-Rad Laboratories, Inc.

Genomics Co., Ltd.

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Danaher Corporation

Exact Sciences Corporation

F. Hoffmann-La Roche Ltd.

Illumina, Inc.

Thermo Fisher Scientific Inc.

Lucence Diagnostics Pte Ltd.

Report Scope:

In this report, the Global Next-Generation Breast Cancer Diagnostic and Screening Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Next-Generation Breast Cancer Diagnostic and Screening Market, By Technology:

Real-Time PCR

Immunohistochemistry (IHC)

Next-Generation Sequencing (NGS)

Fluorescence In-Situ Hybridization (FISH)

Others

Next-Generation Breast Cancer Diagnostic and Screening Market, By Biomarker:

BRCA1/2

ER/PR Receptors

HER-2

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Others

Next-Generation Breast Cancer Diagnostic and Screening Market, By Cancer Sub-Type:

Luminal A

Luminal B

Triple Negative/Basal Like

Human Epidermal Growth Factor Receptor 2 (HER-2) Enriched

Next-Generation Breast Cancer Diagnostic and Screening Market, By Offering:

Products

Services

Next-Generation Breast Cancer Diagnostic and Screening Market, By End User:

Hospitals and Clinics

Diagnostic Centers, and Reference Labs

Academic and Research Institutes

Global Next-Generation Breast Cancer Diagnostic and Screening Market, By region:

North America

United States

Canada

Mexico

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- Asia-Pacific
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  - India
  - South Korea
  - Australia
  - Japan
- Europe
  - Germany
  - France
  - United Kingdom
  - Spain
  - Italy
- South America
  - Brazil
  - Argentina
  - Colombia
- Middle East & Africa
  - South Africa
  - Saudi Arabia
  - UAE

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Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Next-Generation Breast Cancer Diagnostic and Screening Market.

Available Customizations:

Global Next-Generation Breast Cancer Diagnostic and Screening Market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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