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U.S. Breast Cancer Diagnostics Market Size, Share & Trends Analysis Report By Product (Platform-based, Instrument-based), By Type (Imaging, Biopsy, Genomic Tests, Blood Tests), By Application, By End-use, And Segment Forecasts, 2025 - 2033

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Abstracts

Market Size & Trends

The U.S. breast cancer diagnostics market size was estimated at USD 2.26 billion in 2024 and is projected to reach USD 4.53 billion by 2033, registering a CAGR of 8.21% from 2025 to 2033. The growth can be attributed to the increasing prevalence of breast cancer and rising government initiatives to increase the screening & diagnostic rate. For instance, according to the American Cancer Society, Breast cancer remains the most prevalent cancer among women in the U.S., excluding skin cancers, accounting for nearly 30% of all new female cancer cases annually. In 2025, an estimated 316,950 new cases of invasive breast cancer and 59,080 cases of ductal carcinoma in situ (DCIS) were diagnosed. Tragically, 42,170 women are expected to die from the disease. The increasing incidence of breast cancer fuels demand for advanced diagnostic technologies such as mammography, genetic testing, and AI-powered imaging. Rising awareness, government initiatives, and expanding insurance coverage further stimulate the adoption of screening programs and innovative diagnostics across the U.S.

The market in the U.S. is supported by a high disease prevalence, strong policy initiatives, and rapid technological innovation. Breast cancer remains the most common cancer among U.S. women, with the American Cancer Society projecting over 316,950 invasive cases in 2025. Rising incidence in younger demographics, coupled with growing awareness about the importance of early detection, is fueling demand for

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advanced diagnostic tools. The U.S. government and research institutions are actively promoting innovation through grants and funding. For example, in January 2024, Weill Cornell Medicine received a $2.4 million Department of Defense grant to validate the Syantra DX liquid biopsy test, an AI-driven blood-based screening solution that could significantly improve access for women with dense breast tissue, underserved populations, and high-risk groups. The availability of non-invasive, cost-effective tests is expected to improve early detection, reduce aggressive treatments, and shift market demand away from traditional imaging toward liquid biopsy technologies.

The launch of innovative intraoperative diagnostic solutions is also transforming breast cancer care. In January 2025, Lumicell introduced the LumiSystem, the first FDA-approved real-time fluorescence-guided imaging tool for lumpectomy procedures. By integrating the LUMISIGHT optical imaging agent with the Direct Visualization System (DVS), surgeons are able to identify and remove cancerous tissue intraoperatively, thereby minimizing the need for repeat surgeries and improving patient outcomes. Such advancements not only enhance surgical precision but also reduce long-term healthcare costs. Key industry players, including Roche, Thermo Fisher Scientific, QIAGEN, BD, and Danaher, are investing heavily in regulatory approvals and partnerships to expand their market presence. For instance, Roche’s PATHWAY HER2 (4B5) test has been granted successive FDA approvals, first for identifying HER2-low and more recently HER2-ultralow metastatic breast cancer patients eligible for ENHERTU therapy, further strengthening the role of precision diagnostics in treatment selection. Similarly, PreludeDx’s DCISionRT test received FDA Breakthrough Device designation in 2025, enabling physicians to personalize treatment decisions for ductal carcinoma in situ (DCIS) patients and avoid unnecessary interventions.

Biopsy remains a fundamental diagnostic method in the U.S., with more than 1 million procedures conducted annually, of which around 20% confirm malignancy. Needle-based biopsies-comprising fine needle aspiration, core needle, and vacuum-assisted biopsies-represent over 90% of cases due to their minimally invasive nature and higher patient compliance compared to surgical biopsies. The segment is witnessing notable innovation, with Mammotome introducing the AutoCore Single Insertion Core Biopsy System in November 2024, which improves efficiency through real-time visualization, single insertion sampling, and touchless specimen transfer. At the same time, liquid biopsy is rapidly gaining ground, with the FDA approval of FoundationOne Liquid CDx in October 2024 as a companion diagnostic for Itovebi, targeting HR-positive, HER2-negative patients with PIK3CA mutations. These advancements highlight a broader trend toward minimally invasive and precision-guided testing solutions in the

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U.S. diagnostics market.

U.S. Breast Cancer Diagnostics Market Report Segmentation

This report forecasts revenue growth at the country level and provides an analysis of the latest trends in each of the sub-segments from 2021-2033. For this study, Grand View Research has segmented the U.S. breast cancer diagnostics market report by type, product, application, and end use:

Type Outlook (Revenue, USD Million, 2021 - 2033)

Imaging

Biopsy

Genomic Tests

Blood Tests

Others

Product Outlook (Revenue, USD Million, 2021 - 2033)

Platform-based products

Next Generation Sequencing

Microarrays

PCR

Others

Instrument-based products

Imaging

Biopsy

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Application Outlook (Revenue, USD Million, 2021 - 2033)

Screening

Diagnostic & Predictive

Prognostic

Research

End Use Outlook (Revenue, USD Million, 2021 - 2033)

Hospitals & Clinics

Medical labs & Diagnostics Centers

Others

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