HENRY FORD HEALTH
CENTER FOR PRECISION DIAGNOSTICS

# Breast Cancer Solid Tumor Sequencing Panel

This test panel detects mutations in the BRCA1, BRCA2 and PIK3CA genes from DNA extracted from formalin-fixed, paraffin-embedded (FFPE) specimens. This test is used for diagnostic, prognostic, and predictive purposes associated with breast cancers.

## Testing Method and Background

The gene target exons are enriched by hybrid capture method followed by Next Generation Sequencing (NGS). This method was optimized for use with low quantity of input DNA (50 ng) obtained from formalin-fixed, paraffin-embedded (FFPE) tissues providing high on-target coverage with coverage uniformity above 95% throughout the entire target region. This analysis is performed on genomic DNA isolated from FFPE tumor tissue and does not differentiate between germline and somatic mutations.
Assessment of Breast Cancer genes 1 and 2 (BRCA1 and BRCA2) mutation status in breast tumors is important since presence of mutations is predictive for treatment response to poly(ADP-ribose) polymerase (PARP) inhibitors and platinum agents. PIK3CA is altered in up to 30-35% of breast cancers. The alpha-selective PI3-kinase inhibitor alpelisib in combination with the Estrogen Receptor (ER)-antagonist fulvestrant is FDA-approved for the treatment of patients with PIK3CA-mutant ER+/HER2- breast cancer.

## Highlights of Breast Cancer Solid Tumor Sequencing Panel

**Targeted Region**

**BRCA1:** Full Exon Sequencing
**BRCA2:** Full Exon Sequencing
**PIK3CA:** Exons 2, 3, 6, 8, 10, 21

- **Accurate Results from Low-Quality Samples**
  Sensitive variant detection with as little as 50 ng of input DNA, and as low as 5% mutant allele frequency, maximizes the results from low input sample types such as formalin fixed, paraffin embedded (FFPE) sections.
- **Wide-ranging Coverage of Variants**
  Assessment of single-nucleotide variants (SNVs) and small insertions/deletions, and whole gene deletions and amplifications.

## Ordering Information

**Get started (non-HFHS):** Print a Molecular Solid Tumor requisition form online at www.HenryFord.com/HFCPD

**Get started (HFHS):** Order through Epic using test "Breast Cancer Solid Tumor Gene Sequencing Panel" (MOL8025)

**Specimen requirements:**

A surgical pathologist should confirm the presence of adequate tumor in materials submitted for analysis. Section from archival paraffin material or frozen surgical biopsies should be confirmed to contain >50% tumor by a surgical pathologist. If the submitted material for analysis contains < 50% of tumor, areas of predominant tumor will be microdissected, if possible, to enrich for neoplastic cells.

- Formalin-fixed, paraffin-embedded tissue, preferably no older than 2 years
- 5-6 tissue sections at 5-6 micron thickness (please include H&E slide and a copy of pathology report)
- Cytology slides (cell block with 500+ tumor cells, submit block or 5-6 tissue sections at 5-10 micron thickness depending on cellularity)
- Extracted DNA - from a CLIA-certified Laboratory

**Cause for Rejection:** Fresh unfixed tissue, paraffin materials that do not contain tumor cells, improperly labeled specimens, archival paraffin material subjected to acid decalcification.

**TAT:** 5-10 business days (after Prior Authorization obtained)

**Mail test material to:**
**Henry Ford Center for Precision Diagnostics**
Pathology and Laboratory Medicine
Clinic Building, K6, Core Lab, E-655
2799 W. Grand Blvd., Detroit, MI 48202

**CPT Codes:** 81162, 81309, G0452

**Contact us:** Client Services, Account and Billing Set-up, and connect with a Molecular Pathologist at (313) 916-4DNA (4362)

**For more information on Comprehensive Molecular Services, visit our website**
**www.HenryFord.com/HFCPD**

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