HENRY FORD HEALTH
CENTER FOR PRECISION DIAGNOSTICS

Solid Tumor Mutation BRAF

This test detects mutations in the BRAF gene from DNA extracted from formalin-fixed, paraffin-embedded (FFPE) specimens. BRAF mutation status could be a useful biomarker for selecting patients suitable for anti-EGFR treatment.

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.
Somatic mutations in BRAF are associated with several different neoplastic processes including colorectal cancer (CRC), melanoma, non-small cell lung cancer, adenocarcinoma of the lung, non-Hodgkin lymphoma and thyroid cancer. It has been shown that BRAF mutations in colorectal cancer (CRC) cause resistance to anti-EGFR therapy. Wild type BRAF is necessary for anti-EGFR treatment to work. BRAF and KRAS mutations are mutually exclusive. BRAF status could be a useful biomarker for selecting patients suitable for anti-EGFR treatment.

Highlights of Solid Tumor Mutation BRAF

Targeted Region

BRAF: Exons 11, 15

- **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 "BRAF Mutation" (MOL8011)

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

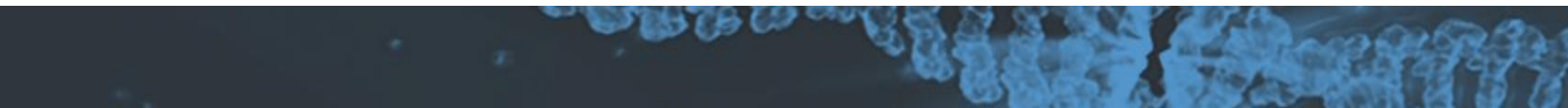
Cause for Rejection: Fresh unfixed tissue, paraffin materials that do not contain tumor cells, improperly labeled specimens, archival paraffin material subjected to acid decalcification.

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: 81210, 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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