

# Solid Tumor NRAS Gene Mutations Analysis

This test detects mutations in the NRAS gene from DNA extracted from formalin-fixed, paraffin-embedded (FFPE) specimens. NRAS gene mutations are present in a variety of human cancers and are associated with a poor prognosis.

### 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. KRAS and NRAS mutations have been known to be present in a variety of human cancers, including lung cancer, colorectal cancer, and pancreatic cancer and are associated with a poor prognosis. Multiple studies have now shown that patients with tumors harboring mutations in KRAS or NRAS exons 2, 3, or 4 predict lack of response to anti-EGFR antibody therapy given in combination with chemotherapy

#### Highlights of Solid Tumor NRAS Gene Mutation Analysis

#### **Targeted Region**

NRAS: Exons 2-4

- 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 "NRAS Mutation" (MOL8019)

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

**CPT Codes:** 81311, G0452

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