HENRY FORD HEALTH
CENTER FOR PRECISION DIAGNOSTICS

Solid Tumor EGFR-TKI (Lung) Gene Mutation

This test EGFR-TKI mutations from DNA extracted from formalin-fixed, paraffin-embedded (FFPE) specimens. EGFR mutation analysis can be used to select patients likely to respond to tyrosine kinase inhibitor therapy.

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.
Mutations in the epidermal growth factor receptor (EGFR) gene, exons 18 to 21, have been identified in patients with lung adenocarcinomas. Two classes of EGFR mutations, exon 19 deletions and exon 21 L858R substitutions, are the most frequent mutations representing 85-90% of EGFR mutations reported. EGFR mutations have been associated with response to tyrosine kinase inhibitors (TKI). However, while some EGFR mutations have a sensitizing effect, others are linked to TKI resistance (T790M mutation and possibly exon 20 insertions). EGFR mutation analysis can be used to select patients likely to respond to tyrosine kinase inhibitor therapy.

Highlights of Solid Tumor EGFR-TKI (Lung) Gene Mutation

Targeted Region

EGFR:	Exon 18-21

- **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 "EGFR-TKI Mutation" (MOL8022)

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

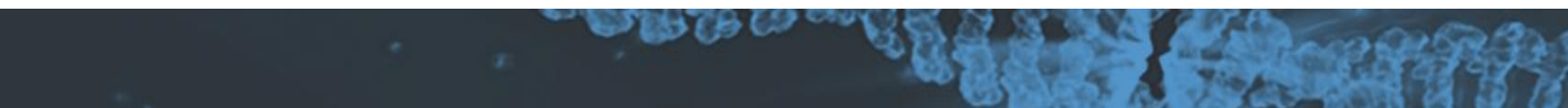
Cause for Rejection: Fresh unfixed tissue, paraffin materials that do not contain tumor cells, improperly labeled specimens, archival paraffin material subjected to acid decalcification.

TAT: 5-7 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: 81235, 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

Revision: 2; 12-02-2024