

EGFR TKI Sensitivity and Resistance Mutation

Indication: 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.

Testing Method: DNA based next generation sequencing. Hot spot mutations in exons 18 to 21 are detected including T790M resistance mutation.

Test Parameters: The limit of detection of this assay has been determined to be approximately 5% of mutant allele(s) in the background of wild type allele.

Turnaround Time: 3-5 business days

Sample Requirements: The presence of adequate tumor in the material submitted for analysis should be confirmed by a surgical pathologist. A 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 macrodissected using a scalpel to trim away non-neoplastic areas.

- Formalin-fixed, paraffin-embedded tissue
- 5-6 tissue sections (please include H&E slide and a copy of pathology report)
- Cytology slides
- Cytology cell blocks
- Fresh or frozen tissue

CPT Codes: 81235, 88381 may apply

Ship Specimens to:

Henry Ford Center for Precision Diagnostics
Henry Ford Hospital
Clinic Building, K6, Core Lab E-655
2799 W. Grand Blvd.
Detroit, MI 48202