

EGFR Mutation Analysis

CERNER ORDERABLE

Using IU Health Pathology requisition; Order through CoPath please call 317.491.6417

CPT CODES

81235

CLINICAL UTILITY

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer and includes squamous cell carcinoma, adenocarcinoma, and large-cell (undifferentiated) carcinoma subtypes. Therapeutic strategies to improve the outcome for NSCLC treatment target epidermal growth factor receptor (*EGFR*), as *EGFR* is frequently overexpressed and aberrantly activated in NSCLCs. Overexpression of *EGFR* has also been associated with lung cancer, glioblastomas, and epithelial neoplasms including head and neck, ovarian, cervical, bladder, gastric, colorectal, and anal cancer. EGFR mutation testing is used to guide treatment decisions for patients involved in TKI therapies including gefitinib (Iressa®) and erlotinib (Tarceva®). Data suggests benefits vary among patients, and those with EGFR mutations will gain the most benefit from EGFR TKIs. EGFR mutations mainly exist in exons 18-21, the first four exons encoding the tyrosine kinase domain. EGFR mutation status does not currently apply in predicting response to anti-EGFR antibodies¹.

METHODOLOGY

This test was performed using the FDA approved *therascreen* EGFR RGQ PCR Kit, which is a real-time qualitative PCR assay used on the Rotor-Gene Q MDx instrument for the detection of mutations in the human EGFR oncogene. Specimens are reviewed by a pathologist before processing. DNA is isolated from the sample and quantified. The *therascreen* EGFR RGQ PCR Kit is only intended to discriminate between wild-type and mutant. False positive or negative results may occur for reasons that include genetic variants, somatic heterogeneity of the sample analyzed, or tumor sampling. Mutations present in a low percentage of cells may not be detected.

SPECIMENS

Preferable primary tumor.

- FFPE tissue (Formalin fixative only), cell block FNAs
For tissue resection: 1 H&E and 8 unstained slides
For a biopsy: 1 section on 1 slide for H&E plus 6 unstained slides with 3 sections/ slide

SPECIMEN STABILITY and SHIPPING

- Transport/Storage of slides at room temperature.

CAUSES FOR REJECTION

Excess necrosis for slides. Inadequate percentage tumor; poor DNA quality.

ASSAY RANGE

- EGFR mutation not detected.
- EGFR mutation detected.

TURNAROUND TIME 7-10 Working days

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.