
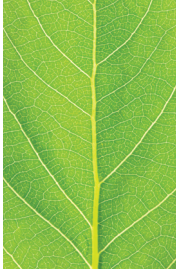


EGFR by PCR
Plasma Specimen for Liquid Biopsy
February 15, 2018

Clinical Use

A non-invasive supplement to biopsy analysis. For use in identifying non-small cell lung cancers that may benefit from treatment with epidermal growth factor receptor-tyrosine kinase or anaplastic lymphoma kinase inhibitors.

Clinical Background

Non-small cell lung carcinoma (NSCLC) accounts for 75%-80% of all lung cancers. Patients with advanced NSCLC may not be healthy enough for a tissue biopsy, or might only be able to undergo limited tissue procedures, like a Fine Needle Aspirate (FNA) or Core Needle Biopsy (CNB) for diagnosis.

After first-line TKI therapy, it is preferable to use a new tumor specimen for EGFR analysis which would require another invasive tissue biopsy procedure. The key benefits of testing with plasma is that it involves a non-invasive procedure for collecting specimen from the patient and can be collected as frequently as needed without putting patients at risk. Patients who are negative for EGFR mutations by this test should be reflexed to tissue biopsy for testing.

EGFR-targeted therapies have been approved by the FDA for use in treating patients with NSCLC who previously failed to respond to traditional chemotherapy. Efficacy of EGFR tyrosine kinase inhibitors, such as gefitinib and erlotinib, is confined to patients with tumors demonstrating EGFR mutations, particularly in exons 19 and 21. This assay detects 42 mutations in exons 18, 19, 20 and 21 including the T790M resistant mutation.

Specimen Requirements:

Specimen: K2 EDTA Plasma. Centrifuge to separate from cells within 4 hours.

Stability: 2-8°C, 72 hours

Cause for Rejection: Serum

Method: Real-Time Polymerase Chain Reaction (PCR)

Turnaround Time: Testing is batched once a week

CPT code:* 81235

SOFT code: EGFRM

*CPT codes provided are for informational purposes only. Questions regarding coding should be directed to the payor.