Lung Carcinoma

EGFR MUTATION BY FRAGMENT ANALYSIS

EGFR gene mutations occur in 10-40% of non-small cell lung cancer (NSCLC) cases. The most common mutations include exon 19 deletions and the exon 21 L858R substitution which together comprise ~85% of all EGFR mutations. The presence of either of these mutation types has been associated with clinical response to tyrosine kinase inhibitor therapies (gefitinib and erlotinib). This fragment analysis test will detect EGFR exon 19 deletion mutations and the L858R mutation in formalin fixed paraffin-embedded blocks, unstained paraffin sections on slides, and fresh/frozen tissue. The submitted specimen should contain an adequate proportion of tumor cells (> 5%) to enable mutation detection.

ALK REARRANGEMENT FOR NSCLC (FISH)

This test detects rearrangements involving the ALK gene (2p23) via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue specimens. This test is FDA-approved to aid in identifying those patients eligible for treatment with crizotinib, a small molecule inhibitor of the ALK tyrosine kinase. FISH is performed using a dual color break-apart probe (Abbott Molecular) to qualitatively assess for the presence of ALK gene rearrangements. This test is intended only for NSCLC tissue specimens that have been fixed in 10% neutral buffered formalin and embedded in paraffin.

KRAS MUTATION

Activating mutations in the KRAS gene occur in approximately 20% of lung adenocarcinomas, 30-40% of colorectal carcinomas, and a variety of other human cancers. Mutations are single nucleotide substitutions, occurring most frequently within codon 12 or 13. These have been associated with a limited clinical response to epidermal growth factor receptor (EGFR) targeted therapies in lung and colorectal cancers, and may indicate prognosis. This DNA sequencing test will detect all mutations within codons 12, 13, and 61 of the KRAS gene from formalin-fixed paraffin-embedded tissue blocks. Specimens should contain an adequate proportion of tumor (>40%) to ensure mutation detection.
HOW TO SEND A SPECIMEN

For assistance 24 hours per day, 7 days per week, call MLabs at 800-862-7284 or visit our website at www.mlabs.umich.edu.

Collection Instructions:

EGFR MUTATION: Send fresh, frozen, or formalin-fixed paraffin-embedded tissue containing greater than 5% tumor. Fresh tissue should be sent on a piece of gauze in saline, or in RPMI, within 24 hours of collection; refrigerate. Frozen tissue should be stored at -70 degrees C; do not allow to thaw at any time. Paraffin-embedded tissue should be stored at room temperature. Please provide an estimate of tumor percentage with paraffin-embedded tissue specimens.

ALK Rearrangement for NSCLC (FISH): Send formalin-fixed paraffin-embedded tissue.

KRAS MUTATION: Send fresh, frozen, or formalin-fixed paraffin-embedded tissue containing greater than 40% tumor. Fresh tissue should be sent on a piece of gauze in saline, or in RPMI, within 24 hours of collection; refrigerate. Frozen tissue should be stored at -80 degrees C; do not allow to thaw at any time. Paraffin-embedded tissue should be stored at room temperature. Please provide an estimate of tumor percentage with paraffin-embedded tissue specimens.

Specimens can be sent by express mail or courier service to:

University of Michigan Health System
Department of Pathology - Specimen Processing
UH 2F367
1500 E. Medical Center Drive
Ann Arbor, MI 48109-5054