Lung Cancer Panel (EGFR + ALK)

Test Code: 4825  
Department: Molecular Oncology

Test Synonyms:  
EGFR Gene Mutation (Exons 18, 19, 20 & 21) and FISH for ALK Gene Rearrangement

CPT Code(s):  
83890  
83892  
83898 x 4  
83903 x 2  
83904 x 2  
83907  
88368

Background:  
Activating mutations in EGFR are present in approximately 10-12% of non-small cell carcinomas of the lung (primarily adenocarcinomas). Based on a number of phase II and III trials, most EGFR mutations predict a good response to treatment with EGFR inhibitors such as gefitinib and erlotinib. The exceptions are insertion mutations in exon 20 and the T790M substitution, which correlate with resistance to these drugs.

Gene rearrangements involving the ALK gene are present in approximately 5% of non-small cell carcinomas of the lung (primarily adenocarcinomas). The most common of these is the EML4-ALK fusion, although other partner genes have been identified. Activation of ALK kinase through these gene fusions contributes to tumor cell growth and can be inhibited by ALK inhibitors such as crizotinib.

Methodology for EGFR screening:  
1. Microscopic examination of the specimen and macrodissection of tumor-rich areas.  
2. DNA extraction and purification.  
3. PCR amplification of EGFR coding exons 18, 19, 20 & 21.  
4. Screening for mutations by one of two methods.  
   a. Direct, bidirectional Sanger sequencing of each exon  
   b. Real-time PCR with high resolution melting curve analysis (HRM), to screen for deletions in exon 19 and insertions in exon 20. DNA sequencing is used to confirm any potential mutations identified by this approach.  
5. Estimated sensitivity: 20% mutant allele.  
6. Estimated specificity: 98% of EGFR mutations reported in non-small cell lung carcinoma.

Methodology for screening for ALK gene fusions:  
1. Fluorescence in-situ hybridization (FISH) is performed using an FDA-approved break-apart probe set for the ALK gene. This testing can be performed on sections of formalin-fixed, paraffin-embedded tissue.

Specimen Requirements:  
- A paraffin block or  
- 15 unstained sections of tumor (4-5 micron sections on positively-charged slides)
Lung Cancer Panel (EGFR + ALK)

A REQUISITION FORM MUST ACCOMPANY ALL SAMPLES. Please include detailed clinical information.

Test Performed (Days):
Mon - Fri

Turn Around Time:
7-10 days

Shipment Sensitivity Requirements:
Package and ship specimen to remain cold, but not frozen. Ship via overnight express, using the FedEx priority overnight label provided. Contact Client Services at (855) 535-1522 for shipping kits and instructions.

References: