

LAB ALERT

Date: September 9th, 2016

New Test Now Available: Lung Cancer Mutation Panel by Next Generation Sequencing

Dear Regional Pathology Services Clients,

We are very excited to be the only laboratory in Nebraska to start offering the new Lung Cancer Mutation Panel using Next Generation Sequencing (NGS). The assay uses multiplex DNA amplification for library preparation, emulsion PCR for clonal amplification and next generation sequencing to identify mutations. The limit of detection for this assay is approximately 5% mutant allele for single nucleotide variants and 10% for small insertions and deletions. NGS is used to identify novel and rare cancer mutations that aid physicians in providing targeted therapies.

This test analyzes hotspot regions in the following genes for somatic mutations (missense mutations and small insertions and deletions): *EGFR*, *BRAF*, *KRAS*, *NRAS*, *ERBB2 (Her2/neu)*, *ERBB4*, *PIK3CA*, *PTEN* and *AKT1*. Please contact the laboratory for specific exon and codon coverage. This test CANNOT identify *MET* exon 14 skipping mutations or *MET* or *ERBB2 (Her2/neu)* amplification. This current test does NOT identify gene fusions such as those involving *ALK* and *ROS1*, which can be identified by FISH analysis. If *ALK* and *ROS1* gene fusion detection is desired, please indicate this request in the comment section of the Lung Cancer Mutation Panel order on the requisition. A separate test for assessment of somatic mutations for the hotspot regions of the *EGFR* gene exclusively (EGFR Mutation test) is still available for ordering. **NOTE: This test is NOT designed for plasma or cell free DNA analysis.**

Test Name: Lung Cancer Mutation Panel

Test code: LCMP

CPT Code: 81445

Ideal Specimen requirements:

1) FFPE tissue block, or 5 Unstained slides- 10µm thick with ≥20% tumor (with one adjacent H&E).

Ideal Volume: 5mmX5mm area if tissue is 100% tumor; 10mm X 10mm if tissue is ≥20% tumor

2) Tissue, snap frozen, on dry ice (-80°C)

Unacceptable specimens: Paraffin blocks with ≤10% tumor. Tissue fixed in heavy metal fixative or decalcified tissue. Peripheral Blood and Plasma are unacceptable at this time.

Turnaround Time: Test performed M-F; turnaround time is 7-10 business days.

For questions or pricing please contact client services at 402-559-6420 or toll free at 1-800-334-0459 and ask to speak with one of our client coordinators.