



MEMO

To: All Regional Medical Laboratory (RML) Clients
From: Dr. Cindi Starkey, M.D., Ph.D., Chief of Molecular Diagnostics.
Sonja Matthews MT (ASCP), SC, Director of Clinical Operations

Date: September 24, 2012

Subject: **KRAS Mutations Testing by Molecular Method**

RML is pleased to announce we are now offering KRAS mutation testing by PCR in house. We will be utilizing Qiagen's FDA approved *therascreen* KRAS RGQ PCR test. This is the only FDA-approved test for KRAS mutation analysis as a companion diagnostic test for the use of Erbitux (cetuximab) in the treatment of metastatic colorectal adenocarcinoma. Activating mutations in KRAS are a strong predictor for resistance to anti-EGFR therapy in metastatic colorectal carcinoma as well as non small cell adenocarcinomas of lung.

This is a qualitative, in vitro, diagnostic molecular test that detects 7 common somatic mutations of the KRAS gene involving exons 12 and 13. This assay utilizes ARMS (amplification refractory mutation system) and Scorpions technology to detect these mutations, which requires much less tumor than previous methodologies. Specifically, the *therascreen* KRAS test can detect as little as 2.5% tumor cells or 0.8 – 6.4% mutant DNA in a background of wild-type DNA. Additionally, turn around time will be improved by performing this assay in house.

The specimen requirements are formalin fixed, paraffin embedded tissue samples. Other fixatives and decalcification agents will be unacceptable. This may be performed on archived tissue previously collected in our laboratory, or on tissue blocks sent in from outside laboratories. This may also be automatically ordered for any new diagnosis of metastatic colorectal adenocarcinoma or lung adenocarcinoma for patients of your practice if desired by calling Client Services at 918-744-2150.

Test Name: **KRAS MUTATION ANALYSIS**

Order Mnemonic: **KRAS MUTAT**

Test number: **9100040**

Methodology: Real time PCR (RT-PCR)

Reference Range: Negative for mutation

Specimen Required: Formalin fixed, paraffin embedded sample (FFPE)

CPT code: 83891, 83892, 88381, 83907, 83912, 83896(x8), 83898 (x8), 83914 (x7)

If you have questions, please contact Dr. Cindi Starkey, M.D., Ph.D. Chief of Molecular Diagnostics or Sonja Matthews, MT (ASCP), SC, Director of Clinical Operations at 918-744-2553 or 800-722-8077.