

## Memorandum

**TO:** All Regional Medical Laboratory (RML) clients

**FROM:** Dr. Cindi Starkey, M.D., Ph.D., Chief of Molecular Pathology  
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**DATE:** January 10, 2014

**SUBJECT:** EGFR Mutations testing by Molecular Method

RML is pleased to announce we are now offering EGFR mutation testing by PCR in house. We will be utilizing Qiagen's FDA approved *therascreen*<sup>®</sup> EGFR RGQ PCR test. This is a qualitative, in vitro diagnostic molecular test that detects common somatic mutations, deletions and insertions of the EGFR gene involving exons 18, 19, 20, and 21. This assay utilizes ARMS (amplification refractory mutation system) and Scorpions technology to detect these mutations, which requires much less tumor than previous methodologies, detecting as little as 2.5% tumor cell DNA in a background of wild-type DNA. Additionally, turn around time will be improved by performing this assay in house.

Recent consensus recommendations by the College of American Pathologists (CAP), International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP) are that EGFR mutation analysis should be performed for all lung carcinomas with any component of adenocarcinoma. Based upon these recommendations, the National Comprehensive Cancer Network (NCCN) also recommends EGFR testing for all patients with lung adenocarcinoma. It is not indicated for pure squamous cell carcinoma of the lung. Activating mutations of EGFR are a strong predictor for response to anti-EGFR therapy in adenocarcinomas of lung. Pretreatment T790M mutations and most exon 20 insertions are associated with lack of or reduced response to first-generation EGFR TKIs.

Insurance pre-authorization may be required for this test. RML will fax the pre-authorization form to you if needed. This form should be returned to RML by FAX at 918-744-3327.

The specimen requirements are formalin fixed, paraffin embedded tissue samples. Other fixatives and decalcification agents will be unacceptable. This testing may be performed on archived tissue previously collected in our laboratory, or on tissue blocks sent in from outside laboratories.

Test Name: EGFR MUTATION ANALYSIS  
Order Mnemonic: EGFR MUTAT  
Test number: 9103095  
Methodology: real time PCR (RT-PCR)  
Reference Range: Negative for mutation  
Specimen Required: formalin fixed, paraffin embedded sample (FFPE)  
CPT code: 88381, 81235, G0452-26

If you have questions, please contact Dr. Cindi Starkey, M.D., Ph.D., Chief of Molecular Pathology, Sonja Matthews, MT (ASCP), SC, Director of Clinical Operations or Patty Loykasek, HTL (ASCP), QIHC, BS, Molecular Test Development Specialist at 918-744-2553 or 800-722-8077.