

LAB ALERT – NEW TEST**NOTIFICATION DATE: 1/7/2014**
EFFECTIVE DATE: 1/21/2014**KRAS MUTATION BY PCR: *THERASCREEN*® FDA-APPROVED ASSAY FOR ROTOR-GENE****NEW TEST CODE:** MDFCPKRASPT**INTERFACE CODE:** 1004021**OLD TEST/INTERFACE
CODES TO BE
DEACTIVATED:** MDFCPKRASPNB/1001054**METHODOLOGY:** Real-time qualitative PCR

CLINICAL UTILITY: The *therascreen*® KRAS RGQ PCR Kit is an FDA-approved, qualitative real-time PCR assay intended to aid in the identification of colorectal cancer patients for treatment with Erbitux® (cetuximab) based on a KRAS no mutation detected test result. Mutations in the KRAS oncogene are frequently found in human cancers. The presence of these mutations correlates with a lack of response to certain EGFR inhibitor cancer therapies in patients with metastatic colorectal cancer. The *therascreen*® KRAS RGQ PCR Kit enables the detection of seven mutations in codons 12 and 13 of the KRAS oncogene against a background of wild-type genomic DNA. Based on data in the COSMIC database (2012 v59), the seven mutations detected by the KRAS Kit account for >97% of all reported KRAS mutations in CRC patients.

NOTES: This test is performed using the *therascreen*® KRAS RGQ PCR Kit, which has been approved by the U.S. Food and Drug Administration (FDA) for in vitro diagnostic use.

PERFORMED: Wednesday**COLLECTION:** Tissue (see specimen preparation)

SPECIMEN PREPARATION:	Paraffin embedded Tissue accompanied by a circled H & E slide indicating the area to be examined: submit in sterile biohazard plastic bag. Slides: submit in slide holder. Do not submit decalcified tissue specimen.
STABILITY (FROM COLLECTION TO INITIATION OF TESTING):	Ambient: Indefinitely; Refrigerated: Indefinitely; Frozen: Unacceptable
TRANSPORT:	Ambient or on ice pack in summer; Slides: Ambient
REFERENCE RANGE:	An interpretive report will be provided.
RESULTS REPORTED:	2-9 days
CPT CODE(S):	81275
PERFORMING LAB:	med fusion
ORDER/CONTACT INFORMATION:	med fusion Client Services: 972-966-7300/Fax: 927-966-7231 Thomas P. Lohmann, MD: 972-966-7135



Thomas P. Lohmann, MD
Chief Medical Officer