

## **KRAS Mutation**

For in vitro diagnostic use

### **CERNER ORDERABLE**

Order through CoPath, please call 317.491.6417

### **CPT CODE**

81275

### **CLINICAL UTILITY**

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. Such mutations in the KRAS oncogene are present in around 40% of cases. Using Scorpions® and ARMS® (Allele Refractory Mutation System) technologies, 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. The *therascreen* KRAS RGQ PCR Kit is intended to aid in the identification of colorectal cancer patients for treatment with Erbitux® (cetuximab) based on a KRAS no mutation detected test result<sup>1</sup>.

### **METHODOLOGY**

Real Time PCR utilizing Scorpions® and ARMS® (Allele Refractory Mutation System) technologies

### **SPECIMENS**

Preferable primary tumor.

- FFPE tissue (Formalin fixative only)  
For tissue resection: 1 H&E and 8 unstained slides  
For a biopsy: 1 section on 1 slide for H&E plus 6 unstained slides with  
3 sections per slide
- FNA and cyst fluids

### **SPECIMEN STABILITY and SHIPPING**

- Transport/Storage of slides at room temperature.
- FNA and cyst fluids refrigerated between 2-8° C. If greater than 48 hours must be frozen at minus 80°C.

### **CAUSES FOR REJECTION**

Excess necrosis for slides. FNA and cyst fluids not refrigerated or too old.

### **ASSAY RANGE**

- KRAS mutation not detected.
- KRAS mutation detected. Results will specify which KRAS mutation was found. Treatment with EGFR inhibitors is not recommended based on ASCO PCO.

### **TURNAROUND TIME**

7-10 days

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.