

## **KRAS Mutation Testing**

**Test Code:** KRAS

**Use:** KRAS PCR assay is used for the detection of seven somatic mutations in codons 12 and 13 of the KRAS oncogene, using DNA extracted from colorectal cancer or lung cancer formalin fixed paraffin embedded tissue and cell blocks. This test is intended to aid in the identification of EGFR- inhibitors.

**Clinical Significance:** 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 cancer therapies in patients with metastatic colon cancer. Such mutations in the KRAS oncogene are present in around 40% of cases. KRAS mutation testing may be useful in the algorithm of lung cancer molecular testing because EGFR mutations only rarely exist with KRAS mutations.

Results of the test must be considered in correlation with clinical information and other pathologic data. Results of this test alone should not be used to diagnosis malignancy. The test is not designed for minimal residual disease detection.

**Methodology:** Tissue sections are reviewed and assessed for tumor viability and cellularity. Following micro-dissection of tumor tissue, DNA is extracted for testing. Allele specific real time PCR is then used to test for seven mutation specific reactions in codons 12 and 13 of exon 2 of the KRAS oncogene and a wild-type control in exon 4. Acceptable results from positive and negative controls are necessary for interpretation.

**Reference Range:** No mutation detected

**Reportable Range:** Positive or No mutation detected

**Assay Availability:** Batched weekly

**Results Reported:** 7 days

**Specimen:** Formalin fixed paraffin embedded tissue sections representing tumor OR cytology cell block sections representing tumor.

**Volume:** One H&E slide and at least 5 unstained slides.

**Storage:** Tissue blocks can be stored at room temperature.

**Causes for Rejection:** Insufficient tumor cellularity (<10%); decalcified specimens; specimens treated with Bouin's, B5, or other fixatives.

**Laboratory Contact:** For further information, please call the Molecular Diagnostics

Laboratory at (501) 526-6439.