

### Test Description

KRAS mutation test is an in vitro diagnostic test for the qualitative detection of mutations in codons 12, 13, 59, 61, 117 and 146 of KRAS oncogene.

### Patient Demographic

**Name:** Naresh Malhotra  
**Sex:** Male  
**Date of Birth/Age:** 61 Years  
**Disease:** Colorectal liver metastasis

### Clinician

**Clinician Name:** Dr Bhuvan Chugh  
**Medical Facility:** Medanta Hospital  
**Pathologist:** Not Provided

### Specimen

**Site:** Gall Bladder  
**Sample Type:** FFPE block B 11630/19  
**Date of Collection:** 05-03-2020  
**Date of Booking:** 05-03-2020

# KRAS Mutation Analysis

## Result

## No Mutation Detected in KRAS

### GENOMIC FINDINGS

No Mutation detected in KRAS codon 12, 13, 59, 61, 117 and 146.

### INTERPRETATION

#### No Mutation detected

Current data suggest that the efficacy of EGFR-targeted therapies in colorectal cancer is limited to patients with tumors lacking KRAS mutations.

### METHODOLOGY

The KRAS Mutation test, performed on the Biocartis Idylla™ system, is an *in vitro* diagnostic test for the qualitative detection of 21 mutations (G12D, G12A, G12C, G12V, G12S, G12R, G13D, A59T/E/G, Q61H/Q61H, Q61K/Q61K, Q61R/L, K117N/K117N and A146P/T/V) in codons 12, 13, 59, 61, 117 and 146 of the KRAS gene. Formalin-fixed paraffin-embedded (FFPE) human cancer tissue is lysed liberate DNA for subsequent real-time PCR amplification using allele specific primers. Amplification of a KRAS sequence in intron4/exon5, serving as a sample processing control, is included in each run. The presence of a mutant genotype is determined by calculating the difference between the KRAS Sample Processing Control Cq and the Cq obtained for the KRAS mutant signal(s). The analytic sensitivity of this assay has been determined at < or = 5%

### REFERENCES

1. Maertens G. et al. A solution for same-day extended RAS testing. Poster ESMO 2015
2. Vandenbroucke I. et al. A rapid and fully automated multiplex assay for KRAS-BRAF mutations with high mutation sensitivity using novel selective amplification and detection technologies. Poster AACR 2014
3. Solassol J. et al. Multi-Center Evaluation of the Fully Automated PCR-Based Idylla™ KRAS Mutation Assay for Rapid KRAS Mutation Status Determination on Formalin-Fixed Paraffin-Embedded Tissue of Human Colorectal Cancer. PLOS ONE 2016
4. Weyn C. et al. Clinical performance evaluation of a sensitive, rapid low-throughput test for KRAS mutation analysis using formalin-fixed, paraffin-embedded tissue samples. BMC Cancer 2017
5. Dario de Biase. et al. Fully automated PCR detection of KRAS mutations on pancreatic endoscopic ultrasound fine-needle aspirates. J Clin Path 2016.



March 07, 2020

Dr Gulshan Yadav, MD, Consultant Pathology

Date