

### 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:** Mufeed Abdulmajeed  
**Sex:** Male  
**Date of Birth/Age:** 63 Years  
**Disease:** Metastatic Adenocarcinoma Colon

### Clinician

**Clinician Name:** Dr Randeep Singh  
**Medical Facility:** Artemis Hospital  
**Pathologist:** Not Provided

### Specimen

**Site:** Rectosigmoid  
**Sample Type:** FFPE block S 1903/19(2)  
**Date of Collection:** 09-04-2019  
**Date of Booking:** 09-04-2019

# KRAS Mutation Analysis

## Result

## Mutation Detected in *KRAS* codon 12

### GENOMIC FINDINGS

Mutation: G12D  
Protein: p.Gly12Asp  
Nucleotide Change: c.35G>A

### INTERPRETATION

#### Mutation detected in *KRAS* codon 12

Current data suggest that the efficacy of EGFR-targeted therapies in colorectal cancer is limited to patients with tumors lacking *KRAS* mutations. Thus, the detection of a *KRAS* mutation within this tumor specimen suggests that such therapies may have limited therapeutic value for this patient.

### 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.



April 11, 2019

Dr Gulshan Yadav, MD, Consultant Pathology

Date