

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: Ishwar Chand Gurg
Sex: Male
Date of Birth/Age: 61 Years
Disease: Moderately Differentiated Rectal Lesion

Clinician

Clinician Name: Dr Archit Pandit
Medical Facility: Max Hospital
Pathologist: Not Provided

Specimen

Site: Rectal lesion
Sample Type: FFPE block H 5201/19 B
Date of Collection: 27-08-2019
Date of Booking: 27-08-2019

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.



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Date