

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: Dinesh Singh Yadav
Sex: Male
Date of Birth/Age: 51 Years
Disease: Colorectal cancer

Clinician

Clinician Name: Dr Sandeep Batra
Medical Facility: Max Hospital
Pathologist: Not Provided

Specimen

Site: Rectal Sigmoid Growth
Sample Type: FFPE block B 5852/19
Date of Collection: 11-05-2019
Date of Booking: 11-05-2019

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**

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. Vandembroucke 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.



May 11, 2019

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Date