PATIENT	REPORT DATE	BOOKING ID
Praveen Rohatgi	18 March 2020	012003170334

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.

Clinician

Clinician Name: Dr Amit Verma
Medical Facility: Max Hospital
Pathologist: Not provided

Patient Demographic

Name: Praveen Rohatgi
Sex: Male
Date of Birth/Age: 60 Years
Disease: Metastatic Well Differentiated Adenocarcinoma rectum

Specimen

Site: Rectal Biopsy
Sample Type: FFPE block TB 8189
Date of Collection: 16-03-2020
Date of Booking: 17-03-2020

KRAS Mutation Analysis

Result Mutation Detected in *KRAS* codon 12

GENOMIC FINDINGS

Mutation: G12V
Protein: p.Gly12Val
Nucleotide Change: c.35G>T

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. 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 18, 2020

Dr Gulshan Yadav, MD, Consultant Pathology — Date