

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: Girish Dev Singh

Sex: Male

Date of Birth/Age: 72 Years

Disease: Well differentiated squamous cell carcinoma of Lip

PATIENT Girish Singh REPORT DATE 22 February 2020 BOOKING ID 012002210034

Clinician

Clinician Name: Not Provided Medical Facility: Dr Lal Pathlabs Pathologist: Dr Atul Thatai

Specimen

Site: Wide local excision right lower lip Sample Type: FFPE block 276074492 Date of Collection: 21-02-2020 Date of Booking: 21-02-2020

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^M 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

- $1. \ Maertens \ G. \ et \ al. \ A \ solution \ for \ same-day \ extended \ RAS \ testing. \ Poster \ ESMO \ 2015$
- 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