REKHA RANI PID NO: P54180202584 Age: 74 Year(s) Sex: Female	**Reference:** Sample Collected At: DR VINAY KUMAR CHOPRA KOS Diagnostic Lab, 6349/I, Nicholson Road, Ambala Cantt, HRY 133001. **133001**	**VID: 54183197876** Registered On: 17/10/2018 12:33 PM Collected On: 18/10/2018 7:20AM Reported On: 26/10/2018 07:10 PM

Test Name : **KRAS-12/13 Mutation Analysis**

Specimen : Paraffin Block (1818759/A1),
Transverse colectomy,
Moderately differentiated adenocarcinoma

Results

KRAS Codon 12 Mutation	**Not Detected**
KRAS Codon 13 Mutation	**Not detected**

Method : PCR-SNPE

- The assay detects six mutations in codon 12 (gly12ala, gly12asp, gly12arg, gly12cys, gly12ser, and gly12val) and one in codon 13 (gly13asp).
- The assay is performed on tumor rich region of the FFPE tissue with > 40%-50% cancer cells.
- The overall sensitivity of the assay is 20%, i.e. it detects 20% of mutant sequence in the background of wild-type sequence.

Interpretation

- A “Not Detected” report indicates absence of *KRAS* codon 12 and 13 mutation.
- A “Detected” report indicates presence of *KRAS* codon 12 and 13 mutation and the patient is unlikely to benefit from anti-EGFR therapy.

Fragmentation of DNA due to formalin fixation of tissue may lead to amplification failure and invalid results.

Clinical Significance and Utility:

- KRAS mutation analysis is proven to predict an individual’s response to monoclonal antibodies cetuximab and panitumumab for treating metastatic colorectal cancer.
- Current therapies targeting EGFR are used to treat colorectal cancer (CRC) and non-small-cell lung cancer (NSCLC) and employ either monoclonal antibodies (eg, cetuximab and panitumumab) that prevent ligand binding or EGFR activation or tyrosine kinase inhibitors (eg, erlotinib) that prevent activation of the signaling pathways.
- Tumors with activating somatic mutations of *KRAS* are present in approximately 20-30% of human malignancies, including 30-50% of colorectal cancers and 30% of adenocarcinomas of the lung.
- Besides Kras, mutations in BRAF, NRAS and PIK3CA have also been associated with resistance to anti-EGFR therapy.

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- The National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO) recommends the determination of *KRAS* mutation status in all patients with metastatic colorectal cancer who are candidates for anti-EGFR therapy. When *KRAS* is mutation-negative, the NCCN suggests considering *BRAF* mutation testing.

Note:

This test has been developed and its performance is validated at Metropolis Healthcare Ltd.

Limitation of the Assay:

Presence of PCR inhibitors in the sample may prevent DNA amplification. Paradoxical results may arise due selection of inappropriate specimens and contamination during specimen collection.

References:

- Wolf et al. 2010, J Clin Pathol; 64: 30-36
- Chang et al. 2010, Clinical Biochemistry, 43, 296–301
- Gao et al., 2010, World J Gastroenterol, 16(38): 4858-4864

-- End of Report --

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