PATIENT	REPORT DATE	BOOKING ID
Mohammad Masud	24 January 2020	012001230248

Test Description

EGFR mutation test is an *in vitro* diagnostic test for the qualitative detection of mutations in exons 18, 20, 21; deletions in exon 19 and insertions in exon 20 of *EGFR* oncogene.

Clinician

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

Patient Demographic

Name: Mohammad Masud
Sex: Male
Date of Birth/Age: 50 Years
Disease: Non Small Cell Lung Carcinoma

Specimen

Site: Lung mass (Right lower lobe)
Sample Type: FFPE block S19- 3148
Date of Collection: 23-01-2020
Date of Booking: 23-01-2020

EGFR Mutation Analysis

Result

Deletion in Exon 19

GENOMIC FINDINGS

Deletion in Exon 19

INTERPRETATION

Mutation in exon 19 of *EGFR* gene is detected.

For valid batch test results specific controls are being run with every batch.

METHODOLOGY

The Biocartis Idylla™ EGFR Mutation Test is an *in vitro* diagnostic test intended for the qualitative detection of 51 alterations in exon 18 (G719A/C/S), exon 21 (L858R, L861Q), exon 20 (T790M, S768I) mutations, exon 19 deletions and exon 20 insertions in the *EGFR* oncogene. The Test uses formalin-fixed, paraffin-embedded (FFPE) tissue sections from human non-small cell lung cancer (NSCLC) tissue. A conserved fragment in the transmembrane region of the *EGFR* gene is amplified simultaneously. This PCR reaction, EGFR total, serves as a sample processing control (SPC) that checks for adequate execution of the complete process from sample to result, and is present in each of the five multiplexes. In addition, the EGFR control reaction is a measure for the amount of amplifiable DNA in the sample and is used in the analysis of the mutation status of the sample. This test is carried out on Idylla platform using the EGFR/1.0 Cartridge based kit which is CE IVD approved.

The Idylla™ EGFR Mutation Test is able to detect allelic frequencies at: ≤ 5% for mutations in exons 19, 20 and 21 of the *EGFR* oncogene; and ≤ 10% for mutations in exon 18 of the *EGFR* oncogene

REFERENCES

1. Montpreville et al. Path Res &Prac (2017) 213:793-98
2. Lambros et al. J clin Path (2017) 0:1-6

January 24, 2020

Dr Gulshan Yadav, MD, Consultant Pathology — Date