PATIENT	REPORT DATE	BOOKING ID
Abdul Rahman Afghan	09 June 2019	011906080128

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

Patient Demographic

Name: Abdul Rahman Afghan
Sex: Male
Date of Birth/Age: 58 Years
Disease: Metastatic NSCLC - Adenocarcinoma

Specimen

Site: Left lung mark biopsy
Sample Type: FFPE block SC-1756/19
Date of Collection: 08-06-2019
Date of Booking: 08-06-2019

EGFR Mutation Analysis

Result

No mutation detected

GENOMIC FINDINGS

No mutation detected

INTERPRETATION

No mutation in exon 18, 19, 20 and 21 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

June 09, 2019

Dr Gulshan Yadav, MD, Consultant Pathology — Date