

CR Name	:		Age/Sex	:	__ YRS/ __
Referred By	:				
Sample On	:	__-__-__	Report On	:	__-__-__

Name of Test: EGFR L858R, E746_A750del & T790M Mutation in **Circulating Cell-free DNA**.

Test Method: Digital droplet polymerase chain reaction

Specimen : 12 ml Peripheral Blood in EDTA

EGFR GENE	Mutation Status	% cfDNA
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L858R

E746_A750del

T790M

Interpretation : A liquid biopsy is a liquid biomarker that can be isolated from body fluids, such as blood, saliva, urine, ascitic fluid or pleural fluid. The armamentarium of liquid biopsy practically comprises of Circulating tumour cells (CTC) and Circulating tumour DNA (ctDNA).

Cell-free or circulating tumour DNA (ctDNA) is tumour DNA circulating freely in the blood of a cancer patient. Analysis of the fraction of mutant-alleles from ctDNA compared to normal-alleles from the patients normal genome provides opportunities for minimally-invasive cancer diagnosis, prognosis and tumour monitoring.

Cell Free DNA has an added advantage in Lung Cancer patients.

- It can be used to look for resistance mutation T790M in EGFR positive patients (found in 60% of tyrosine kinase inhibitor resistance).
 - It is non invasive. Usually blood sample is employed. Other body fluids can also be used.
 - It addresses the heterogeneity in tumor. Biopsy is usually taken from a small area which may not represent the entire spectrum of mutations.
 - The mutations present can be quantified and thus response to treatment and tumor load can be measured by serial values. It can be used to look for minimal residual disease.
 - Can be used as a substitute for primary biopsy in sick patients.
- This liquid biopsy test is done detects employing highly sensitive Digital PCR.

Limitations:

- Limit of detection – based upon amplifiable DNA, the limit of detection ranges from 0.5% to <0.01% mutant allele.
- Optimal clinical testing intervals are unknown.
- Mutations other than EGFR L858R, E746_A750 del and T790M are not detected.
- Presence or absence of EGFR T790M does not guarantee a response to EGFR T790M-specific drug therapy

Approved By

Dr. Moushumi Suryavanshi
Head Molecular Diagnostic and Cell Biology
RGCI & RC

Please correlate the test results with clinical history of the patient. Test results are dependent on the quality of the sample received by the Laboratory. Test results are not valid for Medico legal purposes.