MAYO CLINIC LABORATORIES

1-800-533-1710

T790M

Cell-Free DNA EGFR T790M Mutation Analysis, Blood

Patient ID	Patient Name		Birth Date	Gender	Age
SA00100843	TESTINGRNV, ATLAS		1994-06-13	F	23
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00100843	SA00100843	CLIENT, CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		21 Nov 2017 12:00			

cfDNA EGFR T790M Test, Blood

Result Summary

MCR

NEGATIVE

Result

MCR

Negative

Interpretation

[1] MCR

A negative result with this test does not rule out the presence of the T790M EGFR mutation in the patient's tumor. Analysis of the patient's tumor tissue for a EGFR mutation is recommended if the result is needed for clinical decision-making.

ADDITIONAL INFORMATION

Cell-free DNA was isolated from the plasma and evaluated for the presence of the EGFR T790M mutation using digital droplet PCR analysis. Mutation nomenclature is based on GeneBank accession number NM_005228. The limit of detection of this assay for the detection of the EGFR T790M mutation is influenced by the amount of cfDNA in the blood. The limit of detection for this assay is 15 EGFR T790M copies per mL plasma.

This assay was designed to detect the EGFR T790M specifically. No additional EGFR mutations would be detected by this assay.

This test has been evaluated by our laboratory as an alternative to assessing paraffin embedded tumor specimens for the EGFR T790M mutation in patients with advanced lung cancer.

This test cannot differentiate between somatic and germline alterations. Additional testing may be necessary to clarify the significance of results if there is a potential hereditary risk.

Patients with a negative test result may still harbor the EGFR T790M mutation and testing of a tissue specimen for EGFR mutations is recommended.

This test has not been clinically validated for use as a tool to monitor response to therapy or for early detection of tumors.

Specimen

MCR

WB Whole Blood

Released By

MCR

Benjamin R. Kipp, Ph.D.

Received: 22 Nov 2017 15:26 **Reported:** 13 Dec 2017 13:53

Laboratory Notes

[1] This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292