MAYO CLINIC LABORATORIES

1-800-533-1710

# T790M

Cell-Free DNA EGFR T790M Mutation Analysis, Blood

| Patient ID | Patient Name | | Birth Date | Gender | Age |
|---|---|---|---|---|---|
| SA00100845 | TESTINGRNV, ATLAS | | 1999-05-09 | F | 18 |
| **Order Number** | **Client Order Number** | **Ordering Physician** | **Report Notes** | | |
| SA00100845 | SA00100845 | CLIENT, CLIENT | | | |
| **Account Information** | | **Collected** | | | |
| C7028846 DLMP Rochester | | 21 Nov 2017 12:00 | | | |

## cfDNA EGFR T790M Test, Blood

### Result Summary

MCR

POSITIVE

### Result

MCR

EGFR status: Mutant (T790M)

### Interpretation

[1] MCR

EGFR mutations, primarily those occurring in the kinase domain (exons 18–21), result in constitutive activation of the RAS/MAPK signaling pathway.

Current data suggests that the efficacy of EGFR-targeted therapies in patients with non-small cell lung cancer is limited to tumors with activating mutations in the EGFR gene (1,2). The EGFR T790M mutation identified in this patient is associated with acquired resistance to tyrosine kinase inhibitor (TKI) therapy in about 60% of patients with disease progression after initial response to erlotinib, gefitinib or afatinib. Recent data suggest that patients with metastatic NSCLC and the T790M mutation may benefit from Tagrisso (osimertinib), an FDA approved oral TKI that inhibits both EGFR activating mutations and the T790M mutation (3). Thus, the detection of the T790M mutation within this specimen suggests that this patient may benefit from treatment with Tagrisso (osimertinib).

### REFERENCES

1. Int J Cancer 2011;131(5):E822–829 (PMID 22161771)
2. Nat Rev Clin Oncol. 2011 Aug 23;8(11):661–8 (PMID 21862980)
3. N Engl J Med. 2015 Apr 30;372(18):1689–99 (PMID 25923549)

### 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 15:27 **Reported:** 13 Dec 2017 13:55



### 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 |