MAYO CLINIC LABORATORIES

1-800-533-1710

MCLBP

MayoComplete Liquid Biopsy Panel, Next-Generation Sequencing, Cell-Free DNA

Patient ID	Patient Name		Birth Date	Sex	Age
SA00154862	TESTING, MCLBP NORMAL		1990-10-18	F	32
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00154862	SA00154862	CLIENT,CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		18 Oct 2022 07:00			

MayoComplete Liquid Biopsy Panel

Result

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Reason for Referral: lung cancer

MSI-H status: Not detected

No reportable alterations, gene amplifications or fusions (translocations) were identified within the analyzed regions of the tested genes listed in the method description.

Interpretation

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No evidence of microsatellite instability was detected. Additional testing on a tumor (tissue) sample is recommended.

The absence of detectable alterations, gene fusions (translocations), or gene amplification in the blood of this patient does not rule out these being present in the patient's tumor. Additional testing on a tumor (tissue) sample is recommended.

Additional Information

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Percent (%) of exons with sufficient coverage: 98.96

Specimen

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WB Whole Blood

Method

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Blood samples are collected in Streck Cell-Free DNA BCT tubes and cell-free DNA (cfDNA) is then isolated from double spun plasma. Next generation sequencing is performed on the cfDNA using the PGDx Elio Plasma Resolve chemistry. The following variant types and molecular profiles were evaluated: microsatellite high instability (MSI-H) status, sequence variants in 33 genes (AKT1, ALK, APC, ARID1A, ATM, BRAF, BRCA1, BRCA2, BRIP1, CCND1, CD274, CDH1, CSF1R, EGFR, ERBB2, EZH2, FGFR1, FGFR2, HRAS, KIT, KRAS, MET, MYC, NRAS, NTRK1, PDGFRA, PIK3CA, POLD1, POLE, RAF1, RET, ROS1, TP53), gene amplification in 8 genes (CCND1, CD274, EGFR, ERBB2, FGFR2, KIT, MET, MYC), and fusions (translocations) involving 5 genes (ALK, FGFR2, NTRK1, RET, ROS1).

Variant nomenclature is based on build GRCh37 (hg19). For details about gene transcripts (GenBank accession numbers), targeted gene coverage and additional information on this test, see www.mayocliniclabs.com
(Test ID MCLBP)

Disclaimer

1 MCR

CLINICAL CORRELATIONS

Test results should be interpreted in the context of clinical, tumor sampling, histopathological, and other laboratory data. If results obtained do not match other clinical or laboratory findings, contact the laboratory for discussion. Misinterpretation of results may occur if the information provided is inaccurate and/or incomplete.

Patients with a negative test result may still harbor a genomic alteration. Testing of a tissue specimen for mutations should be considered for patients with who have a negative result with this test.

Variant allele frequency (VAF) is the percentage of sequencing reads supporting a specific variant divided by the total sequencing reads at that position. In somatic testing, VAF should be interpreted in the context of several factors including, but not limited to: tumor heterogeneity/copy number status (ploidy, gains/losses, loss of heterozygosity) and sequencing artifact/misalignment [PMID: 27144058, PMID: 29769535].

The limit of detection (LOD) for single nucleotide variants (SNVs) is 0.5% for hotspot mutations, 1% for other SNVs; 2.5% for deletion-insertions (delin), and 2 supporting reads for fusions. LOD for amplification is between 1.2–1.6 fold changes (2.4–3.2 copies) depending on specific genes and presence of sufficient SNPs for allelic imbalance assessment. LOD for microsatellite instability (MSI) is 2% tumor DNA. MSI status is classified as MSI-H detected (≥2 sites unstable), and MSI-H not detected (<2 sites unstable).

This test can be used to report gene amplifications but does not

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

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detect deletions or duplications.

The limit of detection of this assay for the detection mutations is influenced by the amount of cell-free DNA (cfDNA) in the blood. This is a biological variable that cannot be controlled.

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

This test does not differentiate between tumor somatic alterations and CHIP (Clonal Hematopoiesis of Indeterminate Potential) mutations. Additional testing may be necessary to clarify the origin of mutations detected.

Rare polymorphisms may be present that could lead to false negative or false positive results.

The presence or absence of a variant or rearrangement may not be predictive of response to therapy in all patients.

Released By MCR

Gang Zheng, M.D., Ph.D.

Received: 18 Oct 2022 08:11 **Reported:** 20 Oct 2022 13:43

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.

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