MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: November 4, 2022
Effective Date: November 4, 2022

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

Test ID: MCLBP

Useful for:

- As an alternative to invasive tissue biopsies to assist in tumor profiling for diagnosis, predicting prognosis, and identifying targeted therapies for the treatment and management of patients with solid tumors
- As an alternative to invasive tissue biopsies for assessment of microsatellite instability status

Genetics Information:

- This test uses targeted next-generation sequencing to determine microsatellite instability status and identify sequence variants, gene amplifications, and fusions translocation using circulating free DNA (cfDNA) in plasma. This test detects sequence variants in 33 genes, amplifications in 8 genes, and translocations in 5 genes.
- For more information see Targeted Genes Interrogated by MayoComplete Liquid Biopsy Panel for details regarding gene interrogated by this test.
- **Note:** This test is performed to evaluate for somatic (ie, tumor-specific) alterations within the genes listed. Although germline (ie, inherited) alterations may be detected, this test cannot distinguish between germline and somatic alterations with absolute certainty. Follow-up germline testing using whole blood can be performed for confirmation of suspected clinically relevant germline alterations. Germline testing should be performed along with genetic counselling.

Highlights:

In addition to single nucleotide variants and small insertions/deletions sequence variants, this test also identifies gene amplifications and fusions. Microsatellite instability status is also determined as a part of this test and often clinically actionable for determining the efficacy of immunotherapy in solid tumors.

Methods:

Sequence Capture and Targeted Next-Generation Sequencing (NGS)

Reference Values:

An interpretive report will be provided.

Specimen Requirements:

Supplies:	**Streck Black/Tan Top Tube Kit (T715)**
Container/Tube:	Streck Cell-Free DNA (cfDNA) blood collection kit
Specimen Volume:	Two 10-mL Streck Cell-Free DNA blood collection tubes
Additional Information:	Only blood collected in Streck Cell-Free DNA BCT tubes will be accepted for analysis. Whole blood will be processed to produce platelet-poor plasma before cfDNA isolation.
Specimen Minimum Volume:	One 10-mL Streck tube

Shipping Information:

1. Specimens should be transported at ambient or refrigerated (4 degrees C) temperature.
2. Specimens are viable for 7 days when collected using the Streck Black/Tan Top Tube Kit.

Necessary Information:

Paperwork (pathology report, oncology request form, or similar document) that indicates the cancer diagnosis must be provided. Testing may proceed without this information; however, it aids in providing a more thorough and accurate interpretation of results. Ordering providers are strongly encouraged to provide the information and send with the specimen.

Specimen Stability Information:

Specimen Type	Temperature	Time	Special Container
Whole Blood	Ambient (preferred)	7 days	Streck Black/Tan top
	Refrigerated	7 days	Streck Black/Tan top

Ordering Guidance:

This test is **not** a prenatal screening test. For prenatal screening, consider QUAD1 / Quad Screen (Second Trimester) Maternal, Serum.

Cautions:

- 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 by calling 800-533-1710. Misinterpretation of results may occur if the information provided is inaccurate 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 who have a negative result with this test.
- This test can be used to report gene amplifications but does not detect deletions.
- This assay's limit of detection for detected 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 alterations (ie, 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.

NY State Information:

NY State Available: No

CPT Code:

81445

Day(s) Performed: Monday through Friday

Report Available: 7 to 10 days

Questions

Contact Michelle Raths, Laboratory Resource Coordinator at 800-533-1710.