MAYO CLINIC LABORATORIES

FILE DEFINITION TEST CHANGE

Notification Date: March 1, 2023 Effective Date: March 30, 2023

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

Test ID: MCLBP

Explanation:

On the effective date, MCLBP will have a Reporting Name update to Result Code MG143. In addition, Genetics Information will be updated, as shown below.

Current Result Codes	
Result ID	Reporting Name
614940	Result Summary
614465	Result
614466	Interpretation
614467	Additional Information
614468	Specimen
614469	Source
614470	Method
614471	Disclaimer
614472	Released By
MG143	MCLBP Reason for Referral

New Result Codes	
Result ID	Reporting Name
614940	Result Summary
614465	Result
614466	Interpretation
614467	Additional Information
614468	Specimen
614469	Source
614470	Method
614471	Disclaimer
614472	Released By
MG143	Reason for Referral – Cancer Type

Current 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.

New 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.

See <u>Targeted Genes Interrogated by</u>
<u>MayoComplete Liquid Biopsy Panel</u> for details regarding genes 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 counseling.

- Genes tested for single-nucleotide variants and deletions-insertions: 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, and TP53.
- Genes tested for amplifications: CCND1, CD274, EGFR, ERBB2, FGFR2, KIT, MET, and MYC
- Genes tested for translocations: ALK, FGFR2, NTRK1, RET, and ROS1

See <u>Targeted Genes Interrogated by MayoComplete</u> <u>Liquid Biopsy Panel</u> for details regarding genes 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 counseling.

Questions