MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: May 28, 2021
Effective Date: June 9, 2021

MayoComplete Solid Tumor Panel, Next-Generation Sequencing, Tumor

Test ID: MCSTP

Genetics Information:

This test uses targeted next-generation sequencing to estimate tumor mutational burden (TMB), determine microsatellite instability (MSI) status, and identify somatic sequence variants, gene amplifications, fusions, and specific transcript variants in solid tumors. This panel includes a DNA subpanel for the detection of sequence alterations in 514 genes and amplification of 59 genes as well as an RNA subpanel for the detection of fusions involving 55 genes and specific splice variants involving *EGFR*, *AR*, and *MET*.

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.

Useful for:

- Assisting in tumor profiling for diagnosis, predicting prognosis, and identifying targeted therapies for the treatment and management of patients with solid tumors
- Identifying somatic alterations including single nucleotide variants (SNV), small insertions/deletions (INDEL), gene amplifications, fusions, and splice variants in genes known to be associated with the tumorigenesis of solid tumors
- Assessment of microsatellite instability and tumor mutational burden status

Additional Tests:

Test ID	Reporting Name	Available Separately	Always Performed
SLIRV	Slide Review in MG	No (Bill Only)	Yes

Methods:

Sequence Capture and Targeted Next-Generation Sequencing (NGS)

Reference Values:

An interpretive report will be provided.

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Ambient (preferred)	
	Refrigerated	

Specimen Requirements:

This assay requires at least 20% tumor nuclei. However, 40% tumor is preferred.
-Preferred amount of tumor area: 360 mm(2) tissue on up to 15 unstained slides
-Minimum amount of tumor area: 144 mm(2) tissue on up to 15 unstained slides
-Tissue fixation: 10% neutral buffered formalin, not decalcified
-For this test, at least 6mm x 6mm areas on 15 unstained slides is preferred: this is approximately equivalent to 540 mm(2). The minimum acceptable area is 3.1mm x 3.1mm on 15 unstained slides: approximately equivalent to 144 mm(2).

Preferred:
Specimen Type: Tissue block
Collection Instructions: Submit a formalin-fixed, paraffin-embedded tissue block with acceptable amount of tumor tissue

Acceptable:
Specimen Type: Tissue slide
Slides: 1 stained and 15 unstained
Collection Instructions: Submit 1 hematoxylin and eosin (H and E) stained slide and 15 unstained, nonbaked 5-micron thick sections
Note: The total amount of required tumor can be obtained by scraping up to 15 slides from the same block.

Specimen Type: Cytology slides (direct smears or ThinPrep)
Slides: 2 to 6 slides
Collection Instructions: Submit 2 to 6 stained and cover slipped slides with a preferred total of 10,000 nucleated cells or a minimum of at least 6,000 nucleated cells
Note: Glass coverslips are preferred; plastic coverslips are acceptable but will result in longer turnaround times.
Additional Information: Cytology slides will not be returned. An image of the slides will be stored per regulatory requirements.

Cautions:

Next-generation sequencing is performed to estimate tumor mutational burden (TMB) and microsatellite instability (MSI) status, somatic sequence variants, gene amplifications, fusions, and specific transcript variants in solid tumors. This test detects single nucleotide variants and small insertions and deletion within 514 genes, amplification of 59 genes, gene fusions involving 55 genes, and splice variants involving *EGFR*, *AR*, and *MET*.(Instruction manual: TruSight Oncology 500 High-Throughput. Illumina; 11/2020)

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.

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 detect large structural variants, copy number changes, or insertions, deletions, or duplications greater than approximately 20 base pairs in size.

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

A negative (ie, wildtype) result does not rule out the presence of an alteration that may be present but below the limits of detection of this assay.

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

A list of genomic regions in the DNA panel that have insufficient coverage to reliably detect single nucleotide variants (SNV) and small insertions/deletions (INDEL) are listed in MayoComplete Solid Tumor Panel DNA Panel Excluded DNA Regions in Special Instructions.

CPT Code:
81455, 88381

Report Available:
14 to 21 days

Questions

Contact Heather Flynn Gilmer or Melissa Lonzo Green, Laboratory Technologist Resource Coordinators, at 800-533-1710.