MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: December 30, 2025
Effective Date: January 29, 2026

MayoComplete Targeted RNA Sequencing Panel, Next-Generation Sequencing, Tumor

Test ID: MCRSP

Useful for:
Primarily for identifying gene fusions that help in the diagnosis of solid tumors

Secondarily, for identifying gene fusions that have therapeutic or prognostic significance

Genetics Information:
This test uses next-generation sequencing to evaluate 1445 genes for the presence of somatic gene fusions, known abnormal transcript variants in the *MET* and *EGFR* genes, and *BCOR* exon 15 internal tandem duplications. See Targeted Fusion Genes for MayoComplete Targeted RNAseq Panel for details regarding the targeted gene regions evaluated by this test.

This test is performed to evaluate for somatic gene fusions within solid tumor samples. It **does not assess** for germline alterations.

Testing Algorithm:
When this test is ordered, slide review will always be performed at an additional charge.

Reflex 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.

Necessary Information:

A pathology report (final or preliminary), at minimum containing the following information, **must accompany specimen for testing to be performed**:

1. Patient name
2. Block number-must be on all blocks, slides, and paperwork (can be handwritten on the paperwork)
3. Tissue collection date
4. Source of the tissue
5. Diagnosis, potential diagnosis, or differential diagnoses

Specimen Requirements:

This assay requires at least 10% tumor nuclei.

-Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 144 mm(2)
-Minimum amount of tumor area: tissue 36 mm(2)
-These amounts are cumulative over up to 10 unstained slides and must have adequate percent tumor nuclei.
-Tissue fixation: 10% neutral buffered formalin, not decalcified
-For specimen preparation guidance, see Tissue Requirements for Solid Tumor Next-Generation Sequencing. In this document, the sizes are given as 4 mm x 4 mm x 10 slides as preferred: approximate/equivalent to 144 mm(2) and the minimum as 3 mm x 1 mm x 10 slides: approximate/equivalent to 36 mm(2).

Preferred: Submit 3, if available, or 2 of the following specimens.
Acceptable: Submit **at least one** of the following specimens.

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

Specimen Type: Tissue slides
Slides: 1 Hematoxylin and eosin-stained and 10 unstained
Collection Instructions:
Submit the followings slides:
1 Slide stained with hematoxylin and eosin
AND
10 Unstained, nonbaked slides with 5-micron thick sections of the tumor tissue.
Note: The total amount of required tumor nuclei can be obtained by scraping up to 10 slides from the same block.
Additional Information: Unused unstained slides will not be returned.

Specimen Type: Cytology slides (direct smears or ThinPrep)
Slides: 1 to 3 Slides
Collection Instructions: Submit 1 to 3 slides stained and coverslipped with a total of 5000 nucleated cells (preferred) or at least 3000 nucleated cells (minimum).
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.

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Ambient (preferred)	
	Refrigerated	

Cautions:

This assay is not validated for the detection of single nucleotide variations, deletions-insertions, copy number alterations, or gene expression.

Fusions of uncertain significance may be identified.

The sensitivity of this assay for gene fusions depends on several variables including decreased sensitivity with decreased tumor percentage, and decreased sensitivity with decreased level of expression of a variant. A negative result does not rule out the presence of a gene fusion, splice variant, or *BCOR* exon 15 internal tandem duplication that may be present but below the limits of detection of this assay. The analytical sensitivity of this assay is a minimum coverage of 5 unique variant molecules in a sample with at least 10% tumor content.

This assay can detect in-frame and out-of-frame fusions involving 1445 genes. Sensitivity for detecting out-of-frame fusions, such as exon-intron, intron-intron or big insertions, may be lower due to bioinformatics detection limitations. This assay will only detect fusions involving at least 1 gene in the defined gene fusion target list of interest. This assay may not detect fusions involving deep intron or intergenic regions and will not detect chromosomal rearrangements that do not create a fusion transcript (ie, enhancer repositioning). Variants not expressed, or expressed at very low level, are not detected by this assay.

Rare variants, or alterations derived from the production of a gene fusion, may be present that could lead to false-negative or false-positive results.

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

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

Reliable results are dependent on adequate specimen collection and processing. This test has been validated on cytology slides and formalin-fixed, paraffin-embedded tissues; other types of fixatives are discouraged. Improper treatment of tissues, such as decalcification, may cause polymerase chain reaction failure.

RNA is particularly labile and degrades quickly. Rapid preservation of the tumor sample after collection reduces the likelihood of degradation. Still, there can be biological factors, such as tumor necrosis, which interfere with obtaining a high-quality RNA specimen despite rapid preservation.

CPT Code:
81456

Day(s) Performed: Monday through Friday **Report Available:** 12 to 20 days

Questions

Contact Melissa Tricker-Klar, Laboratory Resource Coordinator at 800-533-1710.