MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: September 23, 2022
Effective Date: October 24, 2022

MayoComplete Colorectal Cancer Panel, Next-Generation Sequencing, Tumor

Test ID: MCCRC

Useful for:

- Primarily for determining will respond to various targeted therapies/immunotherapy
- Predicting prognosis from microsatellite instability status

Additional Tests:

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

Testing Algorithm:

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

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

Specimen Requirements:

This assay requires at least 20% tumor nuclei.

-Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 216mm(2)

-Minimum amount of tumor area: tissue 36mm(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 Requirement for Solid Tumor Next-Generation Sequencing.
In this document, the sizes are given as 4mm x 4mm x 10 slides as preferred: approximate/equivalent to 144 mm(2) and the minimum as 3mm x 1mm x 10 slides: approximate/equivalent to 36mm(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 slides**
Slides:	1 Stained and 10 unstained
Collection Instructions:	Submit 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 cover slipped with a preferred total of 5000 nucleated cells, or a minimum of at least 3000 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.

Specimen Stability Information:

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)		
	Refrigerated		

Cautions:

- This test cannot differentiate between somatic and germline alterations. Additional testing may be necessary to clarify the significance of results if there is a potential hereditary risk.
- DNA variants of uncertain significance may be identified.
- A negative result does not rule out the presence of a variant that may be present but below the limits of detection of this assay. The analytical sensitivity of this assay for sequence reportable alterations is 5% mutant allele frequency with a minimum coverage of 500X in a sample with 20% or more tumor content.

- Point mutations and small insertion/deletion mutations will be detected in the *APC, BRAF, HRAS, KRAS, MLH1, MSH2, MSH6, NRAS,* and *PMS2* genes. This test may detect single exon deletions but does not detect multi-exon deletions, duplications, or genomic copy number variants in any of the genes tested.
- Rare alterations (ie, polymorphisms) may be present that could lead to false-negative or false-positive results.
- The presence or absence of a variant may not be predictive of response to therapy in all patients.
- 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 cannot reliably determine if a variant identified in *PMS2* exons 11-15 originated from *PMS2* or the highly homologous pseudogene *PMS2CL*. In the instance that a reportable variant is detected in *PMS2* exons 11-15, additional testing will be recommended in the patient report.
- 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.

CPT Code:

88381 - Microdissection, manual
81445

Day(s) Performed: Monday through Friday

Report Available: 12-20 days

Questions

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