TEST STATUS - ON HOLD



Notification Date: October 13, 2022 Effective Date: October 24, 2022

MayoComplete Lung Cancer-Targeted Gene Panel with Rearrangement, Tumor

Test ID: MCLNG

Explanation:

Effective October 24, 2022, we will be unable to perform New York client testing for MayoComplete Lung Cancer-Targeted Gene Panel with Rearrangement, Tumor (MCLNG). As a novel platform gene fusion assay, New York State Department of Health has requested additional information before providing continued approval to perform this laboratory testing on New York State patients.

We are actively working to provide the New York State Department of Health with the additional information that is being requested. An update will be provided once we are able to resume New York client testing.

Recommended Alternative Test:

Lung Cancer-Targeted Gene Panel with Rearrangement, Tumor

Test ID: LNGPR

Methodology:

Polymerase Chain Reaction (PCR)-Based Next Generation Sequencing

Reference Values:

An interpretative report will be provided.

Specimen Requirements:

This assay requires at least 20% tumor nuclei.

- -Preferred amount of tumor area with sufficient percent tumor nuclei: tissue144 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 <u>Tissue Requirement for Solid Tumor Next-Generation Sequencing</u>. 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 slide

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.

Specimen Type: Cytology slide (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)		
	Frozen		
	Refrigerated		

CPT Code:

81445-Targeted genomic sequence analysis panel, solid organ neoplasm Slide Review 88381-Microdissection, manual

Day(s) Performed: Monday Report Available: 14-22 days

Questions

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