

MayoComplete Lung Rearrangements, Rapid, Tumor

Test ID: MCLNR

Useful for:

- Identifying lung tumors that may respond to targeted therapies by simultaneously assessing multiple genes involved in rearrangements resulting in fusion transcripts
- Diagnosis and management of patients with lung cancer

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:

Polymerase Chain Reaction (PCR)

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 10% tumor nuclei.

-Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 36 mm(2)

- Minimum amount of tumor area: tissue 18 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

Preferred:

Specimen Type: Tissue block and cell block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded tissue block or cell block with acceptable amount of tumor tissue

Acceptable:

Specimen Type: Tissue slides

Slides: 1 Stained and 5 unstained

Collection Instructions: Submit 1 slide stained with hematoxylin and eosin and 5 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 5 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 for smears

Collection Instructions: Submit 1 to 3 slides unstained or stained with Diff Quick or Pap and cover slipped with a preferred total of 5,000 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 used in testing will have everything scraped and 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.
- A negative result does not rule out the presence of a rearrangement (fusion) that may be present but below the limits of detection of this assay.
- Gene fusions (rearrangements) and expression imbalance involving the *ALK*, *ROS1*, *RET*, *NTRK1*, *NTRK2*, and *NTRK3* genes only will be detected. This test does not detect point mutations, insertion/deletion mutations, large single or multiexon deletions or 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 findings, tumor sampling, and other laboratory data. If results obtained do not match other clinical or laboratory findings, please contact the laboratory for 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.

CPT Code:

81191
81193
81405
81479

Day(s) Performed: Monday through Friday**Report Available:** 4-8 days**Questions**

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