

Notification Date: September 9, 2025 Effective Date: September 9, 2025

MayoComplete Lung Rearrangements, Rapid Test, Tumor

Test ID: MCLNR

Explanation: On the effective date, the Specimen Required will be updated to clarify tissue preferences and standardize amongst molecular tissue assays. This update will not affect assay-specific acceptance criteria.

Current Specimen Required

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 wit 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)

Slides: 1 to 3 Slides for smears

Collection Instructions: Submit 1 to 3 slides unstained or stained with Diff Quik or Pap and coverslipped with a preferred total of 5000 nucleated cells or a minimum of at least 3000 nucleated cells.

New Specimen Required

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: 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 slide

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.

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 Type: Cytology slide (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.

Questions

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