

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

MLH1 Hypermethylation Analysis, Tumor

Test ID: ML1HM

Explanation: On the effective date, the Specimen Required will be updated to clarify tissue preferences and standardize amongst molecular tissue assays. Cytology slides will now be an acceptable specimen.

Current Specimen Required

Specimen Type: Tissue block or slide Collection Instructions:

1. Submit formalin-fixed, paraffin-embedded tissue block (preferred) or 1 slide stained with hematoxylin and eosin and 10 unstained, nonbaked slides (5-micron thick sections) of the tumor tissue.

2. Sections should contain tumor tissue.

New Specimen Required

This assay requires at least 20% tumor nuclei.

- -Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 216 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</u>
 Requirement for <u>Solid Tumor Next-Generation</u>
 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 slide

Slides: 1 Hematoxylin and eosin-stained and 10

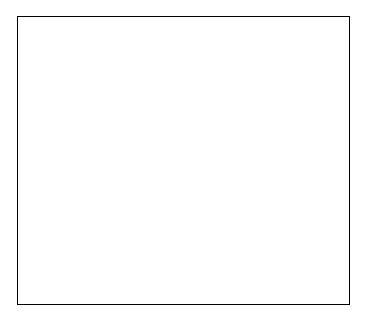
unstained

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.

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.