

## MLH1 Hypermethylation Analysis, Tumor

Test ID: ML1HM

### Explanation: Correction — Specimen Requirements

Cytology slides have been removed from the Specimen Required section. They were inadvertently listed in the September 9, 2025 Test Change update.

#### Current 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 [Tissue Requirement for Solid Tumor Next-Generation 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

#### 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 [Tissue Requirement for Solid Tumor Next-Generation 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 2, if available, 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.

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.

## Questions

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