

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

# MayoComplete Melanoma Panel, Next-Generation Sequencing, Tumor

**Test ID: MCMLN** 

**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 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>
  Requirements 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:

Specimen Type: Tissue block

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

## Acceptable:

Specimen Type: Tissue slides 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

Additional Information: Unused unstained slides will

not be returned.

#### **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>
  Requirements 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

Specimen Type: Cytology slides (direct smears or

ThinPrep)

Slides: 1 to 3 Slides

**Collection Instructions:** Submit 1 to 3 slides stained and coverslipped 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

**Additional Information:** Cytology slides will not be returned

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