

## POLE Mutation Analysis, Next-Generation Sequencing, Tumor

**Test ID:** POLET

**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 [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:**

**Specimen Type: Tissue block**

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

**Acceptable:**

**Specimen Type: Tissue slide**

**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 block.

**Additional Information:** Unused unstained slides will not be returned.

**Specimen Type: Cytology slide** (direct smears or

### 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 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 following slides:

1 slide stained with hematoxylin and eosin

AND

10 unstained, nonbaked slides with 5-micron thick sections of the tumor tissue.

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 times.

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

**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 a minimum of 3000 nucleated cells.

**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 Rath, Laboratory Resource Coordinator at 800-533-1710.