

## PIK3CA Mutation Analysis, Tumor

**Test ID:** PIK3T

**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.**

The amount of tissue needed is dependent on a variety of preanalytical factors (eg, cellularity, ischemic time, fixation).

The FFPE input required is equivalent to a 4 to 5 micron slide thickness with a total tumor surface area of 100 mm<sup>2</sup>. This can be created by combining material from multiple slides from one tissue block.

**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.

**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.

### New Specimen Required

**This assay requires at least 20% tumor nuclei.**

-Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 108 mm<sup>2</sup>)

-Minimum amount of tumor area: tissue 18 mm<sup>2</sup>)

-These amounts are cumulative over up to 10 unstained slides and must have adequate percent tumor nuclei

-Tissue fixation: formalin-fixed paraffin-embedded (FFPE), non-decalcified

**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.

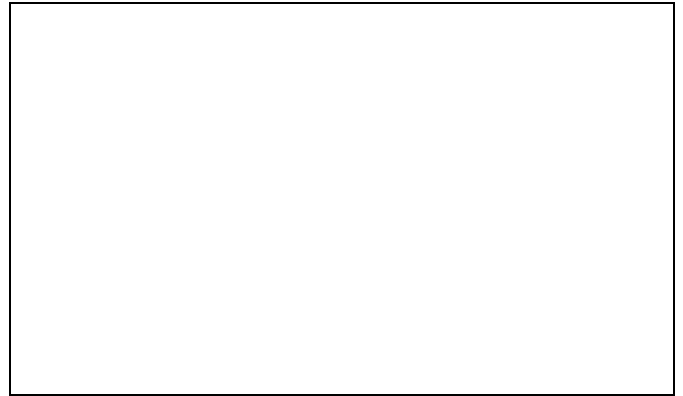
**Specimen Type: Cytology slide** (direct smears or ThinPrep)

**Slides:** 1 to 3 Slides

**Collection Instructions:** Submit 1 to 3 slides stained and coverslipped with a total of 5000 nucleated cells (preferred), or 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.