MAYO CLINIC LABORATORIES

**NEW TEST**

Notification Date: June 20, 2022
Effective Date: June 30, 2022

# *PIK3CA* Mutation Analysis, Tumor

**Test ID:** PIK3T

## Useful for:

Identification of hormone receptor positive and human epidermal growth factor receptor 2 negative (HR+/HER2-) advanced breast cancer tumors that may be eligible for treatment with targeted kinase inhibitor therapy (eg, alpelisib).

## Methods:

Polymerase Chain Reaction (PCR)

## Reference Values:

An interpretive report will be provided

## Specimen Requirements:

**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(2). This can be created by combining material from multiple slides from one tissue block.

**Preferred:**

| | |
|---|---|
| **Specimen Type:** | Tissue block |
| **Collection Instructions:** | Submit a formalin-fixed, paraffin-embedded tissue block. |

**Acceptable:**

| | |
|---|---|
| **Specimen Type:** | Tissue slide |
| **Collection Instructions:** | Submit 1 slide stained with hematoxylin and eosin and 10 unstained, nonbaked slides with 5-micron thick sections of the tumor tissue. |

## Specimen Stability Information:

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Varies | Ambient (preferred) | | |
| | Refrigerated | | |

## Cautions:

- A negative (wildtype) result does not rule out the presence of a mutation that may be present but below the limits of detection of this assay. It also does not rule out the presence of other types of alterations in the *PIK3CA* gene outside those that the assay was designed to detect.
- This test is not designed to differentiate between somatic and germline alterations. Additional testing may be necessary to clarify the significance of results if there is a potential hereditary risk.
- Not all tumors that have *PIK3CA* mutations will respond to targeted therapies.
- Rare genetic alterations exist that could lead to false-negative or false-positive results.
- Test results should be interpreted in context of clinical findings, tumor sampling, and other laboratory data. If results obtained do not match other clinical or laboratory findings, please contact the laboratory for possible interpretation. Misinterpretation of results may occur if the information provided is inaccurate or incomplete.

## CPT Code:

81309

**Day(s) Performed:** Monday through Friday **Report Available:** 8 to 12 days

## Questions

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