MAYO CLINIC LABORATORIES

NEW TEST

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

Cell-Free DNA *PIK3CA* Test, Blood

Test ID: PIK3B

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:

Supplies: Streck Black/Tan Top Tube Kit (T715)

Specimen Volume: Two, 10-mL Streck cell-free DNA (cfDNA) blood collection tubes
Minimum Volume: One 10 mL Streck cell-free DNA tube

Additional Information: 1. Only blood collected in Streck cfDNA tubes will be accepted for analysis.
2. Whole blood will be processed to produce platelet-poor plasma before cfDNA isolation.

Specimen Stability Information:

Specimen Type	Temperature	Time	Special Container
Whole blood	Ambient (preferred)	7 days	Streck Black/Tan top
	Refrigerated	7 days	Streck Black/Tan top

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.
- This test has not been clinically validated for use as a tool to monitor response to therapy for early detection of tumors.
- 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:** 5 to 10 days

Questions

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