

Case Number:

Patient Name:

Age/Sex:

Patient Location:

Hospital Name:

Physician Name:

Date & Time of Accessioning:

Date & Time of Reporting:

### TEST NAME

liquiCORE PIK3CA

### SPECIMEN INFORMATION

Peripheral blood in PAX gene tube collected on 08/11/2022.

### CLINICAL HISTORY

Carcinoma breast.

### METHODOLOGY

Real-Time Polymerase Chain Reaction (RT-PCR)

### RESULTS

No mutation detected in the *PIK3CA* gene

### COMMENTS

1. This assay helps in identifying breast cancer patients who may be eligible for treatment with PIQRAY® (alpelisib), a-selective PI3K-inhibitor, based on a PIK3CA Mutation Detected result.
2. The *therascreen* PIK3CA RGQ PCR Kit is the first companion diagnostic (CDx) test to be approved by the FDA.
3. Mutations in the PIK3CA gene have been identified in carcinomas arising from colon, breast, ovary, liver, stomach, and lung as well as in Glioblastomas.
4. Evidence suggests that such mutations lead to constitutive activation of the PI3K pathway.
5. Patients whose plasma specimen produces a negative result using this test should be reflexed to testing with FFPE tumor tissue for the presence of possible PIK3CA mutations, if any.



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### TEST INFORMATION

This test covered the following exons/mutations of PIK3CA gene.

Exons	Amino acid change	Base change
7	C420R	1258T>C
9	E542K	1624G>A
	E545A	1634A>C
	E545D	1635G>T
	E545G	1634A>G
	E545K	1633G>A
	Q546E	1636C>G
	H1047L	3140A>T
20	H1047R	3140A>G
	H1047Y	3139C>T

### REFERENCES

1. Katso, R., Okkenhaug, K., Ahmadi, K., et al. (2001) Cellular function of phosphoinositide 3-kinases: implications for development, homeostasis, and cancer. *Annu. Rev. Cell. Dev. Biol.* 17, 615.
2. Samuels, Y., Wang, Z., Bardelli, A., et al. (2004) High frequency of mutations of the PIK3CA gene in human cancers. *Science.* 304, 554.
3. Cancer Genome Atlas Network (2012) Comprehensive molecular portraits of human breast tumors. *Nature.* 490, 61.



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## Question?

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