

## TRUPCR® PIK3CA Mutations Detection Kit

### NEED

The PIK3CA gene encodes for the  $\alpha$ -isoform of the catalytic subunit (p110 $\alpha$ ) of class IA PI3K kinase. PIK3CA somatic mutations occur in around 20%–40% of early breast cancers (eBCs) and are more frequent in hormone receptor-positive (HR+) disease. PIK3CA gene spanning 20 exons encodes for a protein of 1068 amino acids and mutations present in exons 9 and 20 are considered as mutational hot spots harboring 90 % of somatic mutations of the PIK3CA gene. PIK3CA mutations occur most frequently in three hotspots: p.E542K and p.E545K in exon 9 (corresponding to the helical domain), and p.H1047R in exon 20 (corresponding to the kinase domain) and result in overactivation of its protein. The presence of PIK3CA mutations is associated with poor prognosis and lack of response to specific therapies in patients with breast, endometrial, or colon cancer. It has been reported that the treatment with selective inhibitors such as olaparib & alpelisib can overcome resistance to endocrine treatment in HER2 negative advanced breast cancer with PI3KCA mutations. Therefore, identifying patients with PIK3CA mutations that can benefit from PI3K-targeted therapy could help to guide treatment decisions to improve patient prognosis.

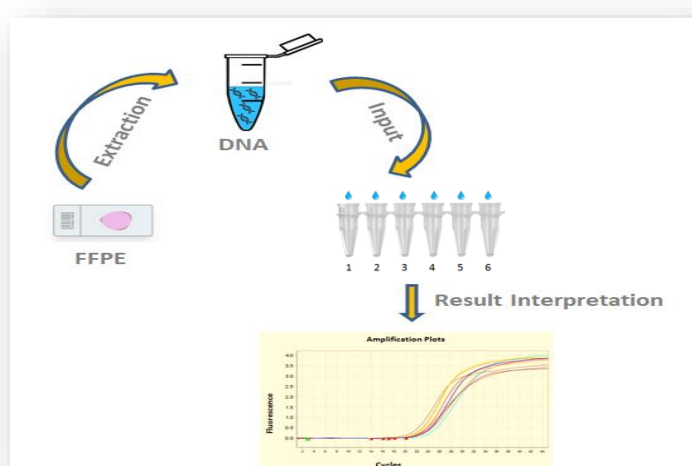
### SOLUTION BY TRUPCR®

The TRUPCR® PIK3CA Mutations Detection Kit is intended for the qualitative detection of somatic mutations in exons 7, 9 and 20 of Phosphatidylinositol-4,5-Bisphosphate 3-Kinase (PIK3CA) gene from tumor tissue DNA (fresh, frozen or formalin fixed paraffin-embedded tissue) using Real Time PCR. Results from this kit are intended to aid the clinician in identifying patients with breast cancer who may benefit from treatment with PIK3CA tyrosine kinase inhibitors.

The kit is designed to selectively amplify mutant specific sequences using allele-specific primers in samples that contain a mixture of wild-type and mutated DNA. The kit can detect 24 different mutations in a single run that are found in codons 12, 13, 59, 61, 117 & 146.

The kit contains primers and probes for the detection of the all target (FAM) as well as endogenous control gene as internal control (VIC/HEX). Internal control is included to verify the extraction procedure and also the possible presence of inhibitors, which may cause false negative results.

### TEST PROCEDURE



### PRODUCT HIGHLIGHTS:

- Detects 13 different mutations in a single run
- Sensitive to detect up to 5% mutation in PIK3CA gene

### TECHNICAL SPECIFICATIONS

- Selective Amplification of DNA containing mutation with ARMS Technology
- Endogenous Internal control included to avoid false-negative results
- Compatible Instruments – Applied Biosystems™ 7500 series, Applied Biosystems™ StepOne series, Applied Biosystems™ QuantStudio® series, Rotor-Gene Q, Bio-Rad CFX96, CFX384, AriaMx Real-Time PCR, Roche - LightCycler® 480 –II, Line gene K Real-Time PCR

**LIST OF DETECTABLE MUTATIONS**

Mutation	Nucleotide Change	Remarks
PIK3CA C420R	C420R_1258 T>C	
PIK3CA E545x	E545D_1635 G>T	It detects 2 mutations but does not distinguish between them.
	E545K_1633 G>A	
PIK3CA E542x	E542K_1624 G>A	It detects 3 mutations but does not distinguish between them.
	E542G_1625 A>G	
	E542V_1625 A>T	
PIK3CA E545G & PIK3CA Q546x	E545G_1634 A>G	It detects 3 mutations but does not distinguish between them.
	Q546E_1636 C>G	
	Q546R_1637 A>G	
PIK3CA E545A	E545A_1634 A>C	
PIK3CA H1047X	H1047L_3140 A>T	It detects 3 mutations but does not distinguish between them.
	H1047R_3140 A>G	
	H1047Y_3139 C>T	

**ORDERING INFORMATION**

Cat. No.	Description	Size
3B1345	TRUPCR® PIK3CA Mutations Detection Kit	24 Reactions
3B1346	TRUPCR® PIK3CA Mutations Detection Kit	48 Reactions

