



Assay Technologies Ltd.



APIS PIK3CA qPCR Kit

The APIS PIK3CA qPCR Kit is a real-time qualitative PCR test for the detection of the five most prevalent activating mutations in the *PIK3CA* gene, using DNA extracted from either formalin-fixed, paraffin-embedded (FFPE) breast tumour tissue (gDNA) or blood plasma (cfDNA).

The kit includes mutation-specific probes to enable highly sensitive detection of the target mutations. Additionally, it uses PCR clamp and blocker technology, which ensures specific amplification of the mutant sequence, even in the presence of a high wild-type background.

Advantages of the APIS PIK3CA qPCR Kit



Detects 5 *PIK3CA* mutations, covering > 95% of actionable mutations



Highly sensitive detection at $\leq 0.5\%$ mutant allele frequency (MAF)



Designed for FFPE tumour tissue (gDNA) or plasma (cfDNA)

Assay Mutations and Analytical Sensitivity

Synthetic DNA samples were prepared at $\leq 0.5\%$ mutant allele frequency (MAF), with a total input of 5000 copies per reaction. A total of 24 replicates were generated per target, across 2 instruments and 2 kit lots. The Limit of Detection (LoD) is based on the highest MAF with $\geq 95\%$ correct calls observed for each target. The LoD was established at $\leq 0.5\%$ MAF for all targets (Table 1).

Table 1. Five *PIK3CA* mutations detected by the APIS PIK3CA qPCR Kit. LoD in % MAF.

Exon	Detected Mutations	COSMIC ID	LoD (%MAF)	Mutant DNA copies at LoD	WT DNA copies at LoD
7	H1047L	COSV55873401	0.50%	25	4975
9	H1047R	COSV55873195	0.50%	25	4975
	C420R	COSV55874020	0.50%	25	4975
20	E542K	COSV55873227	0.36%	18	4982
	E545K	COSV55873239	0.50%	25	4975

APIS PIK3CA qPCR Kit Specifications

The kit has undergone testing as part of APIS unique RUO assay development pipeline, including both *in silico* and wet laboratory testing. As a result, researchers can depend on the kit for consistent and high-quality detection of *PIK3CA* mutations. A positive and negative control (PC and NTC), which monitor assay set up and assay performance, are also supplied with the kit.

Format	6 Tubes: 2 PP Mixes (Primer-Probes), 2x Enzyme Mix, 1 Positive Control, 1 Negative Control
PCR Method	qPCR
Turnaround time (TAT)	< 2 hours
Instrument	Any qPCR instrument with compatible cycling and emission detection capabilities
Probe Modifications	5' FAM™/3' BHQ [®] 1 5' HEX™/3' BHQ [®] 1 5' Cy [®] 5/3' BHQ [®] 2
No. of Samples	Standard kit is sufficient for 24 samples (20 µL reaction), including pipetting overage
Concentration	4X PP Mix 2X Enzyme Mix
Sample Type	DNA extracted from FFPE (gDNA) or plasma (cfDNA)

APIS ESR1 and APIS PIK3CA qPCR Kits Bundle

The APIS ESR1 Mutations Kit and the APIS PIK3CA qPCR Kit are available as a bundle for the detection of five *PIK3CA* mutations and eleven *ESR1* mutations from DNA (both FFPE or cfDNA) using real-time qualitative PCR.

See [APIS website](#) or the [APIS ESR1 Mutations and APIS PIK3CA qPCR Kits Bundle Flyer](#) for more information.



APIS PIK3CA qPCR Kit Ordering Information

Assay Name	Test Type	Kit Size	Catalogue Number	Price
APIS PIK3CA qPCR Kit	RUO	24 samples plus controls	03101 (distributed by APIS)	Available upon request
APIS PIK3CA qPCR Kit	RUO	24 samples plus controls	03102 (distributed by Biocartis)	Available upon request

Please visit the product web page, for the list of countries that Biocartis distributes the APIS PIK3CA qPCR Kit. APIS is the distributor for all other countries. Data and conclusions provided in this leaflet have not been validated by Biocartis NV. All scientific and analytical information in this flyer comes from the APIS PIK3CA qPCR Kit Handbook ART0176.

International distributor:

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**The APIS PIK3CA qPCR Kit is a Research Use Only (RUO) product.
 Not for use in diagnostic procedures.**