



Assay Technologies Ltd.

Achieve $\leq 0.5\%$ MAF Detection with the APIS ESR1 and PIK3CA qPCR Kits

Discover the advanced capabilities of the APIS ESR1 and PIK3CA qPCR Kits, both designed to achieve a $\leq 0.5\%$ mutant allele frequency (MAF) Limit of Detection (LoD).

The APIS ESR1 qPCR Kit is an advanced qPCR assay for the sensitive and precise detection of mutations within the oestrogen receptor gene (*ESR1*). The APIS ESR1 qPCR Kit is a qualitative test, detecting eleven *ESR1* mutations from DNA extracted from plasma (cfDNA).

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, from DNA extracted from formalin-fixed, paraffin-embedded (FFPE) breast tumour tissue (gDNA) or blood plasma (cfDNA).

Both APIS ESR1 qPCR Kit and APIS PIK3CA qPCR Kit demonstrated sensitivity of $\leq 0.5\%$ MAF in 5,000 or 10,000 total copies input. This detection capability applies to all *ESR1* mutations detected in the kit: E380Q, S463P, P535H, L536R, L536Q, L536H, L536P, Y537C, Y537S, Y537N, and D538G each reaching $\leq 0.5\%$ MAF sensitivity.

Benefits of the APIS ESR1 and PIK3CA qPCR Kits Bundle



Wide target coverage – detects 11 *ESR1* mutations and 5 *PIK3CA* mutations



High sensitivity – mutations are detected at $\leq 0.5\%$ MAF



Streamlined workflow – identical run conditions allow detection on a single plate



Accessibility – compatible with a variety of real-time PCR instruments

Mutations Detected by the APIS ESR1 qPCR Kit and APIS PIK3CA qPCR Kit

APIS Kit	Mutation	Nucleic Acid Change	COSMIC ID	Prevalence*	Sensitivity (%MAF)
APIS ESR1 qPCR Kit	E380Q	c.1138G>C	COSM3829320	7.18%	≤0.50%
	S463P	c.1387T>C	COSM4771561	1.67%	≤0.50%
	P535H	c.1604C>A	COSM4944018	N/A	≤0.50%
	L536R	c.1607T>G	COSM4774826	1.67%	≤0.50%
	L536Q	c.1607_1608delinsAG (TC>AG)	COSM4766050	0.24%	≤0.50%
	L536H	c.1607T>A	COSM6843697	3.83%	≤0.50%
	L536P	c.1607T>C	COSM6906109	2.15%	≤0.50%
	Y537S	c.1610A>C	COSM1074639	21.05%	≤0.50%
	Y537N	c.1609T>A	COSM1074635	15.31%	≤0.50%
	Y537C	c.1610A>G	COSM1074637	3.35%	≤0.50%
	D538G	c.1613A>G	COSM94250	33.01%	≤0.50%
APIS PIK3CA qPCR Kit	C420R	1258 T>C	COSM757	2.06%	0.50%
	E542K	1624 G>A	COSM760	14.21%	0.50%
	E545K	1633 G>A	COSM763	23.31%	0.30%
	H1047L	3140 A>T	COSM776	6.53%	0.35%
	H1047R	3140 A>G	COSM776	50.32%	0.50%

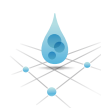
*Prevalence based on number of observed mutation in the EMERALD (NCT03778931) and SOLAR-1 (NCT02437318) trials

APIS ESR1 and PIK3CA qPCR Kits 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
APIS ESR1 qPCR Kit	RUO	24 samples plus controls	03201 (distributed by APIS)	Available upon request
APIS ESR1 qPCR Kit	RUO	24 samples plus controls	03202 (distributed by Biocartis)	Available upon request

Please visit the product web page for the list of distributors of the APIS ESR1 and PIK3CA qPCR Kits. Data and conclusions provided in this leaflet have not been validated by Biocartis NV.

International distributor:



Distributed by
BIOCARTIS
For Research Use Only.

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The APIS ESR1 qPCR Kit and APIS PIK3CA qPCR Kit are both Research Use Only (RUO) products. Not for use in diagnostic procedures.