



Assay Technologies Ltd.

## APIS ESR1 Mutations Kit

Performance with SensID ESR1 Reference Set 1% AF cfDNA

Technical Sheet

The APIS ESR1 Mutations Kit is an advanced qPCR assay for the sensitive and precise detection of mutations within the oestrogen receptor 1 (ER/*ESR1*) gene. The APIS ESR1 Mutations Kit is a qualitative test, detecting eleven *ESR1* mutations across three exons: exon 5 (E380Q), exon 7 (S463P) and exon 8 (P535H, L536R, L536Q, L536H, L536P, Y537C, Y537S, Y537N and D538G).

### APIS ESR1 Mutations Kit

- Cost effective, rapid and highly sensitive ( $\leq 1\%$  MAF) alternative to NGS, and dPCR assays
- Targeted qPCR-based assay detecting eleven *ESR1* mutations across exons 5, 7 & 8 (Table 1)
- Designed for circulating-free DNA (cfDNA) specimens
- Providing researchers in both centralised and decentralised laboratory settings the flexibility to explore *ESR1* mutations with precision

We demonstrate the performance of the APIS ESR1 Mutations Kit using the first commercially available cfDNA reference set (SensID ESR1 Reference Set 1% AF cfDNA) including nine *ESR1* mutations.

**Table 1.** Mutations detected with the APIS ESR1 Mutations Kit. LoD for all targets  $\leq 1\%$  Mutant Allele Frequency (MAF). Targets included in the SensID Reference Set shown in bold.

Exon	Mutations to be detected	Nucleic acid change	COSMIC ID	LoD (MAF)
5	<b>E380Q</b>	c.1138G>C	COSM3829320	1.00%
7	<b>S463P</b>	c.1387T>C	COSM4771561	0.08%
8	P535H	c.1604C>A	COSM4944018	0.40%
	<b>L536R</b>	c.1607T>G	COSM4774826	0.70%
	L536Q	c.1607_1608delinsAG (TC>AG)	COSM4766050	0.80%
	<b>L536H</b>	c.1607T>A	COSM6843697	0.80%
	<b>L536P</b>	c.1607T>C	COSM6906109	0.90%
	Y537S	c.1610A>C	COSM1074639	0.10%
	Y537N	c.1609T>A	COSM1074635	0.20%
	Y537C	c.1610A>G	COSM1074637	0.40%
	D538G	c.1613A>G	COSM94250	0.40%



Visit the APIS website for more information

Scan the QR code or visit  
[www.apisassay.com/apis-esr1-mutations-kit](http://www.apisassay.com/apis-esr1-mutations-kit)

## Performance with SensID ESR1 Reference Set 1% AF cfDNA

The SensID *ESR1* standards were assessed with the APIS ESR1 Mutations Kit. All vials were diluted with nuclease-free water to 3 ng/μL, resulting in 15 ng total input per reaction. Samples were run according to the APIS ESR1 Mutations Kit handbook. All PCR runs were performed using QuantStudio™ 5 Dx Real-Time PCR System.

**Table 2.** APIS ESR1 Mutations Kit performance with SensID ESR1 Reference Set 1% AF cfDNA (SID-000144)

SensID Reference Set	Mutations (1% MAF)	APIS ESR1 Mutations Kit Result											Reference		
		L536H	Y537C	L536P	Y537S	L536R	D538G	E380Q	S463P	Y537N	P535H	L536Q			
Samples	Vial 1	L536H	+	-	-	-	-	-	-	-	-	-	-	-	+
		Y537C	-	+	-	-	-	-	-	-	-	-	-	-	+
	Vial 2	L536P	-	-	+	-	-	-	-	-	-	-	-	-	+
		Y537S	-	-	-	+	-	-	-	-	-	-	-	-	+
	Vial 3	L536R	-	-	-	-	+	-	-	-	-	-	-	-	+
		D538G	-	-	-	-	-	+	-	-	-	-	-	-	+
	Vial 4	E380Q	-	-	-	-	-	-	+	-	-	-	-	-	+
		S463P	-	-	-	-	-	-	-	+	-	-	-	-	+
	Vial 5	Y537N	-	-	-	-	-	-	-	-	+	-	-	-	+
		Wildtype	-	-	-	-	-	-	-	-	-	-	-	-	+

The APIS ESR1 Mutations Kit successfully detected all *ESR1* mutations, with expected target calls for the nine mutations at 1% MAF. No false positive results were observed in any vials, including vial 5 containing the wildtype (WT) sample, reaffirming the kit's accuracy in distinguishing WT and mutant samples.



Highly sensitive and specific detection of SensID *ESR1* Mutation Reference Set at 1% MAF

## Ordering Information

Product Name	Test Type	Kit Size	Catalogue Number	Price
APIS ESR1 Mutations Kit	RUO	24 Samples plus controls	02201 (distributed by APIS)	Available upon request
APIS ESR1 Mutations Kit	RUO	24 Samples plus controls	02202 (distributed by Biocartis)	Available upon request

Please visit the product web page for the list of countries that Biocartis distributes the APIS ESR1 Mutations Kit. APIS is the distributor for all other countries.

The APIS ESR1 Mutations Kit is for Research Use Only (RUO). Not for use in diagnostic procedures.

## International distributor:



Distributed by  
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