



Assay Technologies Ltd.



APIS ESR1 qPCR Kit

The APIS ESR1 qPCR Kit is an advanced qPCR-based assay designed for the sensitive and precise detection of mutations in the oestrogen receptor (*ESR1*) gene. This qualitative test identifies 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).

Advantages of APIS ESR1 qPCR Kit



Wide target coverage – designed to cover 11 *ESR1* mutations



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



Instrument agnostic – compatible with a variety of real-time PCR instruments



Simultaneous *ESR1* & *PIK3CA* testing – when combined with the APIS *PIK3CA* qPCR Kit in one run

Assay Mutations and Analytical Sensitivity

Synthetic DNA samples were prepared at 0.5% mutant allele frequency (MAF), with a total input of 10,000 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 0.5% MAF for all targets (Table 1).

Table 1: 11 *ESR1* mutations detected by the APIS ESR1 qPCR Kit. LoD in % MAF

Target	LoD (% MAF)	Mutant DNA copies at LoD	WT DNA copies at LoD
E380Q, S463P, P535H, L536R, L536Q, L536H, L536P, Y537C, Y537S, Y537N, and D538G	0.50%	50	9,950

APIS ESR1 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 *ESR1* mutations. A positive and negative control (PC and NTC), which monitor assay set up and assay performance, are also supplied with the kit.

Format	8 Tubes: 4 PP Mixes (Primer-Probes), 2 Enzyme Mixes, 1 Positive Control, 1 Negative Control
PCR Method	qPCR
Instrument	Any compatible qPCR instrument (Cy [®] 5, FAM [™] , HEX [™] , ROX)
Probe Modifications	5' FAM [™] /3' BHQ [®] 1 5' HEX [™] /3' BHQ [®] 1 5' ROX/3' BHQ [®] 2 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
Shelf Life	15 months stored at -25°C to -15°C

APIS ESR1 and APIS PIK3CA qPCR Kits Bundle

The APIS ESR1 qPCR 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 qPCR Kit and APIS PIK3CA qPCR Kits Bundle Flyer for more information.



APIS ESR1 qPCR Kit Ordering Information

Product Name	Test Type	Kit Size	Catalogue Number	Price
APIS ESR1 qPCR Kit	RUO	24 samples	03201	Available upon request

All scientific and analytical information in this brochure comes from the APIS ESR1 qPCR Kit Handbook ART0188.

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