



Assay Technologies Ltd.



APIS ESR1 dPCR Kit

The APIS ESR1 dPCR Kit is a digital PCR (dPCR) workflow allowing for reliable detection of mutations within the oestrogen receptor (*ESR1*) gene. The kit detects 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 the APIS ESR1 dPCR Kit



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



High sensitivity – all mutations are detected at $\leq 0.1\%$ MAF



High specificity – clamp & blocking technology to ensure no WT detection



Instrument agnostic – compatible with most digital PCR systems

Analytical Sensitivity

The Limit of Detection (LoD) was established for each target using samples contrived with wild-type (WT) and mutant DNA at 0.1% mutant allele frequency (MAF). A total of 6 replicates were generated per target, across one instrument and two kit lots. The LoD was defined as the highest MAF with 100% correct calls.

Table 1. Mutations detected by the APIS ESR1 dPCR Kit. LoD in % MAF and copies. The mutant copies at LoD and WT copies at LoD describe the copies of each DNA fragment in the contrived LoD samples.

Target	Nucleic Acid Change	COSMIC ID	LoD % MAF	Mutant DNA Copies at LoD	WT DNA Copies at LoD
D538G	c.1613A>G	COSM94250	0.10%	20	19,980
S463P	c.1387T>C	COSM4771561	0.10%	10	9,990
Y537C	c.1610A>G	COSM1074637	0.10%	10	9,990
Y537S	c.1610A>C	COSM1074639	0.10%	10	9,990
L536X (L536P)	c.1607T>C	COSM6906109	0.10%	10	9,990
L536X (L536R)	c.1607T>G	COSM4774826	0.10%	10	9,990
L536X (L536H)	c.1607T>A	COSM6843697	0.10%	10	9,990
L536X (L536Q)	c.1607_1608TC>AG	COSM4766050	0.10%	10	9,990
Y537N	c.1609T>A	COSM1074635	0.10%	10	9,990
E380Q	c.1138G>C	COSM3829320	0.10%	10	9,990
P535H	c.1604C>A	COSM4944018	0.10%	10	9,990

Analytical Specificity

The Limit of Blank (LoB) was determined by testing mutation-negative samples contrived with WT DNA fragments (10,000 and 20,000 copies). For each target, the overall rate of correct sample interpretation was 100%.

APIS ESR1 dPCR Kit Specifications

The kit has undergone testing as part of the APIS unique assay development pipeline, which includes in silico and wet laboratory testing. An appropriate instrument and compatible dPCR enzyme mix, suitable for use with probe-based chemistry, is required for use.

Format	6 Tubes: 4 PP mixes (Primer-Probes), 1 Positive Control, 1 Negative Control
PCR Method	Any digital PCR system with compatible emission detection capabilities
Detection Capabilities Required	FAM™, ROX, HEX™, Cy®5
Turnaround Time	< 3 hours per PCR plate
Hands-on Time	< 1 hours per PCR plate
Intended Sample Type	DNA (e.g. cfDNA)
Instrument	Digital PCR instrument
Storage Conditions	-30°C to -15°C
Shelf Life	15 months

APIS ESR1 dPCR Kit Ordering Information

Assay Name	Test Type	Kit Volumes	Catalogue Number	Price
APIS ESR1 dPCR Kit	RUO	PP mixes: 252 µL Controls: 210 µL	03301 (distributed by APIS)	Available upon request
APIS ESR1 dPCR Kit	RUO	PP mixes: 252 µL Controls: 210 µL	03302 (distributed by Biocartis)	Available upon request

Data and conclusions provided in this leaflet have not been validated by Biocartis NV.

International distributor:

Biocartis NV

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All scientific and analytical information in this flyer comes from the APIS ESR1 dPCR Kit Handbook ART0160.

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