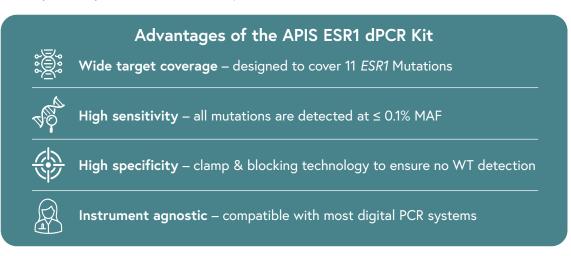




# APIS ESR1 dPCR Kit

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).



## **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<br>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<br>Controls: 210 μL | 03301 (distributed by APIS)      | Available upon request |
| APIS ESR1 dPCR Kit | RUO       | PP mixes: 252 μL<br>Controls: 210 μL | 03302 (distributed by Biocartis) | Available upon request |

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