



Assay Technologies Ltd.

## APIS Breast Cancer Subtyping Kit

The APIS Breast Cancer Subtyping Kit is a highly reproducible, RT-qPCR-based kit for detecting mRNA expression of standard breast cancer biomarkers (HER2, ER, PR, Ki67) and novel proliferative biomarkers from core-needle biopsy (CNB) or resected formalin-fixed paraffin embedded (FFPE) breast tumour tissue. Receptor tyrosine-protein kinase erbB-2 (HER2), oestrogen receptor (ER), progesterone receptor (PR), and marker of proliferation (Ki67) biomarkers play a key role in breast cancer.

The kit also includes a novel four-gene proliferative signature that comprises four markers (MKI67, CCNA2, KIF23, and PCNA) associated with proliferation. These markers are expressed throughout all cell cycle stages, providing a more precise representation of tumour proliferation.



### Advantages of the APIS Breast Cancer Subtyping Kit



Reproducible and precise detection of HER2, ER, PR & Ki67 mRNA expression



Novel four-gene proliferative signature provides a more precise representation of tumour proliferation



Requires only 10µm CNB or resected FFPE sections with as little as 20% tumour content



Only 2 hours from PCR setup to result generation

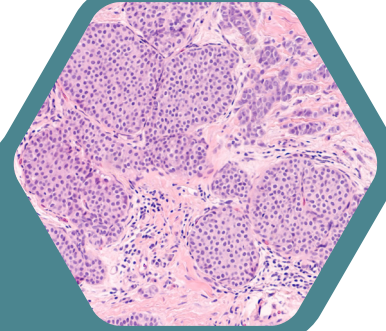
# APIS Breast Cancer Subtyping Kit

Delivering precise results for standard biomarkers and a novel proliferative signature in **less than 5 hours** when processing 10 samples.



## Sample Preparation

- 10µm FFPE tissue section (tumour content ≥ 20%)



## Recommended RNA Extraction & Normalisation

- Use of RNeasy® DSP FFPE Tissue Kit
- Fluorometric RNA Quantification



## APIS Breast Cancer Subtyping Kit Setup

- Master mix prep and plate set up
- Up to 10 samples per plate



## RT-qPCR Reaction

- Recommended for use with QuantStudio™ 5 Dx Instrument



## Analysis and Results Interpretation

- Analysis and target relative expression can be reported as Delta Ct ( $\Delta C_t$ ) values.

The APIS Breast Cancer Subtyping Kit contains an internal control (IC), a synthetic RNA sequence, which monitors for assay set up, reagent performance and interfering substances. Positive and Negative Controls (PC and NTC) which monitor run validity and reagent performance are also supplied with the kit.

## A Comprehensive Molecular Profile for Breast Cancer

The APIS Breast Cancer Subtyping Kit uses One Step RT-qPCR with dye-linked oligonucleotides to detect sequence amplification. To selectively amplify the mRNA sequence, at least one of the oligonucleotides used to generate the amplicon is spanning an exon-exon boundary. The probe binds to the target sequence between the primers.



### Reliable Detection

Reliability detecting HER2, ER, PR & Ki67 mRNA expression levels



### Reproducible

Highly precise, consistent results across multiple samples

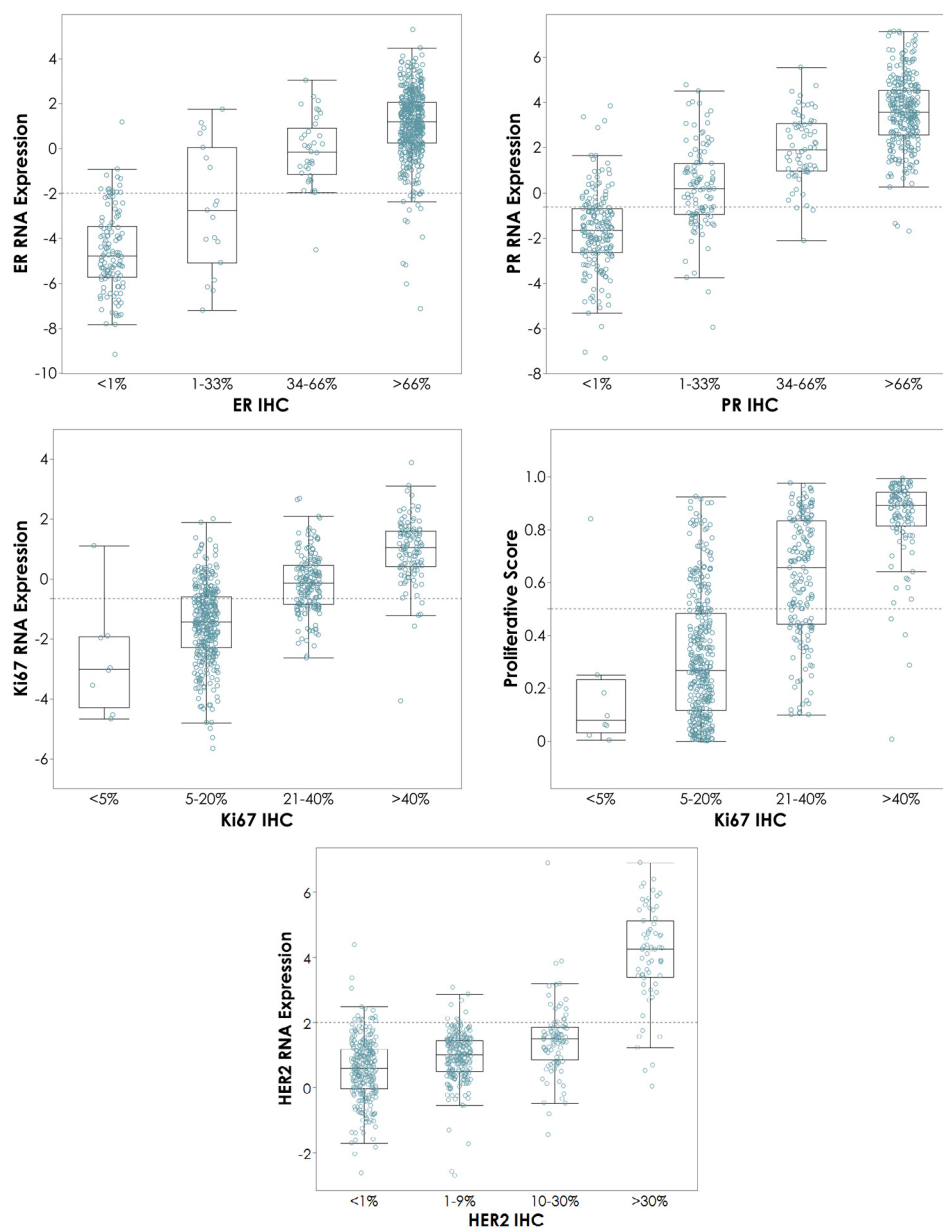


### Quick Setup

Only 2 hours from PCR setup to result generation

## APIS Breast Cancer Subtyping Kit Performance

Comparison of APIS Breast Cancer Subtyping Kit expression measure ( $\Delta\text{Ct}$ ) with IHC% nuclei staining for each target. A strong correlation between IHC% staining and the APIS Breast Cancer Subtyping Kit can be observed.



Y axis; APIS RNA gene expression ( $\Delta\text{Ct}$  value) with assays cut-off (dashed line) indicating positive/negative calling. Cut off values valid only when analysis performed using QS5™Dx instrument. X axis; IHC positive nuclei (%).

## Ordering Information

Product Name	Test Type	Kit Size	Catalogue Number Code	Price
APIS Breast Cancer Subtyping Kit	RUO	24 Samples in duplicate plus controls	00402 (distributed by Biocartis)	Available upon request
APIS Breast Cancer Subtyping Kit	RUO	24 Samples in duplicate plus controls	00403 (distributed by APIS)	Available upon request

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

All scientific and analytical information in this brochure comes from the APIS Breast Cancer Subtyping Kit Instructions for Use ART0049.

The APIS Breast Cancer Subtyping Kit is intended for Research Use Only (RUO). Not for use in medical or clinical diagnostic procedures.



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To order the APIS Breast Cancer Subtyping Kit or to learn more about how our assay can elevate your breast cancer research capabilities, please contact your local distributor using the details below.

**UK sales agent:**



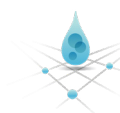
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