APIS
Assay Technologies Ltd.

APIS Breast Cancer Subtyping Kit - Technical Sheet

Kit Overview

The APIS Breast Cancer Subtyping Kit is a highly reproducible, real-time reverse transcription polymerase chain reaction (RT-qPCR)-based kit for detecting mRNA expression of standard breast cancer biomarkers (HER2, ER, PR, Ki67). 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.

Intended Use

The APIS Breast Cancer Subtyping Kit is a gene expression assay based RT-qPCR. The kit detects and enables relative gene expression quantification of ten human mRNA target genes extracted from formalin-fixed, paraffin embedded (FFPE) pre-operative core needle biopsies (CNB) or resected breast tumour tissue.

Features of the Assay

- Reliable and highly precise detection of HER2, ER, PR & Ki67 mRNA expression levels
- Reproducible and consistent results across multiple samples
- Novel four-gene proliferative signature provides a more precise representation of tumour proliferation
- Quick results in less than 5 hours when processing 10 samples

Minimum Sample Requirements

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

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Turnaround Time

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

Result Reporting

Analysis and target relative expression can be reported as Delta Ct (ΔCt) values. ΔCt values should be used to guide the biomarker expression status (positive/high or negative/low). When using QS5™Dx and QS5 instrument and software, ΔCt cut-off values presented in Table 1 below can be used. ΔCt values below the cut-off can be treated as negative for a given biomarker, and any ΔCt values above the cut-off can be treated as positive. ΔCt greater than 12 should be repeated.

Target	ΔCt Cut off
ESR1	-1.98
PGR	-0.63
ERBB2	2.00
MK167	-0.64

Table 1. Assay ΔCt cut off values calculated for the BC Subtyping kit targets

*Gene-level nomenclature, ER = ESR1, PR = PGR, HER2 = ERBB2, Ki67 = MKI67

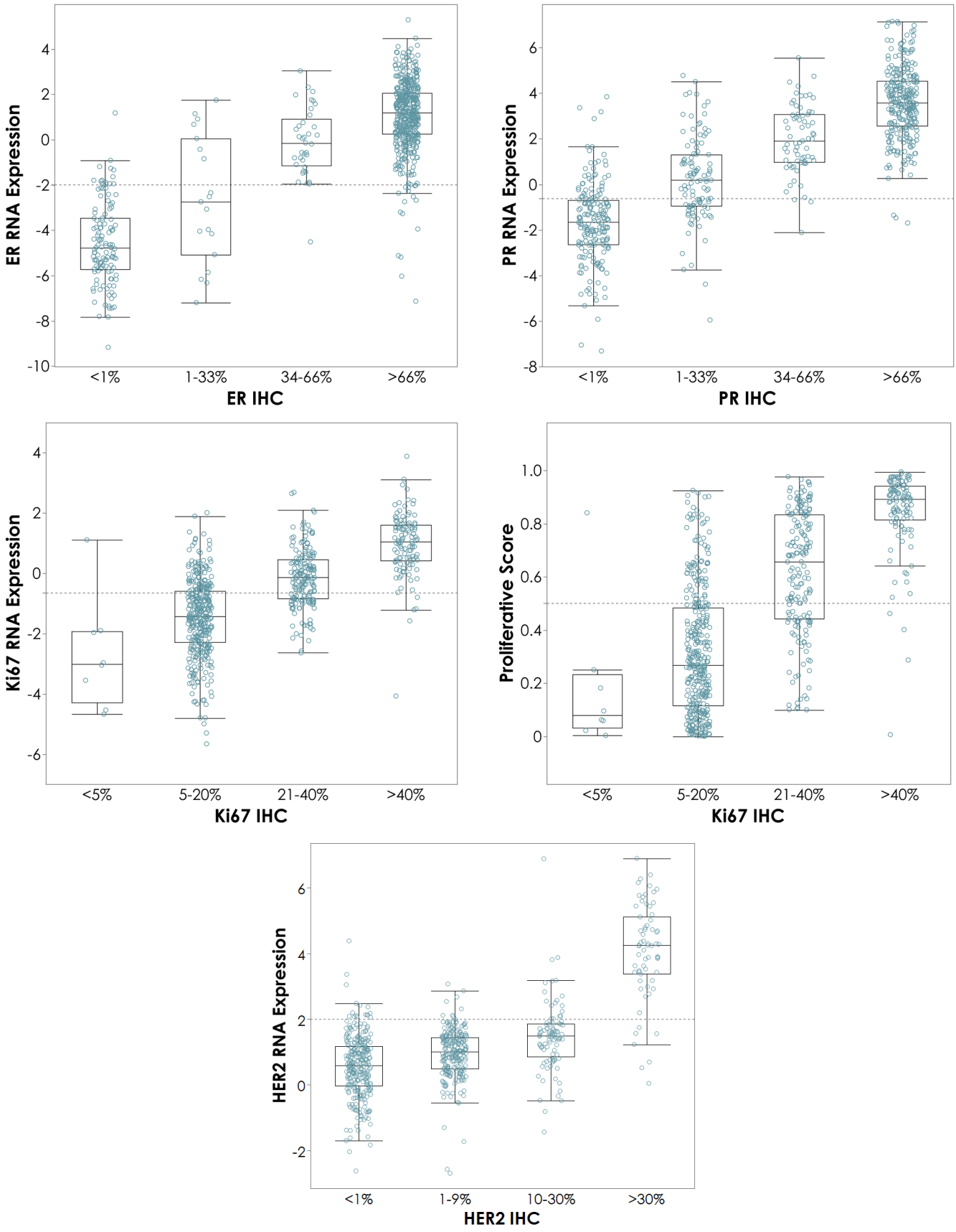
The subtype can be determined based on the individual target calls following Table 2.

Table 2. Subtyping logic table

ESR1	PGR	ERBB2	MKI67	Intrinsic subtype
+	-	-	-	Luminal A-like
+	+	-	-	Luminal A-like
-	+	-	-	Luminal A-like
+	+	-	+	Luminal B-like (HER2 negative)
+	-	-	+	Luminal B-like (HER2 negative)
-	+	-	+	Luminal B-like (HER2 negative)
+	-	+	+	Luminal B-like (HER2 positive)
+	-	+	-	Luminal B-like (HER2 positive)
+	+	+	-	Luminal B-like (HER2 positive)
+	+	+	+	Luminal B-like (HER2 positive)
-	+	+	-	Luminal B-like (HER2 positive)
-	+	+	+	Luminal B-like (HER2 positive)
-	-	+	+	HER2 enriched (non-luminal)
-	-	+	-	HER2 enriched (non-luminal)
-	-	-	-	Triple Negative
-	-	-	+	Triple Negative

APIS Breast Cancer Subtyping Kit Performance

Comparison of APIS Breast Cancer Subtyping Kit expression measure (ΔCt) 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 (ΔCt 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 (%).

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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:

LINK medical

LINK Medical Solutions

Phone: +44 (0) 203 1373 193
Address: 85 Great Portland St, First Floor, London, W1W 7LT
Email: info@linkmedicalsolutions.com

International distributor:

Distributed by BIOCARTIS

Biocartis

Phone: +32 (0) 15 632 600
Address: Generaal De Wittelaan 11B, 2800 Mechelen, Belgium
Email: info@biocartis.com

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.

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