



Assay Technologies Ltd.



## Apis Assay's Breast Cancer Subtyping Kit

The Apis Breast Cancer Subtyping kit is a highly reproducible, RNA-based diagnostic workflow for detecting mRNA expression of standard biomarkers (ER, PR, HER2, Ki67) and novel proliferative biomarkers from pre-operative core-needle biopsy (CNB) or resected formalin-fixed paraffin-embedded (FFPE) breast tumour tissue.

### Breast Cancer Diagnosis

#### Current Clinical Practice

- Understanding breast cancer tumour biology through molecular subtyping of widely used standard markers is critical for the selection of systemic therapy (hormone, targeted, chemotherapy) <sup>1,2,3</sup>
- Current standard-of-care recommends measuring the abundance of these markers using immunohistochemistry (IHC)

### Breast Cancer Subtyping

#### Current Clinical Unmet Needs

- Higher reproducibility of current biomarker calling due to reported high inter- and intra-laboratory variability <sup>4,5,6</sup>
- Faster HER2 result turnaround, without the need for reflex testing (e.g. to resolve initial 2+ cases using ISH)
- Higher accuracy of Ki67 proliferation measurement
- Significantly reduce histopathologist time for results interpretation

#### References

- Senkus et al. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncology* 24 (Supplement 6): vi7–vi23, 2013
- Beyers et al. NCCN clinical practice guidelines in oncology: breast cancer screening and diagnosis. *Journal of the National Comprehensive Cancer Network*. 2009 Nov; 7(10):1060-96
- Curigliano et al. De-escalating and escalating treatments for stage early-stage breast cancer: the St. Gallen International Expert Consensus Conference on the Primary Therapy of Early Breast Cancer 2017. *Annals of Oncology*. 28, 1700–1712 (2017)
- Hammond et al. American society of clinical oncology/college of American pathologists guideline recommendations for immunohistochemical testing of estrogen and progesterone receptors in breast cancer. Vol. 28, *Journal of Clinical Oncology*. American Society of Clinical Oncology; 2010. p. 2784–95
- Van Bockstal et al. Interobserver Variability in Ductal Carcinoma In Situ of the Breast, *American Journal of Clinical Pathology*, Volume 154, Issue 5, November 2020, Pages 596–609
- Van Doijeweert C et al. Histopathologic grading of breast cancer; large variation with major consequences? *Ned Tijdschr Geneeskd*. 2021 Jan 14;164:D5441. Dutch. PMID: 33651508

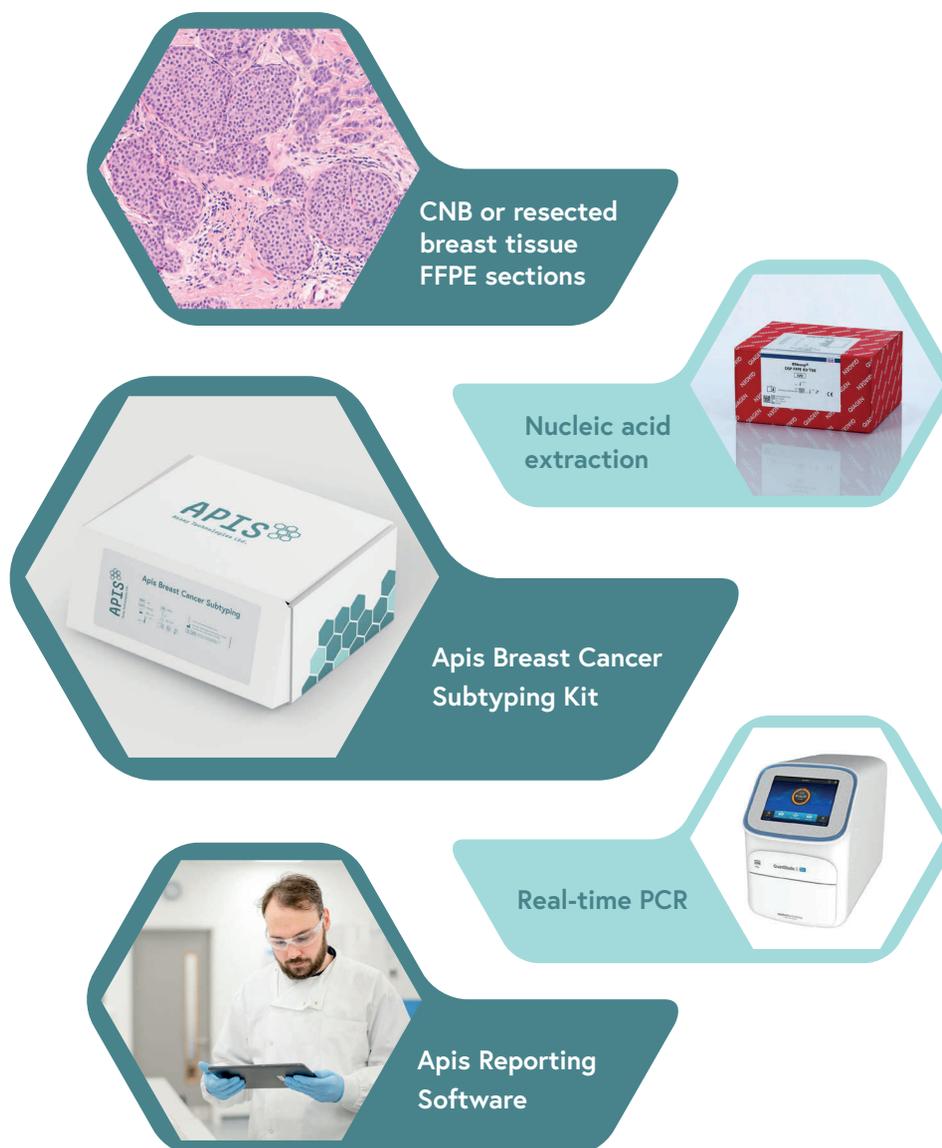
## Apis Assay's Solution Breast Cancer Subtyping Kit

The Apis Breast Cancer Subtyping Kit:

- 1 Delivers highly repeatable and reproducible results for the same patient sample, tested in different laboratories
- 2 Provides a single high-resolution method for determining HER2 amplification
- 3 Utilises a novel four-gene proliferative signature to improve the use of Ki67 alone for measuring proliferation
- 4 Is accompanied by validated software that enables automatic results interpretation

Figure 1.

## Apis Breast Cancer Subtyping Kit Workflow



The Apis Breast Cancer Subtyping Kit is currently available as an IVD product (in certain territories) and as a Research Use Only product. For more information on this product please contact [info@apisassay.com](mailto:info@apisassay.com).