BREAST CANCER ASSAY PORTFOLIO





IDYLLA™ PIK3CA-AKT1 MUTATION ASSAY

The Idylla[™] PIK3CA-AKT1 Mutation Assay (RUO), performed on the Biocartis **Idylla[™]** System, is a **fully automated** real-time PCR Assay for the qualitative detection of **13 PIK3CA** mutations across exons 4, 7, 9 and 20 and **1 AKT1 mutation** in exon 2, using only one **FFPE** tissue section.

The Idylla[™] PIK3CA- AKT1 Mutation Assay covers the **entire process from FFPE sample to result,** including fully integrated sample preparation, liberation of nucleic acids, real-time PCR amplification and detection, and data analysis.







APIS PIK3CA qPCR KIT

The APIS PIK3CA Mutations Kit (RUO) is a real-time qualitative PCR test for the detection of the **5 most prevalent activating mutations in the PIK3CA gene** across exons 7, 9 and 20, using DNA extracted from either **FFPE** breast tumor tissue (gDNA) or **blood** plasma (cfDNA).

The kit includes mutation-specific probes to enable **highly sensitive** detection of the target mutations. Perfect for use in **decentralised laboratories without the need for specialised equipment.**





CONTACT US









APIS ESR1 qPCR KIT

The APIS ESR1 qPCR Kit (RUO) is an advanced real-time qualitative PCR (qPCR) assay designed for the detection of **11 estrogen receptor (ESR1) mutations** across exons 5, 7 and 8, using DNA extracted from either **FFPE** breast tumor tissue (gDNA) or **blood** plasma (cfDNA).

The kit includes mutation-specific probes to enable **highly sensitive** detection of the target mutations. Perfect for use in **decentralised laboratories without the need for specialised equipment.**

APIS ESR1 dPCR KIT

The APIS ESR1 dPCR Kit (RUO) is a digital PCR (dPCR) assay designed for detection of **11 estrogen receptor (ESR1)** mutations across exons 5, 7 and 8, using DNA extracted from either **FFPE** breast tumor tissue (gDNA) or **blood** plasma (cfDNA).

The kit includes mutation-specific probes to enable **highly sensitive** detection of the target mutations. Suitable for both **centralized and decentralized laboratories** and is **compatible with most digital PCR systems.**

APIS BREAST CANCER SUBTYPING KIT

The APIS Breast Cancer Subtyping Kit (RUO) is a gene expression assay based on **RT-qPCR.** The kit detects and enables relative gene expression quantification of standard biomarkers **HER2, ER, PR, Ki67** and a **novel proliferative signature,** using pre-operative core needle biopsies **(CNB)** or **FFPE** breast tumor tissue.

Providing a single resolution method for HER2 detection with the opportunity **to enhance HER2 stratification.** The test serves as an alternative method to current standard of care – IHC.











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Idylla[™] Platform is CE-marked in Europe in compliance with EU IVD Regulation 2017/746. Idylla[™] PIK3CA-AKT1 Mutation Assay is for Research Use Only (RUO), not for use in diagnostic procedures, and has been developed in collaboration with LifeArc. APIS PIK3CA qPCR Kit, APIS ESR1 qPCR Kit, APIS ESR1 dPCR Kit and APIS Breast Cancer Subtyping Kit are for Research Use Only (RUO), not for use in diagnostic procedures, developed by APIS and distributed by Biocartis. APIS data and conclusions provided in this leaflet have not been validated by Biocartis NV. Biocartis and Idylla[™] are registered trademarks in Europe, the US and many other countries. The Biocartis and Idylla[™] trademarks and logos are used trademarks owned by Biocartis. Idylla[™] is available for sale in Europe, the US and many other countries. Please check availability with a Biocartis representative. © April 2025, Biocartis NV. All rights reserved.