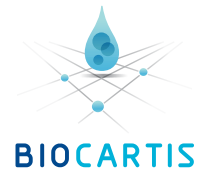


# BREAST CANCER ASSAY PORTFOLIO

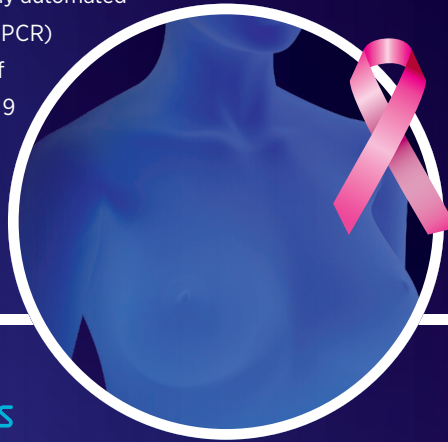


## IDYLLA™ PIK3CA-AKT1 MUTATION ASSAY

For fast, fully automated and sensitive PIK3CA & AKT1 mutations detection via the Idylla™ Platform



The Idylla™ PIK3CA-AKT1 Mutation Assay (RUO), performed on the Biocartis Idylla™ System, is a fully automated real-time polymerase chain reaction (PCR) Assay for the qualitative detection of 13 PIK3CA mutations across exons 4, 7, 9 and 20 and one AKT1 mutation in exon 2, in formalin-fixed, paraffin-embedded (FFPE) tissue sections.



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

For efficient and reliable PIK3CA gene mutations detection via qPCR



The APIS PIK3CA Mutations Kit (RUO) is a real-time qualitative PCR test for the detection of the five most prevalent activating mutations in the PIK3CA gene across exons 7, 9 and 20, using DNA extracted from either formalin-fixed, paraffin-embedded (FFPE) breast tumor tissue (gDNA) or blood plasma (cfDNA). The kit includes mutation-specific probes to enable highly sensitive detection of the target mutations. Additionally, it uses PCR clamp and blocker technology, which ensures specific amplification of the mutant sequence, even in the presence of a high wild-type background.

## APIS BREAST CANCER SUBTYPING KIT

For fast classification of breast cancer



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



## APIS ESR1 dPCR KIT

For reliable and precise estrogen receptor gene mutations detection via dPCR



The APIS ESR1 dPCR Kit (RUO) is a digital PCR (dPCR) workflow allowing for reliable detection of mutations within the estrogen receptor (ESR1) gene. The kit detects 11 ESR1 mutations across exons 5, 7 and 8.



## APIS ESR1 MUTATIONS KIT

For fast and easy estrogen receptor gene mutations detection via qPCR



The APIS ESR1 Mutations Kit (RUO) is an advanced real-time PCR assay for the sensitive and precise detection of mutations within the estrogen receptor gene. The APIS ESR1 Mutations Kit is a qualitative test, detecting 11 ESR1 mutations across exons 5, 7 and 8.

## APIS ESR1 MUTATIONS CONTROLS

For quality control of assays detecting estrogen receptor gene mutations



The APIS ESR1 Mutations Controls (RUO) serve as a quality control material and can be used for estrogen receptor gene (ESR1) mutations assay validations, or alongside the APIS ESR1 Mutations Kit as run validity controls. The product consists of two tubes, a negative and a positive control. The positive control contains DNA fragments encoding eleven mutations within the ESR1 gene, as well as a reference sequence encoding a fragment of exon 3.



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