

BIOCARTIS

BREAST CANCER PORTFOLIO



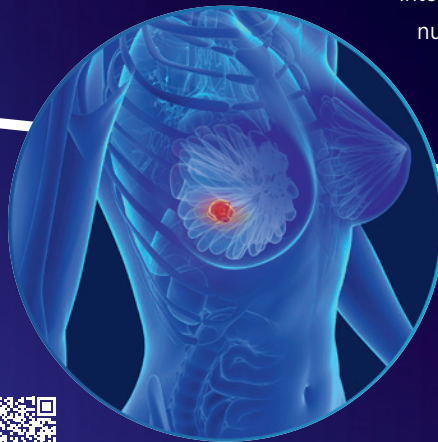
IDYLLA™ PIK3CA-AKT1 MUTATION ASSAY

For fast biomarker results on the fully automated 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 mutations in the *PIK3CA* gene and

one mutation in the *AKT1* gene in formalin-fixed, paraffin-embedded (FFPE) human 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
Analytical Pathology
Innovations



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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 tumour tissue.

APIS ESR1 MUTATIONS KIT

For fast
biomarker
results



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 three exons: exon 5 (E380Q), exon 7 (S463P) and exon 8 (P535H, L536R, L536Q, L536H L536P, Y537C, Y537S, Y537N and D538G).



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Idylla™ Platform is available as an IVD in Europe, the US and many other countries. Idylla™ is available for sale in Europe, the US and many other countries. Idylla™ PIK3CA-AKT1 Mutation Assay is available for Research Use Only. Not for use in diagnostic procedures. APIS Breast Cancer Subtyping Kit and APIS ESR1 Mutations Kit are for Research Use Only (RUO), not for use in diagnostic procedures, developed by APIS and distributed by Biocartis, available for sale in selected European countries. 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. Please check availability with a Biocartis representative. © September 2023, Biocartis NV. All rights reserved.

