

BECAUSE
TIME MATTERS

IDYLLA™
PIK3CA-AKT1
MUTATION ASSAY



THINK IDYLLA™
BECAUSE TIME MATTERS

INTRODUCING IDYLLA™ PIK3CA-AKT1 MUTATION ASSAY

FOR THE MOLECULAR CHARACTERIZATION OF PIK3CA AND AKT1 IN FFPE TUMOR TISSUE SECTIONS



Qualitative detection of **13 PIK3CA** mutations and **1 AKT1** mutation in a single cartridge



Automated result interpretation and test reporting



Less than 2 minutes hands-on time (HOT)
Assay turnaround time (TAT) of approx. 150 minutes



Directly from FFPE tumor tissue sections

SPECIMEN REQUIREMENTS

- 50-600 mm² tissue area for 5 μm FFPE tissue sections
- 25-300 mm² tissue area for 10 μm FFPE tissue sections
- ≥ 20% neoplastic cells



PIK3CA AND AKT1 FACTS

PIK3CA activating mutations have been identified in a broad spectrum of solid tumors¹. In Hormone Receptor (HR)+ breast cancer samples, the prevalence of PIK3CA mutations is 30% to 40%². The Idylla™ PIK3CA-AKT1 Mutation Assay detects the most prevalent PIK3CA mutations in breast cancer.

	Distribution of mutations in PIK3CA mutated breast cancer (%)	Idylla™ PIK3CA-AKT1 Mutation Assay
H1047R	35.0	✓
E545K	17.5	✓
E542K	10.7	✓
N345K	5.5	✓
H1047L	4.0	✓
C420R	1.9	✓
Q546R	1.1	✓
Q546K	< 1.0	✓
E545A	< 1.0	✓
E545G	< 1.0	✓
E545D	< 1.0	✓
Q546E	< 1.0	✓
H1047Y	< 1.0	✓

AKT1-E17K mutations account for 3% of the mutations in HR+ breast cancer samples and are an emerging biomarker in the development of targeted therapies³.



IDYLLA™ PIK3CA-AKT1 MUTATION ASSAY SHOWS EXCELLENT PERFORMANCE AGAINST NGS

The Idylla™ PIK3CA-AKT1 Mutation Assay provides a rapid actionable solution which can be seamlessly integrated into virtually any laboratory workflow. The Assay demonstrated 100% concordance with NGS for the presence or absence of PIK3CA and AKT1 mutations in 31 FFPE breast cancer samples with three replicates. The comparison of the results is shown below.

Idylla™	Next Generation Sequencing							TOTAL
	N345K	E542K	E545K	H1047R	H1047L	E17K	WT	
N345K	15							
E542K		12						
E545K			18					
H1047R				30				
H1047L					3			
E17K						3		
WT							15	
TOTAL								96

Positive Percent Agreement (PPA): 100%

Negative Percent Agreement (NPA): 100%

REFERENCES

- (1) Ligresti et al. PIK3CA mutations in human solid tumors. *Cell Cycle*. 2009; 8(9): 1352-1358.
- (2) Martínez-Sáez et al. Frequency and spectrum of PIK3CA somatic mutations in breast cancer. *Breast Cancer Res*. 2020 May 13;22(1):45.
- (3) Turner et al. Capivasertib in Hormone Receptor-Positive Advanced Breast Cancer. *NEJM*. 2023; 388:2058-70.

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