

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	PIK3CA-E545G 50% AF FFPE Reference Standard		
DESCRIPTION	Human FFPE Reference Standard (curl)		
CATALOG NUMBER	SID-000106		
BATCH NUMBER	00190		
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · Manufactured according to DIN EN ISO 13485:2016 · At room temperature 		
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> · 2D barcoded tube with screw cap · Material: Polypropylen (PP) 		
DATE OF MANUFACTURE	04.03.2021		
EXPIRY DATE	03.03.2023		
FORMAT	10 µm section / curl		
MUTATION * GRCh38 COSMIC v91	PIK3CA p.E545G (COSM764*, COSV55873220*, substitution, c.1634A>G, Exon 9)		
ALLELE FREQUENCY	50.0%		
QUALITY	<p>DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K).</p> <p>The copy number values are metrologically traceable to the natural units count 1 and ratio 1 and International System of Units (SI) derived units of volume.</p>		
STORAGE CONDITIONS	<p>Short term storage (up to 30 days): 2-8°C</p> <p>Long term storage: -18 to -25°C</p>		
MANUFACTURING SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany		
TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method	Acceptance criteria
	Cell density	Visual	> 60%
	Quantification	dsDNA measurement: Qubit** dsDNA BR Assay Kit (Invitrogen) RNA measurement: Qubit** RNA BR Assay Kit (Invitrogen)	dsDNA: > 400 ng RNA > 400 ng
	Allele frequency	Allele frequency analysis by ddPCR** (BioRad QX200™)	AF 50.0 % (45.0-55.0 %)
**Measured after extraction with Qiagen AllPrep DNA/RNA FFPE Kit			

RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Cell density	> 60%		PASS
	Quantification	671.5 ng (dsDNA)		PASS
		1218 ng (RNA)		PASS
	Allele frequency	Mutation	AF in %	PASS / FAIL
PIC3CA p.E545G		50.00	PASS	
COMMENTS / REMARKS	<p>Additional information:</p> <p>1) Theoretical DNA yield from 1 curl (assumption diploid chromosome set) 3164 ng</p> <p>2) Measurement of copy number</p>			
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng extracted DNA	CN mut/ng extracted DNA	
	PIC3CA p.E545G	177	177	
	wt: wildtype; mut: mutation			
	<p><i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~10 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per nanogram extracted DNA are based on droplet digital (ddPCR) assay counts dilution factors, and droplet volume measurements. The detection of the amount of CNs may vary depending on the assay used. Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.</i></p>			

Name and position/title of person authorising the batch release:

Björn Nowack, Managing Director

Date of batch release: 04.05.2021

Signature batch release: Björn Nowack

This document has been created electronically and is valid without signature.