BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	Ashkenazim Son FFPE Reference Standard		
DESCRIPTION	Human FFPE Reference Standard (curl)		
CATALOG NUMBER	SID-000100		
BATCH NUMBER	**00531**		
MANUFACTURING CONDITIONS	· Manufactured according to DIN EN ISO 13485:2016		
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)		
DATE OF MANUFACTURE	10.07.2023		
EXPIRY DATE	09.07.2025		
FORMAT	10 µm section / curl		
MUTATION * GRCh38 COSMIC v97	PIK3CA p.E542K (COSV55873227*, substitution, c.1624G>A, Exon 9)		
	PIK3CA p.E545G (COSV55873220*, substitution, c.1634A>G, Exon 9)		
	PIK3CA p.H1047R (COSV55873195*, substitution, c.3140A>G, Exon 20)		
ALLELE FREQUENCY	0%		
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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.		
STORAGE CONDITIONS	Short term storage (up to 30 days): + 2-8°C Long term storage: - 18 to - 25°C		
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)	dsDNA: > 400 ng
	Quantification	RNA measurement: Qubit** RNA BR Assay Kit (Invitrogen)	RNA > 400 ng
	Allele frequency	Allele frequency analysis by ddPCR** (BioRad QX200™)	AF: 0.00% (0.00 – 0.03%)
	**Measured after extraction with Qiagen AllPrep DNA/RNA FFPE Kit		

RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Cell density	> 60%		PASS
	Quantification	687.9 ng (dsDNA)		PASS
		3024.5 ng (RNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		PIK3CA p.E542K	0.00	PASS
		PIK3CA p.E545G	0.00	PASS
		PIK3CA p.H1047R	0.00	PASS
COMMENTS / REMARKS	Additional information: 1) Theoretical DNA yield from 1 curl (assumption diploid chromosome set) 2833 ng 2) Measurement of copy number			
MEASUREMENT OF COPY NUMBER	Mutation		CN wt/ng extracted DNA	CN mut/ng extracted DNA
	PIK3CA p.E542K		508.00	0.00
	PIK3CA p.E545G		480.02	0.00
	PIK3CA p.H1047R		450.42	0.00
	wt: wildtype; mut: mutation			
	The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of 1 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.			

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

Björn Nowack, Managing Director

Date of batch release: 16.08.2023

Signature batch release: Björn Nowack

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