

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	ESR1 & PIK3CA Reference Vial 4 1 % AF cfDNA		
DESCRIPTION	ESR1 & PIK3CA Reference Vial 4 1 % AF cfDNA is part of ESR1 & PIK3CA Reference Set 1 % AF cfDNA (SID-000157). It consists of highly characterized human DNA from cell line containing ESR1 and PIK3CA mutations.		
CATALOG NUMBER	SID-000161		
BATCH NUMBER	00821		
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · Manufactured and sealed in class 2 safety cabinet · Manufactured according to DIN EN ISO 13485:2016 		
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> · 2D barcoded tube with screw cap · Material: Polypropylen (PP) 		
DATE OF MANUFACTURE	24.10.2024		
EXPIRY DATE	23.10.2026		
TARGET CONCENTRATION	10 ng/μl		
TARGET QUANTITY	250 ng		
NOMINAL VOLUME	25 μl		
MUTATION *GRCh38 COSMIC v99	ESR1 p.S463P (COSV52784970*, substitution, c.1387T>C, Exon 7) ESR1 p.Y537N (COSV52784978*, substitution, c.1609T>A, Exon 8) PIK3CA p.H1047R (COSV55873195* substitution, c.3140A>G, Exon 20) PIK3CA p.E545G (COSV55873220*, substitution, c.1634A>G, Exon 9)		
ALLELE FREQUENCY	1.00 %		
QUALITY	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	+ 2-8 °C		
MANUFACTURING SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany		
TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method	Acceptance criteria
	Fragmentation	Fragment length analysis: Agilent D5000 ScreenTape System (Agilent Technologies)	Peak size 167 bp ± 15 % (142 bp – 192 bp)
	Quantification	dsDNA measurement: Qubit™ 1X dsDNA HS Assay-Kit (Invitrogen)	dsDNA: 10.0 ng/μl ± 15 % (8.5 – 11.5 ng/μl)
	Allele frequency	Allele frequency analysis: dPCR (QIAGEN® QIAcuity Four)	AF 1.00 % ± 40 % (0.60 – 1.40 %)

RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	176 bp		PASS
	Quantification	9.7 ng/μl (dsDNA)		PASS
	Allele frequency	Mutation	AF in %	PASS / FAIL
		ESR1 p.S463P	1.05	PASS
		ESR1 p.Y537N	1.07	PASS
PIK3CA p.H1047R		1.39	PASS	
	PIK3CA p.E545G	0.90	PASS	
COMMENTS / REMARKS	Additional information: Measurement of copy number			
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng	CN mut/ng	
	ESR1 p.S463P	409.25	4.35	
	ESR1 p.Y537N	432.18	4.69	
	PIK3CA p.H1047R	417.60	5.87	
	PIK3CA p.E545G	476.72	4.32	
	wt: wildtype; mut: mutation <i>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 based on ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per nanogram (ng) are based on digital (dPCR) assay counts and dilution factors. 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>			

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

Björn Nowack, Managing Director

Date of batch release: 04.11.2024

Signature batch release: Björn Nowack

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