BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	ESR1 Reference Vial 1 1% AF cfDNA
DESCRIPTION	ESR1 Reference Vial 1 1% AF cfDNA is part of ESR1 Reference Set 1% AF cfDNA (SID-000144). It consists of highly characterized human DNA from cell line containing ESR1 p.L536H and ESR1 p.Y537C.
CATALOG NUMBER	SID-000145
BATCH NUMBER	**00731**
MANUFACTURING CONDITIONS	· Manufactured and sealed in class 2 safety cabinet · Manufactured according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	21.06.2024
EXPIRY DATE	20.06.2026
TARGET CONCENTRATION	10 ng/µl (dsDNA)
TARGET QUANTITY	250 ng (dsDNA)
NOMINAL VOLUME	25 µl
MUTATION * GRCh38 COSMIC v99	ESR1 p.L536H (COSV52795259*, substitution, c.1607T>A, Exon 8)
	ESR1 p.Y537C (COSV52782924*, substitution, c.1610A>G, Exon 8)
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 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	169 bp		PASS
	Quantification	10.3 ng/µl (dsDNA)		PASS
	Allele frequency	Mutation	AF in %	PASS / FAIL
		ESR1 p.L536H	1.06	PASS
		ESR1 p.Y537C	1.12	PASS
COMMENTS / REMARKS	Additional information: Measurement of copy number			
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng	CN mut/ng	
	ESR1 p.L536H	384.69	4.12	
	ESR1 p.Y537C	403.05	4.56	
	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 (ng) are based on digital (dPCR) 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: 02.07.2024

Signature batch release: Björn Nowack

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