

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	ESR1 Reference Vial 5 WT 0% AF cfDNA
DESCRIPTION	ESR1 Reference Vial 5 WT 0% AF cfDNA is part of ESR1 Reference Set 1% AF cfDNA (SID-000144). It consists of highly characterized human DNA from cell line, tested negative for 9 different ESR1 mutations.
CATALOG NUMBER	SID-000149
BATCH NUMBER	00604
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · Manufactured und 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	23.11.2023
EXPIRY DATE	22.11.2025
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	20 μl
MUTATION * GRCh38 COSMIC v99	<p>ESR1 p.L536H (COSV52795259*, substitution, c.1607T>A, Exon 8)</p> <p>ESR1 p.Y537C (COSV52782924*, substitution, c.1610A>G, Exon 8)</p> <p>ESR1 p.L536P (COSV52782930*, substitution, c.1607T>C, Exon 8)</p> <p>ESR1 p.Y537S (COSV52783938*, substitution, c.1610A>C, Exon 8)</p> <p>ESR1 p.L536R (COSV52787207*, substitution, c.1607T>G, Exon 8)</p> <p>ESR1 p.D538G (COSV52781024*, substitution, c.1613A>G, Exon 8)</p> <p>ESR1 p.E380Q (COSV52782264*, substitution, c.1138G>C, Exon 5)</p> <p>ESR1 p.S463P (COSV52784970*, substitution, c.1387T>C, Exon 7)</p> <p>ESR1 p.Y537N (COSV52784978*, substitution, c.1609T>A, Exon 8)</p>
ALLELE FREQUENCY	0.00%
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	+ 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	Total DNA measurement (ssDNA): Spectrophotometry**		Total DNA: not applicable	
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		dsDNA: 20.0 ng/μl ± 15% (17.0 – 23.0 ng/μl)	
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed				
	Allele frequency	Allele frequency analysis: ddPCR (BioRad QX200™)		AF 0.00% (0.00 – 0.03%)	
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL	
	Fragmentation	165 bp		PASS	
	Quantification	43.6 ng/μl (total DNA)		PASS	
		20.3 ng/μl (dsDNA)			
	Allele frequency	Mutation	AF in %	PASS / FAIL	
		ESR1 p.L536H	0.00	PASS	
		ESR1 p.Y537C	0.00	PASS	
		ESR1 p.L536P	0.00	PASS	
		ESR1 p.Y537S	0.00	PASS	
		ESR1 p.L536R	0.00	PASS	
		ESR1 p.D538G	0.00	PASS	
ESR1 p.E380Q		0.00	PASS		
ESR1 p.S463P		0.00	PASS		
ESR1 p.Y537N	0.00	PASS			

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng	CN mut/ng
	ESR1 p.L536H	300.81	0.00
	ESR1 p.Y537C	288.45	0.00
	ESR1 p.L536P	300.77	0.00
	ESR1 p.Y537S	304.53	0.00
	ESR1 p.L536R	301.24	0.01
	ESR1 p.D538G	298.27	0.00
	ESR1 p.E380Q	245.23	0.01
	ESR1 p.S463P	303.69	0.00
	ESR1 p.Y537N	308.80	0.00
	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 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 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: 28.11.2023

Signature batch release: Björn Nowack

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