

## 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
<b>BATCH NUMBER</b>	<b>00735</b>
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> <li>· Manufactured and sealed in class 2 safety cabinet</li> <li>· Manufactured according to DIN EN ISO 13485:2016</li> </ul>
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> <li>· 2D barcoded tube with screw cap</li> <li>· Material: Polypropylen (PP)</li> </ul>
DATE OF MANUFACTURE	21.06.2024
EXPIRY DATE	20.06.2026
TARGET CONCENTRATION	10 ng/μl (dsDNA)
TARGET QUANTITY	800 ng (dsDNA)
NOMINAL VOLUME	80 μl
MUTATION * GRCh38 COSMIC v99	<p>ESR1 p.L536H (COSV52795259*, substitution, c.1607T&gt;A, Exon 8)</p> <p>ESR1 p.Y537C (COSV52782924*, substitution, c.1610A&gt;G, Exon 8)</p> <p>ESR1 p.L536P (COSV52782930*, substitution, c.1607T&gt;C, Exon 8)</p> <p>ESR1 p.Y537S (COSV52783938*, substitution, c.1610A&gt;C, Exon 8)</p> <p>ESR1 p.L536R (COSV52787207*, substitution, c.1607T&gt;G, Exon 8)</p> <p>ESR1 p.D538G (COSV52781024*, substitution, c.1613A&gt;G, Exon 8)</p> <p>ESR1 p.E380Q (COSV52782264*, substitution, c.1138G&gt;C, Exon 5)</p> <p>ESR1 p.S463P (COSV52784970*, substitution, c.1387T&gt;C, Exon 7)</p> <p>ESR1 p.Y537N (COSV52784978*, substitution, c.1609T&gt;A, Exon 8)</p>
ALLELE FREQUENCY	0.00%
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 0.00% (0.00 – 0.03%)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	174 bp		PASS
	Quantification	10.4 ng/μl (dsDNA)		PASS
	Allele frequency	Mutation	AF in %	PASS / FAIL
		ESR1 p.L536H	0.01	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	0.03	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	413.54	0.03
	ESR1 p.Y537C	420.45	0.00
	ESR1 p.L536P	413.57	0.00
	ESR1 p.Y537S	419.55	0.00
	ESR1 p.L536R	411.80	0.00
	ESR1 p.D538G	415.61	0.12
	ESR1 p.E380Q	349.46	0.01
	ESR1 p.S463P	404.96	0.00
	ESR1 p.Y537N	414.80	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 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.</i></p>			

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

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