BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	ESR1 & PIK3CA Reference Vial 5 WT 0 % AF cfDNA
DESCRIPTION	ESR1 & PIK3CA Reference Vial 5 WT 0 % AF cfDNA is part of ESR1 & PIK3CA Reference Set 1 % AF cfDNA (SID-000157). It consists of highly characterized human DNA from cell line, tested negative for eight different ESR1 and eight different PIK3CA mutations.
CATALOG NUMBER	SID-000162
BATCH NUMBER	**00822**
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	24.10.2024
EXPIRY DATE	23.10.2026
TARGET CONCENTRATION	10 ng/µl
TARGET QUANTITY	1250 ng
NOMINAL VOLUME	125 µl
MUTATION / FUSION *GRCh38 COSMIC v99	ESR1 p.E380Q (COSV52782264*, substitution, c.1138G>C, Exon 5)
	ESR1 p.Y537C (COSV52782924*, substitution, c.1610A>G, Exon 8)
	ESR1 p.L536P (COSV52782930*, substitution, c.1607T>C, Exon 8)
	ESR1 p.Y537S (COSV52783938*, substitution, c.1610A>C, Exon 8)
	ESR1 p.L536R (COSV52787207*, substitution, c.1607T>G, Exon 8)
	ESR1 p.D538G (COSV52781024*, substitution, c.1613A>G, Exon 8)
	ESR1 p.S463P (COSV52784970*, substitution, c.1387T>C, Exon 7)
	ESR1 p.Y537N (COSV52784978*, substitution, c.1609T>A, Exon 8)
	PIK3CA p.E545A (COSV55873209*, substitution, c.1634A>C, Exon 9)
	PIK3CA p.C420R (COSV55874020* substitution, c.1258T>C, Exon 7)
	PIK3CA p.E542K (COSV55873227*, substitution, c.1624G>A, Exon 9)
	PIK3CA p.Q546R (COSV55876869* substitution, c.1637A>G, Exon 9)
	PIK3CA p.E545K (COSV55873239*, substitution, c.1633G>A, Exon 9)
	PIK3CA p.H1047Y (COSV55876499* substitution, c.3139C>T, Exon 20)
	PIK3CA p.H1047R (COSV55873195* substitution, c.3140A>G, Exon 20)
	PIK3CA p.E545G (COSV55873220*, substitution, c.1634A>G, Exon 9)
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 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 0.00 % (0.00 – 0.03 %)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	170 bp		PASS
	Quantification	9.8 ng/µl (dsDNA)		PASS
	Allele frequency	Mutation	AF in %	PASS / FAIL
		ESR1 p.E380Q	0.00	PASS
		ESR1 p.Y537C	0.01	PASS
		ESR1 p.L536P	0.02	PASS
		ESR1 p.Y537S	0.00	PASS
		ESR1 p.L536R	0.00	PASS
		ESR1 p.D538G	0.00	PASS
		ESR1 p.S463P	0.02	PASS
		ESR1 p.Y537N	0.02	PASS
		PIK3CA p.E545A	0.00	PASS
		PIK3CA p.C420R	0.00	PASS
		PIK3CA p.E542K	0.00	PASS
		PIK3CA p.Q546R	0.00	PASS
		PIK3CA p.E545K	0.00	PASS
		PIK3CA p.H1047Y	0.00	PASS
		PIK3CA p.H1047R	0.00	PASS
		PIK3CA p.E545G	0.00	PASS

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng	CN mut/ng
	ESR1 p.E380Q	380.38	0.00
	ESR1 p.Y537C	443.92	0.04
	ESR1 p.L536P	406.71	0.09
	ESR1 p.Y537S	447.42	0.01
	ESR1 p.L536R	440.63	0.00
	ESR1 p.D538G	448.39	0.00
	ESR1 p.S463P	425.50	0.09
	ESR1 p.Y537N	440.57	0.07
	PIK3CA p.E545A	494.57	0.00
	PIK3CA p.C420R	530.30	0.00
	PIK3CA p.E542K	461.47	0.02
	PIK3CA p.Q546R	496.35	0.00
	PIK3CA p.E545K	502.11	0.00
	PIK3CA p.H1047Y	461.73	0.00
	PIK3CA p.H1047R	436.69	0.00
	PIK3CA p.E545G	491.17	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 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.		

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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