Bringing Precision to MDx

Release Date	25.10.2024
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BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	ESR1 & PIK3CA Reference Vial 2 1 % AF cfDNA		
DESCRIPTION	ESR1 & PIK3CA Reference Vial 2 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-000159		
BATCH NUMBER	**00819**		
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	250 ng		
NOMINAL VOLUME	25 µl		
MUTATION *GRCh38 COSMIC v99	ESR1 p.L536P (COSV52782930*, substitution, c.1607T>C, Exon 8)		
	ESR1 p.Y537S (COSV52783938*, substitution, c.1610A>C, Exon 8)		
	PIK3CA p.E542K (COSV55873227*, substitution, c.1624G>A, Exon 9)		
	PIK3CA p.Q546R (COSV55876869* substitution, c.1637A>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	174 bp		PASS
	Quantification	10.1 ng/µl (dsDNA)		PASS
	Allele frequency	Mutation	AF in %	PASS / FAIL
		ESR1 p.L536P	1.21	PASS
		ESR1 p.Y537S	1.15	PASS
		PIK3CA p.E542K	0.96	PASS
		PIK3CA p.Q546R	1.17	PASS
COMMENTS / REMARKS	Additional information: Measurement of copy number			

MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng	CN mut/ng
	ESR1 p.L536P	423.71	5.21
	ESR1 p.Y537S	434.11	5.04
	PIK3CA p.E542K	477.30	4.63
	PIK3CA p.Q546R	478.43	5.66
	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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