BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 5 % AF cfDNA
DESCRIPTION	EGFR-Multiplex 5 % AF cfDNA is highly characterized human DNA from cell line.
CATALOG NUMBER	SID-000019
BATCH NUMBER	**00522**
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · Produced according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	16.08.2023
EXPIRY DATE	15.08.2026
TARGET CONCENTRATION	20 ng/µl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	20 µl
MUTATION * GRCh38 COSMIC v97	EGFR p.L858R (COSV51765161*, substitution, c.2573T>G, Exon 21)
	EGFR p.L861Q (COSV51766344*, substitution, c.2582T>A, Exon 21)
	EGFR p.S768I (COSV51768106* substitution, c.2303G>T, Exon 20)
	EGFR p.E746_A750delELREA (COSV51765066*, deletion, c.2236_2250del15, Exon 19)
	EGFR p.T790M (COSV51765492*, substitution, c.2369C>T, Exon 20)
	EGFR p.G719S (COSV51767289*, substitution, c.2155G>A, Exon 18)
	EGFR p.V769_D770insASV (new: p.A767_V769dup) (COSV51850427* Insertion, c.2303_2304insTGTGGCCAG, Exon 20)
	EGFR p.S752_I759delSPKANKEI (COSV51774879*, deletion, c.2254_2277del24, Exon 19)
ALLELE FREQUENCY	5.0 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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	Total DNA measurement (ssDNA): Spectrophotometry**		Total DNA: not applicable
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		dsDNA: >20.0 ng/µl
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed			
	Allele frequency	Allele frequency analysis: ddPCR (BioRad QX200™)		AF 5.0 % ± 30 % (3.5 – 6.5 %)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	176 bp		PASS
	Quantification	37.1 ng/µl (total DNA)		PASS
		22.0 ng/µl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		EGFR p.L858R	3.8	PASS
		EGFR p.L861Q[1)]	6.6 (6.3)	FAIL
		EGFR p.S768I	4.8	PASS
		EGFR p.E746_A750delELREA	6.1	PASS
		EGFR p.T790M	5.6	PASS
		EGFR p.G719S[1)]	6.6 (5.8)	FAIL
		EGFR p.V769_D770insASV	4.6	PASS
		EGFR p.S752_I759delSPANKEI	6.1	PASS
	[1)]Special lot release after internal data review based on: 1. ddPCR results of pre-QC (in brackets) within specification 2. cross-reactivity of highly similar targets at higher concentrations of spiked material causes out of specification result in final QC			

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng	CN mut/ng
	EGFR p.L858R	101	4
	EGFR p.L861Q	183	13
	EGFR p.S768I	80	4
	EGFR p.E746_A750delELREA	185	12
	EGFR p.T790M	184	11
	EGFR p.G719S	171	12
	EGFR p.V769_D770insASV	166	8
	EGFR p.S752_I759delSPANKEI	123	8
	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 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.		

Name and position/title of person authorising the batch release:

Björn Nowack, Managing Director

Date of batch release: 22.08.2023

Signature batch release: Björn Nowack

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