

## BATCH CERTIFICATE

For Research Use Only

### PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 1% AF cfDNA
DESCRIPTION	EGFR-Multiplex 1% AF cfDNA is an highly characterized human DNA from cell line.
CATALOG NUMBER	SID-000017
<b>BATCH NUMBER</b>	<b>00521</b>
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> <li>· Manufactured und sealed in class 2 safety cabinet</li> <li>· Produced 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	16.08.2023
EXPIRY DATE	15.08.2025
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	1.00%
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 1.00% ± 40% (0.60 – 1.40%)	
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	165 bp		PASS
	Quantification	33.5 ng/μl (total DNA)		PASS
		22 ng/μl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		EGFR p.L858R	0.70	PASS
		EGFR p.L861Q	1.07	PASS
		EGFR p.S768I	1.25	PASS
		EGFR p.E746_A750delELREA	1.02	PASS
		EGFR p.T790M	0.87	PASS
EGFR p.G719S		0.86	PASS	
EGFR p.V769_D770insASV		0.77	PASS	
EGFR p.S752_I759delSPANKEI	1.28	PASS		

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng	CN mut/ng
	EGFR p.L858R	101.93	0.72
	EGFR p.L861Q	183.56	1.99
	EGFR p.S768I	81.20	1.03
	EGFR p.E746_A750delELREA	205.12	2.11
	EGFR p.T790M	193.56	1.70
	EGFR p.G719S	180.45	1.56
	EGFR p.V769_D770insASV	177.54	1.38
	EGFR p.S752_I759delSPANKEI	129.29	1.67
	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: 22.08.2023

Signature batch release: Björn Nowack

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