

Batch Certificate

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 0% AF cfDNA
DESCRIPTION	EGFR-Multiplex 0 % AF cfDNA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000003
BATCH NUMBER	00015
MANUFACTURING CONDITIONS	• Manufactured and sealed in clean ISO 5 safety cabinet • Bottled with qualified liquid handling workstation • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
PACKAGE SIZE AND TYPE	
DATE OF MANUFACTURE	16.07.2019
EXPIRY DATE	16.07.2020
CONCENTRATION	20 ng/μl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	20 μl
MUTATION	p.G719S (COSM6252*, COSV51767289*, substitution, c.2155G>A, Exon 18) p.E746_A750delELREA (COSM6225*, COSV51765066*, deletion, c.2236_2250del15, Exon 19) p.S752_I759delSPKANKEI (COSM6256*, COSV51774879*, deletion, c.2254_2277del24, Exon 19) p.S768I (COSM6241*, COSV51768106* substitution, c.2303G>T, Exon 20) p.V769_D770insASV (COSM20884*, COSV51850427* Insertion, c.2303_2304insTGTGGCCAG, Exon 20) p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C>T, Exon 20) p.L858R (COSM6224*, COSV51765161*, substitution, c.2573T>G, Exon 21) p.L861Q (COSM6213*, COSV51766344*, substitution, c.2582T>A, Exon 21) * GRCh38 COSMIC v90
ALLELIC FREQUENCY	0.0%
QUALITY	Quantity traceable to internationally certified reference material ¹
STORAGE CONDITIONS	+ 2-8 °C
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

¹ ERM-AD442k

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method		Acceptance criteria																											
	Fragmentation	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Technologies)		peak size 167 bp ± 10% (151 bp – 183 bp)																											
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen) Total DNA measurement: Spectrophotometry ssDNA [ng/μl] = (A260-A320)*38 ²		15.0 – 25.0 ng/μl ----- n.a.																											
	Allelic Frequency	dPCR Analysis using BioRad QX200™ System		AF 0.0% (0.00-0.04%)																											
RESULTS OF ANALYSIS			Result	PASS/FAIL																											
	Fragmentation	160 bp		PASS																											
	Quantification	22.5 ng/μl (dsDNA) 27.7 ng/μl (total DNA)		PASS																											
	Allelic Frequency	Mutation	AF in %	PASS																											
		L858R	0.00																												
		L861Q	0.00																												
		S768I	0.00																												
		E746_A750delELREA	0.00																												
		T790M	0.03																												
		G719S	0.04																												
V769_D770insASV		0.00																													
S752_I759delSPANKEI	0.00																														
COMMENTS/REMARKS	Additional information:																														
	Copy numbers (CN) of the respective measurements																														
	<table><tr><td>Mutation</td><td>CN WT/μl</td><td>CN Mt/μl</td></tr><tr><td>L858R</td><td>11346</td><td>0</td></tr><tr><td>L861Q</td><td>13525</td><td>0</td></tr><tr><td>S768I</td><td>7638</td><td>0</td></tr><tr><td>E746_A750delELREA</td><td>11752</td><td>0</td></tr><tr><td>T790M</td><td>9632</td><td>3</td></tr><tr><td>G719S</td><td>12604</td><td>8</td></tr><tr><td>V769_D770insASV</td><td>8395</td><td>0</td></tr><tr><td>S752_I759delSPANKEI</td><td>5250</td><td>0</td></tr></table>			Mutation	CN WT/μl	CN Mt/μl	L858R	11346	0	L861Q	13525	0	S768I	7638	0	E746_A750delELREA	11752	0	T790M	9632	3	G719S	12604	8	V769_D770insASV	8395	0	S752_I759delSPANKEI	5250	0	Table 1 indicates the values of the QC assays performed by SensiD GmbH with an DNA input of ~30 ng. The value for the respective mutation results from the mean value of three measured batch products (CN values are rounded). CNs were analysed using ddPCR. The detection of the amount of CNs may vary depending on the assay. Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here
	Mutation	CN WT/μl	CN Mt/μl																												
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² Protocol NK603 – Community Reference Laboratory for GM Food and Feed

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CEO: Björn Nowack

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

Mr. Björn Nowack

Date of batch release: 29.07.2019

Signature batch release: Björn Nowack

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