

Batch Certificate

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 5% AF cfDNA
DESCRIPTION	SensID cfDNA (human) is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000019
BATCH NUMBER	00014
MANUFACTURING CONDITIONS	• Manufactured and sealed in class 2 safety cabinet • Bottled with qualified liquid handling workstation • At room temperature
PACKAGE SIZE AND TYPE	• 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	16.07.2019
EXPIRY DATE	16.07.2020
CONCENTRATION	20 ng/μl
QUANTITY	400 ng
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	5%
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

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CEO: Björn Nowack

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 – 181 bp)	
	Quantification	Qubit dsDNA Broad Range (Invitrogen)	15 - 25 ng/μl	
	Allelic Frequency	dPCR Analysis using BioRad QX200™ System	AF 5% ±30% (3.5-6.5%)	
RESULTS OF ANALYSIS		Result	PASS/FAIL	
	Fragmentation	156 bp	PASS	
	Quantity	23.75 ng/μl	PASS	
	Allelic Frequency	Mutation	AF in %	PASS
		L858R	4.1	
		L861Q	4.5	
		S768I	4.1	
		E746_A750delELREA	4.0	
		T790M	4.0	
		G719S	4.5	
V769_D770insASV		3.5		
S752_I759delSPANKEI		4.4		
COMMENTS/REMARKS	Additional information:			
	Copy numbers (CN) of the respective measurements			
	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	
	L858R	8392	361	
	L861Q	13133	614	
	S768I	7821	330	
	E746_A750delELREA	9707	402	
	T790M	8176	340	
	G719S	11731	558	
V769_D770insASV	7042	258		
S752_I759delSPANKEI	4607	212		

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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