

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 1% AF cfDNA
DESCRIPTION	SensID cfDNA (human) is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000017
BATCH NUMBER	SID-00010
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • Bottled with qualified liquid handling workstation • At room temperature
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	29.04.2019
EXPIRY DATE	29.04.2021
CONCENTRATION	20 ng/μl (total DNA)
QUANTITY	400 ng (total DNA)
NOMINAL VOLUME	25.8 μl
MUTATION	<p>p.G719S (COSM6252*, COSV51767289*, substitution, c.2155G>A, Exon 18)</p> <p>p.E746_A750delELREA (COSM6225*, COSV51765066*, deletion, c.2236_2250del15, Exon 19)</p> <p>p.S752_I759delSPKANKEI (COSM6256*, COSV51774879*, deletion, c.2254_2277del24, Exon 19)</p> <p>p.S768I (COSM6241*, COSV51768106* substitution, c.2303G>T, Exon 20)</p> <p>p.V769_D770insASV (COSM20884*, COSV51850427* Insertion, c.2303_2304insTGTGGCCAG, Exon 20)</p> <p>p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C>T, Exon 20)</p> <p>p.L858R (COSM6224*, COSV51765161*, substitution, c.2573T>G, Exon 21)</p> <p>p.L861Q (COSM6213*, COSV51766344*, substitution, c.2582T>A, Exon 21)</p> <p><small>* GRCh38 COSMIC v90</small></p>
ALLELE FREQUENCY	1%
QUALITY	Quantity traceable to internationally certified reference material ¹
STORAGE CONDITIONS	+ 2-8 °C

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MANUFACTURING AND
QUALITY CONTROL
SITES

SensID GmbH
Schillingallee 68, 18057 Rostock, Germany

TEST METHOD AND
ACCEPTANCE CRITERIA

Quality Control	Test Method	Acceptance criteria
Fragmentation	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)
Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/μl] = (A260-A320)*38 ² dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	12 – 28 ng/μl ----- n.a.
Allele Frequency	dPCR Analysis using BioRad QX200™ System	AF 1% ±40% (0.6–1.4%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	155 bp	PASS
Quantity	14.61 ng/μl (total DNA) 7.24 ng/μl (dsDNA)	PASS
Allele Frequency	Mutation	AF in %
	L858R	0.96
	L861Q	0.99
	S768I	1.10
	E746_A750delELREA	0.78
	T790M	1.15
	G719S	0.91
	V769_D770insASV	0.94
S752_I759delSPANKEI	0.79	
		PASS

COMMENTS/REMARKS

Not applicable

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

Mr. Björn Nowack

Date of batch release: 06.05.2019

Signature batch release: Björn Nowack

² Protocol NK603 – Community Reference Laboratory for GM Food and Feed

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Bringing Precision to MD_x

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