

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	SID-00011
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	28.5 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	5%
QUALITY	Quantity traceable to internationally certified reference material ¹
STORAGE CONDITIONS	+ 2-8 °C

¹ ERM_AD442K

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CEO: Björn Nowack

**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 5% ±30% (3.5–6.5%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	153 bp	PASS
Quantity	12.76 ng/μl (total DNA) 5.72 ng/μl (dsDNA)	PASS
Allele Frequency	Mutation	AF in %
	L858R	3.87
	L861Q	4.05
	S768I	4.41
	E746_A750delELREA	4.74
	T790M	4.72
	G719S	4.47
	V769_D770insASV	4.7
S752_I759delSPANKEI	4.44	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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Page 3/3

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