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	00013
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	15.07.2021
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
ALLELE FREQUENCY	1%
QUALITY	Quantity traceable to internationally certified reference material[1]
STORAGE CONDITIONS	+ 2-8 °C

[1] ERM_AD442K

Phone: +49 (0) 381 377 182 01
Net: www.sens-id.com
Mail: support@sens-id.com
SensID GmbH, Schillingallee 68, 18057 Rostock, Germany

VAT No: DE305142405, district court: Stralsund HRB 20227
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	Qubit dsDNA Broad Range (Invitrogen Technologies)	15 - 25 ng/µl
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	20.34 ng/µl	PASS
Allele Frequency	see table below	PASS

Mutation	AF in %
L858R	0.8
L861Q	0.8
S768I	0.7
E746_A750delELREA	0.7
T790M	0.9
G719S	0.7
V769_D770insASV	0.8
S752_I759delSPANKEI	0.9

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	5895	46
L861Q	11415	88
S768I	5837	39
E746_A750delELREA	7277	49
T790M	7010	68
G719S	9675	71
V769_D770insASV	5350	45
S752_I759delSPANKEI	3422	31

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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