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	00037
MANUFACTURING CONDITIONS	• Manufactured and sealed in class 2 safety cabinet • At room temperature
PACKAGE SIZE AND TYPE	• 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	08.01.2020
EXPIRY DATE	07.01.2022
CONCENTRATION	20 ng/µl (ds DNA)
QUANTITY	400 ng (ds DNA)
NOMINAL VOLUME	20 µl
MUTATION	EGFR 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	5%
QUALITY	DNA quantity metrological traceable to internationally certified reference material[1] The copy number values are metrologically traceable to the natural units count 1 and ratio 1 and International System of Units (SI) derived units of volume.
STORAGE CONDITIONS	+ 2-8 °C

[1] ERM_AD442K

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VAT No: DE305142405, district court: Rostock HRB 14621
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 Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/µl] = (A260-A320)*38[2,3] dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a.[4] dsDNA: 17.5 – 22.5 ng/µl
Allele Frequency	dPCR Analysis using BioRad QX200™ System	AF 5% ±30% (3.5-6.5%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	179 bp	PASS
Quantity	29.6 ng/µl (total DNA) 20.3 ng/µl (dsDNA)	PASS
Allele Frequency	see table below	PASS

Mutation	AF in %
L858R	4.4
L861Q	5.3
S768I	5.3
E746_A750delELREA	3.9
T790M	4.0
G719S	4.6
V769_D770insASV	4.6
S752_I759delSPANKEI	5.3

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 ~20 ng. The value for the respective mutation results from the mean value of five measured QC samples (CN values are rounded). CN concentration values per microliter (µl), are based on droplet digital (ddPCR) assay counts dilution factors, and droplet volume measurements. The detection of the amount of CNs may vary depending on the assay used. 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[5]/µl	CN mut[6]/µl
L858R	4631	213

[2] Measured before spiking in
[3] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[4] not applicable
[5] Wild Type
[6] Mutation

L861Q	5968	332
S768I	4555	253
E746_A750delELREA	4444	180
T790M	4671	195
G719S	4634	225
V769_D770insASV	3683	181
S752_I759delSPANKEI	2509	137

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

Mr. Björn Nowack

Date of batch release: 13.01.2020

Signature batch release: Björn Nowack

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