Batch Certificate
For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL	
NAME OF PRODUCT	EGFR-Multiplex 5% AF cfDNA
DESCRIPTION	EGFR-Multiplex 5% AF cfDNA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000019
BATCH NUMBER	00126
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	• Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	10.11.2020
EXPIRY DATE	09.11.2022
TARGET CONCENTRATION	20 ng/µl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 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 (new: p.A767_V769dup) (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 v91
ALLELE FREQUENCY	5.0%
QUALITY	DNA quantity metrologically 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.

[1] ERM_AD442K

STORAGE CONDITIONS	+ 2 - 8 °C
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]	Total DNA: n.a.[4]
	dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	dsDNA: 17.5 – 22.5 ng/µl
Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 5% ±30% (3.5-6.5%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	177 bp	PASS
Quantity	38.1 ng/µl (total DNA) 22.2 ng/µl (dsDNA)	PASS

Allele Frequency

Mutation	AF in %	PASS/FAIL
EGFR L858R	4.7	PASS
EGFR L861Q	3.9	PASS
EGFR S768I	4.7	PASS
EGFR E746_A750delELREA	4.9	PASS
EGFR T790M	4.6	PASS
EGFR G719S	4.9	PASS
EGFR V769_D770insASV	5.3	PASS
EGFR S752_I759delSPANKEI	4.2	PASS

[2] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[3] Measured before filling in product tube
[4] Not applicable

COMMENTS/REMARKS

ADDITIONAL INFORMATION:

Copy numbers (CN) of the respective measurements

Mutation	CN wt[5]/µl	CN mut[6]/µl
EGFR L858R	4447	219
EGFR L861Q	5717	229
EGFR S768I	3964	195
EGFR E746_A750delELREA	4473	232
EGFR T790M	4126	199
EGFR G719S	4762	244
EGFR V769_D770insASV	3660	204
EGFR S752_I759delSPANKEI	2766	122

Table 1 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~40 ng. The value for the respective mutation results from the mean value of five measured replicates (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.

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

Mr. Björn Nowack, Managing Director

Date of batch release: 13.11.2020

Signature batch release: Björn Nowack

This document was created electronically and is valid without a signature.

[5] Wild Type
[6] Mutation