Batch Certificate
For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL	
NAME OF PRODUCT	EGFR-Multiplex 1% AF cfDNA in Plasma
DESCRIPTION	EGFR-Multiplex 1% AF cfDNA in highly characterized human DNA from cell lines. Human proteins in common plasma concentrations, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations.
CATALOG NUMBER	SID-000016
BATCH NUMBER	00131
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	• Manufactured and sealed in class 2 safety cabinet • Bottled with qualified liquid handling workstation • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	11.11.2020
EXPIRY DATE	10.11.2022
TARGET CONCENTRATION	80 ng/ml (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	5 ml
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	1.0%

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

VAT No: DE305142405, district court: Rostock HRB 14621
CEO: Björn Nowack

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.
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[2] Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
Quantification	dsDNA measurement: Qubit[2] dsDNA BR Assay Kit (Invitrogen) dsDNA amount per ml plasma	80 ng/ml ± 10% (72-88 ng/ml)
Allele Frequency	ddPCR Analysis[2] using BioRad QX200™ System	AF 1% ±40% (0.6-1.4%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	173 bp	PASS
Quantity	80 ng/ml plasma	PASS

Allele Frequency

Mutation	AF in %	PASS/FAIL
EGFR L858R	1.3	PASS
EGFR L861Q	1.0	PASS
EGFR S768I	1.1	PASS
EGFR E746_A750delELREA	0.9	PASS
EGFR T790M	1.0	PASS
EGFR G719S	0.8	PASS
EGFR V769_D770insASV	0.8	PASS
EGFR S752_I759delSPANKEI	0.9	PASS

[1] ERM_AD442K
[2] Measured before filling in product tube

COMMENTS/REMARKS

ADDITIONAL INFORMATION:

Copy numbers (CN) of the respective measurements

Mutation	CN wt[3]/ml	CN mut[4]/ml
EGFR L858R	16000	212
EGFR L861Q	20758	205
EGFR S768I	13842	149
EGFR E746_A750delELREA	17101	164
EGFR T790M	15390	156
EGFR G719S	18273	156
EGFR V769_D770insASV	13972	119
EGFR S752_I759delSPANKEI	10152	89

Table 1 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~20 ng. The value for the respective mutation results from the mean value of three measured replicates (CN values are rounded). CN concentration values per milliliter (ml) plasma 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: 16.11.2020

Signature batch release: Björn Nowack

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

[3] Wild Type
[4] Mutation