

Batch Certificate

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 0.1% AF cfDNA in Plasma
DESCRIPTION	EGFR-Multiplex 0.1% 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-000014
BATCH NUMBER	00132
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	<ul style="list-style-type: none"> • 2D barcoded tube with screw cap
PACKAGE TYPE	<ul style="list-style-type: none"> • 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>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 (new: p.A767_V769dup) (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>* GRCh38 COSMIC v91</p>
ALLELE FREQUENCY	0.1%

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 0.1% ±60% (0.04-0.16%)																										
RESULTS OF ANALYSIS			Result																										
	Fragmentation	174 bp	PASS/FAIL																										
	Quantity	80 ng/ml plasma	PASS																										
	Allele Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>EGFR L858R</td> <td>0.10</td> <td>PASS</td> </tr> <tr> <td>EGFR L861Q</td> <td>0.05</td> <td>PASS</td> </tr> <tr> <td>EGFR S768I</td> <td>0.08</td> <td>PASS</td> </tr> <tr> <td>EGFR E746_A750delELREA</td> <td>0.09</td> <td>PASS</td> </tr> <tr> <td>EGFR T790M</td> <td>0.12</td> <td>PASS</td> </tr> <tr> <td>EGFR G719S</td> <td>0.12</td> <td>PASS</td> </tr> <tr> <td>EGFR V769_D770insASV</td> <td>0.08</td> <td>PASS</td> </tr> <tr> <td>EGFR S752_I759delSPANKEI</td> <td>0.12</td> <td>PASS</td> </tr> </tbody> </table>		Mutation	AF in %	PASS/FAIL	EGFR L858R	0.10	PASS	EGFR L861Q	0.05	PASS	EGFR S768I	0.08	PASS	EGFR E746_A750delELREA	0.09	PASS	EGFR T790M	0.12	PASS	EGFR G719S	0.12	PASS	EGFR V769_D770insASV	0.08	PASS	EGFR S752_I759delSPANKEI	0.12
Mutation	AF in %	PASS/FAIL																											
EGFR L858R	0.10	PASS																											
EGFR L861Q	0.05	PASS																											
EGFR S768I	0.08	PASS																											
EGFR E746_A750delELREA	0.09	PASS																											
EGFR T790M	0.12	PASS																											
EGFR G719S	0.12	PASS																											
EGFR V769_D770insASV	0.08	PASS																											
EGFR S752_I759delSPANKEI	0.12	PASS																											

¹ ERM_AD442K

² Measured before filling in product tube

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

COMMENTS/REMARKS

ADDITIONAL INFORMATION:

Copy numbers (CN) of the respective measurements

Mutation	CN wt ³ /ml	CN mut ⁴ /ml
EGFR L858R	17894	18
EGFR L861Q	20507	11
EGFR S768I	13278	11
EGFR E746_A750delELREA	16166	15
EGFR T790M	15555	18
EGFR G719S	18102	22
EGFR V769_D770insASV	14047	11
EGFR S752_I759delSPANKEI	5867	7

Table 1 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~100 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