

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 5% AF cfDNA in Plasma
DESCRIPTION	EGFR-Multiplex 5% AF cfDNA is highly characterized human DNA from cell lines. Human proteins in common plasma concentrations, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations.
CATALOG NUMBER	SID-000018
BATCH NUMBER	00130
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	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.																																									
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 5% ±30% (3.5–6.5%)																																							
RESULTS OF ANALYSIS	<table border="1"> <thead> <tr> <th></th> <th>Result</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>Fragmentation</td> <td>173 bp</td> <td>PASS</td> </tr> <tr> <td>Quantity</td> <td>80 ng/ml plasma</td> <td>PASS</td> </tr> <tr> <td rowspan="8">Allele Frequency</td> <td colspan="2"> <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>4.6</td> <td>PASS</td> </tr> <tr> <td>EGFR L861Q</td> <td>3.7</td> <td>PASS</td> </tr> <tr> <td>EGFR S768I</td> <td>4.0</td> <td>PASS</td> </tr> <tr> <td>EGFR E746_A750delELREA</td> <td>4.7</td> <td>PASS</td> </tr> <tr> <td>EGFR T790M</td> <td>5.2</td> <td>PASS</td> </tr> <tr> <td>EGFR G719S</td> <td>4.5</td> <td>PASS</td> </tr> <tr> <td>EGFR V769_D770insASV</td> <td>5.4</td> <td>PASS</td> </tr> <tr> <td>EGFR S752_I759delSPANKEI</td> <td>4.2</td> <td>PASS</td> </tr> </tbody> </table> </td> </tr> </tbody> </table>				Result	PASS/FAIL	Fragmentation	173 bp	PASS	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>4.6</td> <td>PASS</td> </tr> <tr> <td>EGFR L861Q</td> <td>3.7</td> <td>PASS</td> </tr> <tr> <td>EGFR S768I</td> <td>4.0</td> <td>PASS</td> </tr> <tr> <td>EGFR E746_A750delELREA</td> <td>4.7</td> <td>PASS</td> </tr> <tr> <td>EGFR T790M</td> <td>5.2</td> <td>PASS</td> </tr> <tr> <td>EGFR G719S</td> <td>4.5</td> <td>PASS</td> </tr> <tr> <td>EGFR V769_D770insASV</td> <td>5.4</td> <td>PASS</td> </tr> <tr> <td>EGFR S752_I759delSPANKEI</td> <td>4.2</td> <td>PASS</td> </tr> </tbody> </table>		Mutation	AF in %	PASS/FAIL	EGFR L858R	4.6	PASS	EGFR L861Q	3.7	PASS	EGFR S768I	4.0	PASS	EGFR E746_A750delELREA	4.7	PASS	EGFR T790M	5.2	PASS	EGFR G719S	4.5	PASS	EGFR V769_D770insASV	5.4	PASS	EGFR S752_I759delSPANKEI	4.2	PASS
	Result	PASS/FAIL																																								
Fragmentation	173 bp	PASS																																								
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>4.6</td> <td>PASS</td> </tr> <tr> <td>EGFR L861Q</td> <td>3.7</td> <td>PASS</td> </tr> <tr> <td>EGFR S768I</td> <td>4.0</td> <td>PASS</td> </tr> <tr> <td>EGFR E746_A750delELREA</td> <td>4.7</td> <td>PASS</td> </tr> <tr> <td>EGFR T790M</td> <td>5.2</td> <td>PASS</td> </tr> <tr> <td>EGFR G719S</td> <td>4.5</td> <td>PASS</td> </tr> <tr> <td>EGFR V769_D770insASV</td> <td>5.4</td> <td>PASS</td> </tr> <tr> <td>EGFR S752_I759delSPANKEI</td> <td>4.2</td> <td>PASS</td> </tr> </tbody> </table>		Mutation	AF in %	PASS/FAIL	EGFR L858R	4.6	PASS	EGFR L861Q	3.7	PASS	EGFR S768I		4.0	PASS	EGFR E746_A750delELREA	4.7	PASS	EGFR T790M	5.2	PASS	EGFR G719S	4.5	PASS	EGFR V769_D770insASV	5.4	PASS	EGFR S752_I759delSPANKEI	4.2	PASS												
	Mutation	AF in %	PASS/FAIL																																							
	EGFR L858R	4.6	PASS																																							
	EGFR L861Q	3.7	PASS																																							
	EGFR S768I	4.0	PASS																																							
	EGFR E746_A750delELREA	4.7	PASS																																							
	EGFR T790M	5.2	PASS																																							
	EGFR G719S	4.5	PASS																																							
EGFR V769_D770insASV	5.4	PASS																																								
EGFR S752_I759delSPANKEI	4.2	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	16466	785
EGFR L861Q	21222	817
EGFR S768I	18457	774
EGFR E746_A750delELREA	17233	853
EGFR T790M	15898	875
EGFR G719S	18659	871
EGFR V769_D770insASV	14242	806
EGFR S752_I759delSPANKEI	10552	468

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:

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.

³ Wild Type

⁴ Mutation