

## Batch Certificate For Research Use Only

### PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 1% AF cfDNA
DESCRIPTION	EGFR-Multiplex 1% AF cfDNA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000017
BATCH NUMBER	00052
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> <li>• Manufactured and sealed in class 2 safety cabinet</li> <li>• At room temperature</li> </ul>
PACKAGE SIZE	<ul style="list-style-type: none"> <li>• 2D barcoded tube with screw cap</li> </ul>
PACKAGE TYPE	<ul style="list-style-type: none"> <li>• Material: Polypropylen (PP)</li> </ul>
DATE OF MANUFACTURE	31.03.2020
EXPIRY DATE	30.03.2022
CONCENTRATION	20 ng/μl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 μl; (505 ng)
MUTATION	<p>p.G719S (COSM6252*, COSV51767289*, substitution, c.2155G&gt;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&gt;T, Exon 20)</p> <p>p.V769_D770insASV (COSM20884*, COSV51850427* Insertion, c.2303_2304insTGTGCCAG, Exon 20)</p> <p>p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C&gt;T, Exon 20)</p> <p>p.L858R (COSM6224*, COSV51765161*, substitution, c.2573T&gt;G, Exon 21)</p> <p>p.L861Q (COSM6213*, COSV51766344*, substitution, c.2582T&gt;A, Exon 21)</p> <p><small>* GRCh38 COSMIC v90</small></p>
ALLELE FREQUENCY	1.0%
QUALITY	<p>DNA quantity metrologically traceable to internationally certified reference material<sup>1</sup></p> <p>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.</p>
STORAGE CONDITIONS	+2 – +8 °C

<sup>1</sup> ERM\_AD442K  
Phone: +49 (0) 381 377 182 01

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 <sup>2,3</sup>  dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a. <sup>4</sup>  dsDNA: 17.5 – 22.5 ng/μl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 1.0% ±40% (0.6-1.4%)

RESULTS OF ANALYSIS	Result		PASS/FAIL																											
	Fragmentation	177 bp		PASS																										
Quantity	30.4 ng/μl (total DNA)		n.a. <sup>4</sup>																											
	20.2 ng/μl (dsDNA)		PASS																											
Allele Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>L858R</td> <td>0.9</td> <td>PASS</td> </tr> <tr> <td>L861Q</td> <td>1.3</td> <td>PASS</td> </tr> <tr> <td>S768I</td> <td>0.7</td> <td>PASS</td> </tr> <tr> <td>E746_A750delELREA</td> <td>0.8</td> <td>PASS</td> </tr> <tr> <td>T790M</td> <td>0.9</td> <td>PASS</td> </tr> <tr> <td>G719S</td> <td>1.0</td> <td>PASS</td> </tr> <tr> <td>V769_D770insASV</td> <td>1.0</td> <td>PASS</td> </tr> <tr> <td>S752_I759delSPANKEI</td> <td>1.0</td> <td>PASS</td> </tr> </tbody> </table>			Mutation	AF in %	PASS/FAIL	L858R	0.9	PASS	L861Q	1.3	PASS	S768I	0.7	PASS	E746_A750delELREA	0.8	PASS	T790M	0.9	PASS	G719S	1.0	PASS	V769_D770insASV	1.0	PASS	S752_I759delSPANKEI	1.0	PASS
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<sup>2</sup> Protocol NK603 – Community Reference Laboratory for GM Food and Feed

<sup>3</sup> Measured before filling in product tube

<sup>4</sup> not applicable

## COMMENTS/REMARKS

## ADDITIONAL INFORMATION:

Copy numbers (CN) of the respective measurements

Mutation	CN wt <sup>5</sup> /μl	CN mut <sup>6</sup> /μl
L858R	3929	37
L861Q	5401	69
S768I	3611	27
E746_A750delELREA	4360	35
T790M	4463	39
G719S	4688	46
V769_D770insASV	3745	37
S752_I759delSPANKEI	2957	30

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 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

Date of batch release: 02.04.2020

Signature batch release: Björn Nowack

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

<sup>5</sup> Wild Type

<sup>6</sup> Mutation