

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 5% AF cfDNA in Plasma
DESCRIPTION	Human proteins in common plasma concentrations, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations
CATALOG NUMBER	SID-000018
BATCH NUMBER	00035
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • At room temperature
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	08.01.2020
EXPIRY DATE	07.01.2022
CONCENTRATION	80 ng/ml (ds DNA)
QUANTITY	400 ng (ds DNA)
NOMINAL VOLUME	14.9 µl in 5 ml plasma
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 (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><small>* GRCh38 COSMIC v90</small></p>
ALLELIC FREQUENCY	5%
QUALITY	<p>DNA quantity metrologically traceable to internationally certified reference material¹</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

¹ ERM_AD442K
Phone: +49 (0) 381 377 182 01

<p>MANUFACTURING AND QUALITY CONTROL SITES</p>	<p>SensID GmbH Schillingallee 68, 18057 Rostock, Germany</p>																																	
<p>TEST METHOD AND ACCEPTANCE CRITERIA</p>	<p>Quality Control</p>	<p>Test Method</p>	<p>Acceptance criteria</p>																															
	<p>Fragmentation</p>	<p>Fragment Length Analysis² Agilent High Sensitivity DNA Kit (Agilent Technologies)</p>	<p>peak size 167 bp ± 10% (151 bp – 181 bp)</p>																															
	<p>Quantification</p>	<p>Total DNA measurement: Spectrophotometry ssDNA [ng/μl] = (A260- A320)*38^{2,3} dsDNA measurement²: Qubit dsDNA BR Assay Kit (Invitrogen)</p>	<p>ssDNA: n.a.⁴ dsDNA: n.a.⁴</p>																															
	<p>Allelic Frequency</p>	<p>dPCR Analysis² using BioRad QX200™ System</p>	<p>AF 5% ±30% (3.5–6.5%)</p>																															
<p>RESULTS OF ANALYSIS</p>	<table border="1"> <thead> <tr> <th></th> <th>Result</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>Fragmentation</td> <td>181 bp</td> <td>PASS</td> </tr> <tr> <td>Quantity</td> <td>29.1 ng/μl (total DNA) 26.8 ng/μl (dsDNA)</td> <td></td> </tr> <tr> <td rowspan="8">Allelic Frequency</td> <td>Mutation</td> <td>AF in %</td> </tr> <tr> <td>L858R</td> <td>4.2</td> </tr> <tr> <td>L861Q</td> <td>4.9</td> </tr> <tr> <td>S768I</td> <td>5.4</td> </tr> <tr> <td>E746_A750delELREA</td> <td>3.8</td> </tr> <tr> <td>T790M</td> <td>3.8</td> </tr> <tr> <td>G719S</td> <td>4.9</td> </tr> <tr> <td>V769_D770insASV</td> <td>4.9</td> </tr> <tr> <td>S752_I759delSPANKEI</td> <td>3.5</td> </tr> <tr> <td></td> <td></td> <td>PASS</td> </tr> </tbody> </table>				Result	PASS/FAIL	Fragmentation	181 bp	PASS	Quantity	29.1 ng/μl (total DNA) 26.8 ng/μl (dsDNA)		Allelic Frequency	Mutation	AF in %	L858R	4.2	L861Q	4.9	S768I	5.4	E746_A750delELREA	3.8	T790M	3.8	G719S	4.9	V769_D770insASV	4.9	S752_I759delSPANKEI	3.5			PASS
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<p>COMMENTS/REMARKS</p>	<p>Additional information:</p> <p>Copy numbers (CN) of the respective measurements</p> <p><i>Table 1 indicates the values of the QC assays performed by SensID GmbH with an DNA input of ~40 ng. The value for the respective mutation results from the mean value of three 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.</i></p>																																	

² Measured before spiking in

³ Protocol NK603 – Community Reference Laboratory for GM Food and Feed

⁴ not applicable

Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.

Mutation	CN wt⁵/μl	CN mut⁶/μl
L858R	4584	203
L861Q	5440	283
S768I	4188	237
E746_A750delELREA	4417	174
T790M	4810	189
G719S	4761	247
V769_D770insASV	4004	207
S752_I759delSPANKEI	2855	105

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

Björn Nowack, Managing Director

Date of batch release: 13.01.2020

Signature batch release: Björn Nowack

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

⁵ Wild Type

⁶ Mutation