

## Batch Certificate For Research Use Only

### PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 5% AF cfDNA
DESCRIPTION	SensID cfDNA (human) is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000019
BATCH NUMBER	00014
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> <li>• Manufactured and sealed in class 2 safety cabinet</li> <li>• Bottled with qualified liquid handling workstation</li> <li>• At room temperature</li> </ul>
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> <li>• 2D barcoded tube with screw cap</li> <li>• Material: Polypropylen (PP)</li> </ul>
DATE OF MANUFACTURE	16.07.2019
EXPIRY DATE	16.07.2021
CONCENTRATION	20 ng/μl
QUANTITY	400 ng
NOMINAL VOLUME	20 μl
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_2304insTGTGGCCAG, 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>* GRCh38 COSMIC v90</p>
ALLELE FREQUENCY	5%
QUALITY	Quantity traceable to internationally certified reference material <sup>1</sup>
STORAGE CONDITIONS	+ 2-8 °C

<sup>1</sup>ERM\_AD442K

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CEO: Björn Nowack

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 <sup>2</sup> Agilent High Sensitivity DNA Kit (Agilent Technologies.)	peak size 167 bp ± 10% (151 bp – 181 bp)
Quantification	Qubit dsDNA Broad Range (Invitrogen)	15 – 25 ng/μl
Allele Frequency	dPCR Analysis <sup>3</sup> using BioRad QX200™ System	AF 5% ±30% (3.5–6.5%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	156 bp	PASS
Quantity	23.75ng/μl	PASS
Allele Frequency	<b>Mutation</b>	<b>AF in %</b>
	L858R	4.13
	L861Q	4.47
	S768I	4.05
	E746_A750delELREA	3.98
	T790M	3.96
	G719S	4.50
	V769_D770insASV	3.53
S752_I759delSPANKEI	4.39	PASS

COMMENTS/REMARKS

Additional information:

**Copy numbers (CN) of the respective measurements**

Mutation	CN WT/μl	CN Mt/μl
L858R	8392	361
L861Q	13133	614
S768I	7821	330
E746_A750delELREA	9707	402
T790M	8176	340

<sup>2</sup> Measured after spiking in

<sup>3</sup> Measured after spiking in

G719S	11731	558
V769_D770insASV	7042	258
S752_I759delSPANKEI	4607	212

*Table 1 indicates the values of the QC assays performed by SensID GmbH with an DNA*

*input of ~30 ng. The value for the respective mutation results from the mean value of three measured batch products (CN values are rounded). CNs were analysed using ddPCR. The detection of the amount of CNs may vary depending on the assay. 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: 29.07.2019

Signature batch release: Björn Nowack

This document was issued electronically and is therefore valid without signature.