

## Batch Certificate

### For Research Use Only

#### PRODUCT INFORMATION AND QUALITY CONTROL

<b>NAME OF PRODUCT</b>	EGFR-Multiplex 1% AF cfDNA
<b>DESCRIPTION</b>	SensID cfDNA (human) is highly characterized human DNA from cell lines.
<b>CATALOG NUMBER</b>	SID-000017
<b>BATCH NUMBER</b>	00013
<b>MANUFACTURING CONDITIONS</b>	<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>
<b>PACKAGE SIZE AND TYPE</b>	<ul style="list-style-type: none"> <li>• 2D barcoded tube with screw cap</li> <li>• Material: Polypropylen (PP)</li> </ul>
<b>DATE OF MANUFACTURE</b>	16.07.2019
<b>EXPIRY DATE</b>	16.07.2020
<b>CONCENTRATION</b>	20 ng/μl
<b>QUANTITY</b>	400 ng
<b>NOMINAL VOLUME</b>	20 μl
<b>MUTATION</b>	<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><small>* GRCh38 COSMIC v90</small></p>
<b>ALLELIC FREQUENCY</b>	1%
<b>QUALITY</b>	Quantity traceable to internationally certified reference material <sup>1</sup>
<b>STORAGE CONDITIONS</b>	+ 2-8 °C
<b>MANUFACTURING AND QUALITY CONTROL SITES</b>	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

<sup>1</sup> ERM\_AD442K

**TEST METHOD AND  
ACCEPTANCE CRITERIA**

Quality Control	Test Method	Acceptance criteria
<b>Fragmentation</b>	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)
<b>Quantification</b>	Qubit dsDNA Broad Range (Invitrogen Technologies)	15 - 25 ng/μl
<b>Allelic Frequency</b>	dPCR Analysis using BioRad QX200™ System	AF 1% ±40% (0.6-1.4%)

**RESULTS OF ANALYSIS**

	Result	PASS/FAIL
<b>Fragmentation</b>	155 bp	PASS
<b>Quantity</b>	20.34 ng/μl	PASS
<b>Allelic Frequency</b>	<b>Mutation</b>	<b>AF in %</b>
	L858R	0.8
	L861Q	0.8
	S768I	0.7
	E746_A750delELREA	0.7
	T790M	0.9
	G719S	0.7
	V769_D770insASV	0.8
S752_I759delSPANKEI	0.9	
		PASS

**COMMENTS/REMARKS**

Additional information:

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

*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*

Mutation	CN WT/μl	CN Mt/μl
L858R	5895	46
L861Q	11415	88
S768I	5837	39
E746_A750delELREA	7277	49
T790M	7010	68
G719S	9675	71
V769_D770insASV	5350	45
S752_I759delSPANKEI	3422	31



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**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

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