

Batch Certificate
For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 0.1% AF cfDNA
DESCRIPTION	EGFR-Multiplex 0.1% AF cfDNA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000015
BATCH NUMBER	00012
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 AND TYPE	<ul style="list-style-type: none"> • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	16.07.2019
EXPIRY DATE	16.07.2020
CONCENTRATION	20 ng/μl
QUANTITY (dsDNA)	400 ng
NOMINAL VOLUME	20 μl
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	0.1%
QUALITY	Quantity traceable to internationally certified reference material ¹
STORAGE CONDITIONS	+ 2-8 °C
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

¹ ERM_AD442K

Phone: +49 (0) 381 377 182 01

Net: www.sens-id.com

SensID GmbH, Schillingallee 68, 18057 Rostock, Germany

Mail: support@sens-id.com

VAT No: DE305142405, district court: Stralsund HRB 20227

CEO: Björn Nowack

**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	Qubit dsDNA Broad Range (Invitrogen)	15 – 25 ng/μl
Allelic Frequency	dPCR Analysis using BioRad QX200™ System	AF 0.1% ±60% (0.04-0.16%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	161 bp	PASS
Quantity	23.3 ng/μl	PASS
Allelic Frequency	Mutation	AF in %
	L858R	0.09
	L861Q	0.09
	S768I	0.09
	E746_A750delELREA	0.06
	T790M	0.11
	G719S	0.09
	V769_D770insASV	0.07
S752_I759delSPANKEI	0.11	
		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	6805	7
L861Q	9949	9
S768I	5503	5
E746_A750delELREA	7532	5
T790M	7189	10
G719S	9270	12
V769_D770insASV	5520	4
S752_I759delSPANKEI	3652	4



Bringing Precision to MD_x

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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.

Phone: +49 (0) 381 377 182 01

Net: www.sens-id.com
SensID GmbH, Schillingallee 68, 18057 Rostock, Germany

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