

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	SID-00009
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	29.04.2019
EXPIRY DATE	29.04.2020
CONCENTRATION	20 ng/µl
QUANTITY	400 ng
NOMINAL VOLUME	25,3 µl
MUTATION	<p>p.G719S (COSM6252*, substitution, c.2155G>A, Exon 18)</p> <p>p.E746_A750delELREA (COSM6225*, deletion, c.2236_2250del15, Exon 19)</p> <p>p.S752_I759delSPKANKEI (COSM6256*, deletion, c.2254_2277del24, Exon 19)</p> <p>p.S768I (COSM6241*, substitution, c.2303G>T, Exon 20)</p> <p>p.V769_D770insASV (COSM20884*, Insertion, c.2303_2304insTGTGGCCAG, Exon 20)</p> <p>p.T790M (COSM6240*, substitution, c.2369C>T, Exon 20)</p> <p>p.L858R (COSM6224*, substitution, c.2573T>G, Exon 21)</p> <p>p.L861Q (COSM6213*, substitution, c.2582T>A, Exon 21)</p> <p><small>* GRCh38 COSMIC v88</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	<p>SensID GmbH</p> <p>Schillingallee 68, 18057 Rostock, Germany</p>

¹ERM_AD442K
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TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria	
	Fragmentation	Fragment Length Analysis ² Agilent High Sensitivity DNA Kit (Agilent Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)	
	Quantification	Spectrophotometry ^{3,4} ssDNA [ng/μl] = (A260- A320)*38	12 - 28 ng/μl	
	Allelic Frequency	dPCR Analysis ⁵ using BioRad QX200™ System	AF 0,1% ±60% (0,04-0,16%)	
RESULTS OF ANALYSIS		Result	PASS/FAIL	
	Fragmentation	157 bp	PASS	
	Quantity	12,54 ng/μl	PASS	
	Allelic Frequency	Mutation	AF in %	PASS
		L858R	0,13	
		L861Q	0,05	
		S768I	0,14	
		E746_A750delELREA	0,08	
T790M		0,12		
G719S		0,13		
V769_D770insASV	0,09			
S752_I759delSPANKEI	0,08			
COMMENTS/REMARKS	Not applicable			

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

Mr. Björn Nowack

Date of batch release: 06.05.2019

Signature batch release: Björn Nowack

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

² Measured after spiking in

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

⁴ Measured after spiking in

⁵ Measured after spiking in

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