

## Batch Certificate For Research Use Only

### PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	Ashkenazim son cfDNA in Plasma (EGFR)
DESCRIPTION	Human proteins in common plasma concentrations, electrolytes, EDTA and cfDNA / ctDNA in common plasma concentrations
CATALOG NUMBER	SID-0002
BATCH NUMBER	SID-00006
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 and dispenser tool</li> <li>• At room temperature</li> <li>• 2D barcoded tube with screw cap</li> <li>• Material: Polypropylen (PP)</li> </ul>
PACKAGE SIZE AND TYPE	
DATE OF MANUFACTURE	18 Dec 2018
EXPIRY DATE	18 Dec 2019
CONCENTRATION	80 ng/ml
QUANTITY	400 ng
NOMINAL VOLUME	5 ml
MUTATION	<p>p.G719S (COSM6252*, substitution, c.2155G&gt;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&gt;T, Exon 20)</p> <p>p.V769_D770insASV (COSM20884*, Insertion, c.2303_2304insTGTGGCCAG, Exon 20)</p> <p>p.T790M (COSM6240*, substitution, c.2369C&gt;T, Exon 20)</p> <p>p.L858R (COSM6224*, substitution, c.2573T&gt;G, Exon 21)</p> <p>p.L861Q (COSM6213*, substitution, c.2582T&gt;A, Exon 21)</p> <p><small>* GRCh38 COSMIC v88</small></p>
ALLELIC FREQUENCY	0,0%
QUALITY	Quantity traceable to internationally certified reference material <sup>1</sup>
STORAGE CONDITIONS	+ 2-8 °C
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

<sup>1</sup>ERM-AD442k  
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TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria	
	Fragmentation	Fragment Length Analysis <sup>2</sup> Agilent High Sensitivity DNA Kit (Agilent Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)	
	Quantification	Spectrophotometry ssDNA [ng/μl] = (A260- A320)*38 <sup>3,4</sup>	18,5 – 21,5 ng/μl	
	Allelic Frequency	dPCR Analysis <sup>5</sup> using BioRad QX200™ System	AF 0,0% (0,00-0,00%)	
RESULTS OF ANALYSIS		Result	PASS/FAIL	
	Fragmentation	167,0 bp	PASS	
	Quantification	20 ng/μl	PASS	
	Allelic Frequency	Mutation	AF in %	PASS
		L858R	0,0	
		L861Q	0,0	
		S768I	0,0	
		E746_A750delELREA	0,0	
T790M		0,0		
G719S		0,0		
V769_D770insASV	0,0			
S752_I759delSPANKEI	0,0			
COMMENTS/REMARKS	-			

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

Mr. Björn Nowack

Date of batch release: 20 Dec. 2018

Signature batch release: Björn Nowack

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

<sup>2</sup> Measured after extraction

<sup>3</sup> Protocol NK603 – Community Reference Laboratory for GM Food and Feed

<sup>4</sup> measured cfDNA conc. before spiking in

<sup>5</sup> Measured after spiking in

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