

## Batch Certificate For Research Use Only

### PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	Ashkenazim son cfDNA (human) AF: 0% in Plasma
DESCRIPTION	Human proteins in common plasma concentrations, electrolytes, EDTA and cfDNA / ctDNA in common plasma concentrations
CATALOG NUMBER	SID-000002
BATCH NUMBER	00025
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	18.09.2019
EXPIRY DATE	17.09.2020
CONCENTRATION	80 ng/ml
QUANTITY	400 ng
NOMINAL VOLUME	5 ml
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><small>* GRCh38 COSMIC v90</small></p>
ALLELIC FREQUENCY	0.0%
QUALITY	Quantity traceable to internationally certified reference material <sup>1</sup>
STORAGE CONDITIONS	+ 2–8 °C

<sup>1</sup>ERM-AD442k  
Phone: +49 (0) 381 377 182 01

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 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% (0.0–0.0%)																		
RESULTS OF ANALYSIS		Result	PASS/FAIL																		
	Fragmentation	167 bp	PASS																		
	Quantification	20 ng/μl	PASS																		
	Allelic Frequency	<table border="1"> <thead> <tr> <th data-bbox="831 1055 1145 1122">Mutation</th> <th data-bbox="1145 1055 1259 1122">AF in %</th> </tr> </thead> <tbody> <tr><td data-bbox="831 1122 1145 1155">L858R</td><td data-bbox="1145 1122 1259 1155">0.0</td></tr> <tr><td data-bbox="831 1155 1145 1189">L861Q</td><td data-bbox="1145 1155 1259 1189">0.0</td></tr> <tr><td data-bbox="831 1189 1145 1223">S768I</td><td data-bbox="1145 1189 1259 1223">0.0</td></tr> <tr><td data-bbox="831 1223 1145 1256">E746_A750delELREA</td><td data-bbox="1145 1223 1259 1256">0.0</td></tr> <tr><td data-bbox="831 1256 1145 1290">T790M</td><td data-bbox="1145 1256 1259 1290">0.0</td></tr> <tr><td data-bbox="831 1290 1145 1323">G719S</td><td data-bbox="1145 1290 1259 1323">0.0</td></tr> <tr><td data-bbox="831 1323 1145 1357">V769_D770insASV</td><td data-bbox="1145 1323 1259 1357">0.0</td></tr> <tr><td data-bbox="831 1357 1145 1377">S752_I759delSPANKEI</td><td data-bbox="1145 1357 1259 1377">0.0</td></tr> </tbody> </table>	Mutation	AF in %	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	PASS
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COMMENTS/REMARKS	-																				

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

Mr. Björn Nowack

Date of batch release: 20 Dec. 2019

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

Phone: +49 (0) 381 377 182 01

 Net: [www.sens-id.com](http://www.sens-id.com)

 Mail: [support@sens-id.com](mailto:support@sens-id.com)

SensID GmbH, Schillingallee 68, 18057 Rostock, Germany

VAT No: DE305142405, district court: Rostock HRB 14621

CEO: Björn Nowack