

## Batch Certificate

### For Research Use Only

#### PRODUCT INFORMATION AND QUALITY CONTROL

<b>NAME OF PRODUCT</b>	cfDNA (human) AF: 0% Ashkenazim Son
<b>DESCRIPTION</b>	cfDNA (human) AF: 0% Ashkenazim Son in highly characterized human DNA from cell lines.
<b>CATALOG NUMBER</b>	SID-000003
<b>BATCH NUMBER</b>	00020
<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>	02.09.2019
<b>EXPIRY DATE</b>	01.09.2021
<b>CONCENTRATION</b>	20 ng/μl (dsDNA)
<b>QUANTITY</b>	400 ng (dsDNA)
<b>NOMINAL VOLUME</b>	20 μl
<b>MUTATION</b>	AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G>A, Exon 2) BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T>A, Exon 15) ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSM20959*/ COSM404915*, COSV54062409*, insertion, c.2313_2324dup/ c.2310_2311ins12, Exon 19) KRAS p.G12D (COSM521*, COSV55497369*, substitution, c.35G>A, Exon 1) KRAS p.Q61K (COSM549*, COSV55502066*, substitution, c.181C>A, Exon 2) KRAS p.A146T (COSM19404*, COSV55501778*, substitution, c.436G>A, Exon 3) PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A>G, Exon 20) PIK3CA p.E545K (COSM763*, COSV55873239* substitution, c.1633G>A, Exon 9) <small>* GRCh38 COSMIC v90</small>
<b>ALLELIC FREQUENCY</b>	0%
<b>QUALITY</b>	DNA quantity metrological traceable to internationally certified reference material <sup>1</sup>  The copy number values are metrologically traceable to the natural units count 1 and ratio 1 and International System of Units (SI) derived units of volume.
<b>STORAGE CONDITIONS</b>	+ 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 Agilent High Sensitivity DNA Kit (Agilent Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/μl] 0 (A260-A280)*38 <sup>2</sup> dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	ssDNA: n.a. <sup>3</sup>  dsDNA: 18.5 – 22.5 ng/μl
	Allelic Frequency	dPCR Analysis using BioRad QX200™ System	AF 0,0% (0.00–0.04%)

RESULTS OF ANALYSIS		Result	PASS/FAIL
Fragmentation		179 bp	PASS
Quantification		35.18 ng/μl (total DNA) 20.7 ng/μl (dsDNA)	PASS
Allelic Frequency	Mutation	AF in %	PASS
	AKT1 E17K	0.02	
	BRAF V600E	0.00	
	PIK3CA H1047R	0.01	
	ERBB2 E770_A771insAYVM (Y772_A775dup)	0.01	
	KRAS G12D	0.04	
	KRAS Q61K	0.00	
	KRAS A146T	0.02	
PIK3CA E545K	0.01		

COMMENTS/REMARKS
<p>Additional information:</p> <p><b>Copy numbers (CN) of the respective measurements</b></p> <p><i>Table 1 indicates the values of the QC assays performed by SensID GmbH with an DNA input of ~40 ng. The value for the respective mutation results from the mean value of three measured batch products (CN values are rounded). CN concentration values per microliter (μl), are based on droplet digital (ddPCR) assay counts dilution factors, and droplet volume measurements. The detection of the amount of CNs may vary depending on the assay used. Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.</i></p>

<sup>2</sup>Protocol NK603 – Community Reference Laboratory for GM Food and Feed

<sup>3</sup>not applicable

Phone: +49 (0) 381 377 182 01

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

SensID GmbH, Schillingallee 68, 18057 Rostock, Germany

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

VAT No: DE305142405, district court: Rostock HRB 14621

CEO: Björn Nowack

<b>Mutation</b>	<b>CN wt<sup>4</sup>/μl</b>	<b>CN mut<sup>5</sup>/μl</b>
AKT1 E17K	2481	0
BRAF V600E	2110	0
ERBB2 E770_A771insAYVM (Y772_A775dup)	3393	0
KRAS G12D	3045	1
KRAS Q61K	3644	0
KRAS A146T	3900	1
PIK3CA H1047R	4216	1
PIK3CA E545K	2907	0

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

Mr. Björn Nowack

Date of batch release: 20.09.2019

Signature batch release: Björn Nowack

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

<sup>4</sup> Wild Type

<sup>5</sup> Mutation