

## 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	00040
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> <li>• Manufactured and sealed in class 2 safety cabinet</li> <li>• Bottled with qualified dispenser</li> <li>• At room temperature</li> </ul>
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> <li>• 2D barcoded tube with screw cap</li> <li>• Material: Polypropylen (PP)</li> </ul>
DATE OF MANUFACTURE	04.02.2020
EXPIRY DATE	03.02.2022
CONCENTRATION	80 ng/ml (dsDNA)
QUANTITY	≥ 400 ng (dsDNA)
NOMINAL VOLUME	17 µl (in 5 ml Plasma); (420 ng)
MUTATION	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>
ALLELIC FREQUENCY	0%
QUALITY	DNA quantity metrologically 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.
STORAGE CONDITIONS	+ 2-8 °C

<sup>1</sup> ERM\_AD442K  
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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 Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	Total DNA measurement Spectrophotometry ssDNA [ng/μl] = (A260-A320)*38 <sup>2,3</sup>  dsDNA measurement Qubit dsDNA BR Assay Kit (Invitrogen) <sup>2</sup>	Total DNA: n.a. <sup>4</sup>  dsDNA: n.a. <sup>4</sup>
	Allelic Frequency	dPCR Analysis <sup>2</sup> using BioRad QX200™ System	AF 0.00% (≤0.03%)

  

RESULTS OF ANALYSIS	Result	PASS/FAIL	
	Fragmentation	175 bp	PASS
	Quantity	37.8 ng/μl (total DNA) 24.7 ng/μl (dsDNA)	PASS

  

Allelic Frequency	Mutation	AF in %	PASS/FAIL
	AKT1 E17K	0.03	PASS
	BRAF V600E	0.00	PASS
	PIK3CA H1047R	0.02	PASS
	PIK3CA E545K	0.02	PASS
	ERBB2 E770_A771insAYVM (Y772_A775dup)	0.00	PASS
	KRAS G12D	0.03	PASS
	KRAS Q61K	0.00	PASS
	KRAS A146T	0.01	PASS

<sup>2</sup> Measured before spiking in

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

<sup>4</sup> not applicable

## COMMENTS/REMARKS

Additional information:

**Copy numbers (CN) of the respective measurements**

Mutation	CN wt <sup>5</sup> /ml	CN mut <sup>6</sup> /ml
AKT1 E17K	10968	4
BRAF V600E	8409	0
PIK3CA H1047R	17125	5
PIK3CA E545K	11737	3
ERBB2 E770_A771insAYVM (Y772_A775dup)	13411	0
KRAS G12D	11940	4
KRAS Q61K	14475	0
KRAS A146T	14002	1

*Table 1 indicates the values of the QC assays performed by SensID GmbH with an DNA input of ~20 ng. The value for the respective mutation results from the mean value of three measured replicates (CN values are rounded) before spiking in. 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.*

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

Mr. Björn Nowack, Managing Director

Date of batch release: 13.02.2020

Signature batch release: Björn Nowack

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

<sup>5</sup> Wild Type

<sup>6</sup> Mutation