

Batch Certificate

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	cfDNA (human) AF: 0% Ashkenazim Son
DESCRIPTION	cfDNA (human) AF: 0% Ashkenazim Son is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000003
BATCH NUMBER	00039
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • 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	04.02.2020
EXPIRY DATE	03.02.2022
CONCENTRATION	20 ng/μl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	23 μl; (407 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 metrological traceable to internationally certified reference material ¹ 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
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

¹ ERM_AD442K

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria																											
	Fragmentation	Fragment Length Analysis 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 ^{2,3} dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a. ⁴ dsDNA: 17.5 – 22.5 ng/μl																											
	Allelic Frequency	dPCR Analysis using BioRad QX200™ System	AF 0.00% (≤0.03%)																											
RESULTS OF ANALYSIS																														
		Result	PASS/FAIL																											
	Fragmentation	178 bp	PASS																											
	Quantity	29,9 ng/μl (total DNA) 17,7 ng/μl (dsDNA)	PASS																											
	Allelic Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>AKT1 E17K</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>BRAF V600E</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>PIK3CA H1047R</td> <td>0.03</td> <td>PASS</td> </tr> <tr> <td>PIK3CA E545K</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>ERBB2 E770_A771insAYVM (Y772_A775dup)</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>KRAS G12D</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>KRAS Q61K</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>KRAS A146T</td> <td>0.03</td> <td>PASS</td> </tr> </tbody> </table>		Mutation	AF in %	PASS/FAIL	AKT1 E17K	0.00	PASS	BRAF V600E	0.00	PASS	PIK3CA H1047R	0.03	PASS	PIK3CA E545K	0.00	PASS	ERBB2 E770_A771insAYVM (Y772_A775dup)	0.00	PASS	KRAS G12D	0.00	PASS	KRAS Q61K	0.00	PASS	KRAS A146T	0.03	PASS
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COMMENTS/REMARKS	Additional information: Copy numbers (CN) of the respective measurements <i>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 eight measured replicates (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.</i>																													

² Protocol NK603 – Community Reference Laboratory for GM Food and Feed

³ Measured before filling in product tube

⁴ not applicable

Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.

Mutation	CN wt⁵/μl	CN mut⁶/μl
AKT1 E17K	2043	0
BRAF V600E	1840	0
PIK3CA H1047R	3800	1
PIK3CA E545K	2562	0
ERBB2 E770_A771insAYVM (Y772_A775dup)	3387	0
KRAS G12D	2544	0
KRAS Q61K	3134	0
KRAS A146T	3871	1

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

Mr. Björn Nowack

Date of batch release: 27.02.2020

Signature batch release: Björn Nowack

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

⁵ Wild Type

⁶ Mutation