

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 line
CATALOG NUMBER	SID-000003
BATCH NUMBER	00164
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · Manufactured und sealed in class 2 safety cabinet · At room temperature · Manufactured according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> · 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	15.07.2021
EXPIRY DATE	14.07.2023
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	20 μl
MUTATION * GRCh38 COSMIC v91	AKT1 p.E17K (COSV62571334*, substitution, c.49G>A, Exon 2) BRAF p.V600E (COSV56056643*, substitution, c.1799T>A, Exon 15) ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSV54062409*, insertion, c.2313_2324dup, Exon 19) KRAS p.G12D (COSV55497369*, substitution, c.35G>A, Exon 1) KRAS p.Q61K (COSV55502066*, substitution, c.181C>A, Exon 2) KRAS p.A146T (COSV55501778*, substitution, c.436G>A, Exon 3) PIK3CA p.C420R (COSV55874020* substitution, c.1258T>C, Exon 7) PIK3CA p.E542K (COSV55873227*, substitution, c.1624G>A, Exon 9) PIK3CA p.E545A (COSV55873209*, substitution, c.1634A>C, Exon 9) PIK3CA p.E545D (COSV55874040*, substitution, c.1635G>T, Exon 9) PIK3CA p.E545G (COSV55873220*, substitution, c.1634A>G, Exon 9) PIK3CA p.E545K (COSV55873239* substitution, c.1633G>A, Exon 9) PIK3CA p.Q546E (COSV55882350* substitution, c.1636C>G, Exon 9) PIK3CA p.Q546R (COSV55876869* substitution, c.1637A>G, Exon 9) PIK3CA p.H1047L (COSV55873401* substitution, c.3140A>T, Exon 20) PIK3CA p.H1047R (COSV55873195*, substitution, c.3140A>G, Exon 20) PIK3CA p.H1047Y (COSV55876499* substitution, c.3139C>T, Exon 20) p.G719S (COSV51767289*, substitution, c.2155G>A, Exon 18) p.E746_A750delELREA (COSV51765066*, deletion, c.2236_2250del15, Exon 19) p.S752_1759delSPKANKEI (COSV51774879*, deletion, c.2254_2277del24, Exon 19) p.S768I (COSV51768106* substitution, c.2303G>T, Exon 20) p.V769_D770insASV (new: p.A767_V769dup) (COSV51850427* Insertion, c.2303_2304insTGTGGCCAG, Exon 20) p.T790M (COSV51765492*, substitution, c.2369C>T, Exon 20) p.L858R (COSV51765161*, substitution, c.2573T>G, Exon 21) p.L861Q (COSV51766344*, substitution, c.2582T>A, Exon 21)
ALLELE FREQUENCY	0%

QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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 SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany			
TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method	Acceptance criteria	
	Fragmentation	Fragment length analysis Agilent D5000 ScreenTape System (Agilent Technologies)	Peak size 167 bp ± 15% (142 bp – 192 bp)	
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry**	Total DNA: not applicable	
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	dsDNA: 17.5 – 22.5 ng/µl	
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed			
Allele frequency	Allele frequency analysis ddPCR (BioRad QX200™)	AF 0.00% (0.00–0.03%, except for PIK3CA E545A: ≤0.70%)		
RESULTS OF ANALYSIS	Quality control	Result	PASS / FAIL	
	Fragmentation	169 bp	PASS	
	Quantification	32.8 ng/µl (total DNA)	PASS	
		20.8 ng/µl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		AKT1 p.E17K	0.00	PASS
		BRAF p.V600E	0.00	PASS
		ERBB2	0.00	PASS
		KRAS p.G12D	0.00	PASS
		KRAS p.Q61K	0.00	PASS
		KRAS p.A146T	0.00	PASS
		PIK3CA p.C420R	0.00	PASS
		PIK3CA p.E542K	0.00	PASS
		PIK3CA p.E545A***	0.00	PASS
		PIK3CA p.E545D	0.00	PASS
		PIK3CA p.E545G	0.00	PASS
		PIK3CA p.E545K	0.00	PASS
		PIK3CA p.Q546E	0.00	PASS
		PIK3CA p.Q546R	0.00	PASS
		PIK3CA p.H1047L	0.00	PASS
		PIK3CA p.H1047R	0.00	PASS
		PIK3CA p.H1047Y	0.03	PASS
		p.G719S	0.00	PASS
p.E746_A750delELREA		0.00	PASS	
p.S752_I759delSPKANKEI	0.00	PASS		
p.S768I	0.00	PASS		
p.V769_D770insASV	0.03	PASS		
p.T790M	0.00	PASS		
p.L858R	0.02	PASS		
p.L861Q	0.00	PASS		

***A BLAST sequence analysis shows 98% homology of PIK3CA E545A mutation sequence to genome locus Homo sapiens chromosome 22, GRCh38.p13. Therefore, a higher false positive rate is expected and measured, most likely due to a cross reaction of gene probe to genome locus Homo sapiens chromosome 22, GRCh38.p13.

COMMENTS / REMARKS	not applicable			
	Additional information: Measurement of copy number			
	Mutation	CN wt/ng	CN mut/ng	
MEASUREMENT OF COPY NUMBER	AKT1 p.E17K	2395.0	0.0	
	BRAF p.V600E	2144.0	0.0	
	ERBB2 p.E770_A771insAYVM	3588.0	0.0	
	KRAS p.G12D	3028.0	0.0	
	KRAS p.Q61K	3497.0	0.0	
	KRAS p.A146T	4196.0	0.0	
	PIK3CA p.C420R	2003.0	0.0	
	PIK3CA p.E542K	4299.0	0.0	
	PIK3CA p.E545A	4681.0	0.0	
	PIK3CA p.E545D	2938.0	0.0	
	PIK3CA p.E545G	4205.0	0.0	
	PIK3CA p.E545K	2660.0	0.0	
	PIK3CA p.Q546E	5000.0	0.0	
	PIK3CA p.Q546R	4961.0	0.0	
	PIK3CA p.H1047L	3734.0	0.0	
	PIK3CA p.H1047R	3647.0	0.0	
	PIK3CA p.H1047Y	3899.0	1.0	
	p.G719S	4935.0	0.0	
	p.E746_A750delELREA	4513.0	0.0	
	p.S752_I759delSPKANKEI	2753.0	0.0	
	p.S768I	3564.0	0.0	
	p.V769_D770insASV	3844.0	1.0	
	p.T790M	3642.0	0.0	
	p.L858R	4315.0	1.0	
	p.L861Q	5554.0	0.0	
		wt: wildtype; mut: mutation		
		<i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of 1 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per nanogram (ng) 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>		

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

Björn Nowack, Managing Director

Date of batch release: 11.01.2022

Signature batch release: Björn Nowack

This document has been created electronically and is valid without signature.