

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	00144
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	20.01.2021
EXPIRY DATE	19.01.2023
TARGET CONCENTRATION	20 ng/µl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 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_I759delSPKANKEI (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%



Release Date 27.01.2021
Version / Index 3 1
Print Date 02.02.2021

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 High Sensitivity DNA Kit (Agilent Technologies)	Peak size 167 bp ± 10% (151 bp – 181 bp)	
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry** dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: not applicable dsDNA: 17.5 – 22.5 ng/µl	
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed; Measured before filling in product tube			
	Allele frequency	Allele frequency analysis ddPCR (BioRad QX200™)	AF 0.0% (0.00–0.03%, except for PIK3CA E545A: ≤0.7%)	
RESULTS OF ANALYSIS	Quality control	Result	PASS / FAIL	
	Fragmentation	172 bp	PASS	
	Quantification	33 ng/µl (total DNA)	PASS	
		20.3 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***	0.70	PASS
		PIK3CA p.E545D	0.00	PASS
		PIK3CA p.E545G	0.02	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		0.00	PASS	
p.G719S		0.02	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	0.03	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	Additional information: Measurement of copy number		
	Mutation	CN wt/ μ l	CN mut/ μ l
MEASUREMENT OF COPY NUMBER	AKT1 p.E17K	2133	0
	BRAF p.V600E	1840	0
	ERBB2 p.E770_A771insAYVM	3096	0
	KRAS p.G12D	2711	0
	KRAS p.Q61K	3416	0
	KRAS p.A146T	3730	0
	PIK3CA p.C420R	1979	0
	PIK3CA p.E542K	4556	0
	PIK3CA p.E545A	4878	35
	PIK3CA p.E545D	2995	0
	PIK3CA p.E545G	4284	1
	PIK3CA p.E545K	2558	0
	PIK3CA p.Q546E	5206	0
	PIK3CA p.Q546R	5171	0
	PIK3CA p.H1047L	3813	0
	PIK3CA p.H1047R	4030	0
	PIK3CA p.H1047Y	3950	0
	p.G719S	4288	1
	p.E746_A750delELREA	3900	0
	p.S752_I759delSPKANKEI	2656	0
	p.S768I	3137	0
	p.V769_D770insASV	3401	1
	p.T790M	3675	0
	p.L858R	3752	1
	p.L861Q	4831	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 ~20 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 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>		

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

Björn Nowack, Managing Director

Date of batch release: 29.01.2021

Signature batch release: Björn Nowack

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