BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	cfDNA (human) AF: 0% Ashkenazim Son in Plasma
DESCRIPTION	cfDNA (human) AF: 0% Ashkenazim Son is highly characterized human DNA from cell line. Human proteins, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations.
CATALOG NUMBER	SID-000002
BATCH NUMBER	**00244**
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · Bottled with qualified liquid handling workstation · At room temperature · Manufactured according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	14.09.2021
EXPIRY DATE	13.09.2023
TARGET CONCENTRATION	80 ng/ml (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	5 ml
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%

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	dsDNA measurement: Qubit** dsDNA BR Assay Kit (Invitrogen) dsDNA amount per ml plasma	80 ng/ml ± 10% (72-88 ng/ml)
	Allele frequency	Allele frequency analysis** ddPCR (BioRad QX200™)	AF 0.0% (0.00-0.03%, except for PIK3CA E545A: ≤0.7%)
	**Measured before filling in product tube		

RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	170 bp		PASS
	Quantification	82.2 ng/ml (dsDNA)		PASS
	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	0.03	PASS
		PIK3CA p.E545A***	0.40	PASS
		PIK3CA p.E545D	0.00	PASS
		PIK3CA p.E545G	0.02	PASS
		PIK3CA p.E545K	0.00	PASS
		PIK3CA p.Q546E	0.01	PASS
		PIK3CA p.Q546R	0.00	PASS
		PIK3CA p.H1047L	0.00	PASS
		PIK3CA p.H1047R	0.03	PASS
		PIK3CA p.H1047Y	0.00	PASS
		p.G719S	0.03	PASS
		p.E746_A750delELREA	0.00	PASS
		p.S752_I759delSPKANKEI	0.00	PASS
		p.S768I	0.00	PASS
		p.V769_D770insASV	0.00	PASS
		p.T790M	0.00	PASS
		p.L858R	0.00	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		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ml	CN mut/ml
	AKT1 p.E17K	2655	0
	BRAF p.V600E	2434	0
	ERBB2 p.E770_A771insAYVM	4156	0
	KRAS p.G12D	3453	0
	KRAS p.Q61K	4279	0
	KRAS p.A146T	4632	0
	PIK3CA p.C420R	2526	0
	PIK3CA p.E542K	5962	2
	PIK3CA p.E545A	6302	23
	PIK3CA p.E545D	5187	0
	PIK3CA p.E545G	6190	1
	PIK3CA p.E545K	3166	0
	PIK3CA p.Q546E	6884	1
	PIK3CA p.Q546R	6876	0
	PIK3CA p.H1047L	4106	0
	PIK3CA p.H1047R	5131	1.6
	PIK3CA p.H1047Y	5482	0
	p.G719S	6216	2
	p.E746_A750delELREA	5579	0
	p.S752_I759delSPKANKEI	3484	0
	p.S768I	4337	0
	p.V769_D770insASV	4913	0
	p.T790M	5273	0
	p.L858R	4996	0
	p.L861Q	6113	0
	wt: wildtype; mut: mutation		
	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 milliliter (ml) 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:

Björn Nowack, Managing Director

Date of batch release: 05.10.2021

Signature batch release: Björn Nowack

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