

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	00157
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · 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	<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	80 ng/ml (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	5 ml
MUTATION * GRCh38 COSMIC v91	<p>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)</p>
ALLELE FREQUENCY	0%



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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	177 bp		PASS	
	Quantification	82 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	0.03	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***	0.25	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	0.02	PASS	
		PIK3CA p.H1047L	0.00	PASS	
		PIK3CA p.H1047R	0.02	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	0.02	PASS			
p.T790M	0.02	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	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ml	CN mut/ml
	AKT1 p.E17K	8150	0
	BRAF p.V600E	7293	0
	ERBB2 p.E770_A771insAYVM	12141	0
	KRAS p.G12D	10611	3
	KRAS p.Q61K	12368	0
	KRAS p.A146T	14298	0
	PIK3CA p.C420R	7718	0
	PIK3CA p.E542K	17941	5
	PIK3CA p.E545A	15462	38
	PIK3CA p.E545D	12038	0
	PIK3CA p.E545G	17139	0
	PIK3CA p.E545K	9968	0
	PIK3CA p.Q546E	20938	0
	PIK3CA p.Q546R	20858	5
	PIK3CA p.H1047L	15462	0
	PIK3CA p.H1047R	15558	3
	PIK3CA p.H1047Y	20858	0
	p.G719S	16954	3
	p.E746_A750delELREA	15584	0
	p.S752_I759delSPKANKEI	9136	0
	p.S768I	12518	0
	p.V769_D770insASV	13078	3
	p.T790M	14416	3
	p.L858R	15123	3
	p.L861Q	19354	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 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.</i>			

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

Björn Nowack, Managing Director

Date of batch release: 03.02.2021

Signature batch release: Björn Nowack

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