

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	00456
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · Bottled with qualified liquid handling workstation · Manufactured according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	13.02.2023
EXPIRY DATE	12.02.2025
TARGET CONCENTRATION	80 ng/ml (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	5 ml
MUTATION * GRCh38 COSMIC v97	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) EGFR p.G719S (COSV51767289*, substitution, c.2155G>A, Exon 18) EGFR p.E746_A750delELREA (COSV51765066*, deletion, c.2236_2250del15, Exon 19) EGFR p.S752_I759delSPKANKEI (COSV51774879*, deletion, c.2254_2277del24, Exon 19) EGFR p.S768I (COSV51768106* substitution, c.2303G>T, Exon 20) EGFR p.V769_D770insASV (new: EGFR p.A767_V769dup) (COSV51850427* Insertion, c.2303_2304insTGTGGCCAG, Exon 20) EGFR p.T790M (COSV51765492*, substitution, c.2369C>T, Exon 20) EGFR p.L858R (COSV51765161*, substitution, c.2573T>G, Exon 21) EGFR 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 ¹ Agilent D5000 ScreenTape System (Agilent Technologies)	Peak size 167 bp ± 15% (142 bp – 192 bp)	
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry ²	Total DNA: not applicable	
		dsDNA measurement: Qubit ¹ dsDNA BR Assay Kit (Invitrogen)	dsDNA: 80 ng/ml ± 10% (72 – 88 ng/ml)	
	Allele frequency	Allele frequency analysis ¹ ddPCR (BioRad QX200™)	AF 0.00% (0.00 – 0.03%, except for PIK3CA E545A: ≤0.70%)	
¹ measured before filling in product tubes ² Protocol NK603 – Community Reference Laboratory for GM Food and Feed; Measured before filling in product tube				
RESULTS OF ANALYSIS	Quality control	Result	PASS / FAIL	
	Fragmentation	174 bp	PASS	
	Quantification	138.4 ng/ml (total DNA)	PASS	
		84 ng/ml (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		AKT1 p.E17K	0.00	PASS
		BRAF p.V600E	0.00	PASS
		ERBB2 p.E770_A771insAYVM	0.00	PASS
		KRAS p.G12D	0.00	PASS
		KRAS p.Q61K	0.00	PASS
		KRAS p.A146T	0.00	PASS
		PIK3CA p.C420R	0.03	PASS
		PIK3CA p.E542K	0.00	PASS
		PIK3CA p.E545A ³	0.26	PASS
		PIK3CA p.E545D	0.01	PASS
		PIK3CA p.E545G	0.00	PASS
		PIK3CA p.E545K	0.00	PASS
		PIK3CA p.Q546E	0.02	PASS
		PIK3CA p.Q546R	0.00	PASS
		PIK3CA p.H1047L	0.01	PASS
PIK3CA p.H1047R		0.00	PASS	
PIK3CA p.H1047Y		0.02	PASS	
EGFR p.G719S	0.00	PASS		
EGFR p.E746_A750delELREA	0.00	PASS		
EGFR p.S752_I759delSPKANKEI	0.00	PASS		
EGFR p.S768I	0.01	PASS		
EGFR p.V769_D770insASV	0.00	PASS		
EGFR p.T790M	0.01	PASS		
EGFR p.L858R	0.00	PASS		
EGFR p.L861Q	0.00	PASS		

³A 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/ng	CN mut/ng	
MEASUREMENT OF COPY NUMBER	AKT1 p.E17K	133.70	0.00	
	BRAF p.V600E	122.81	0.00	
	ERBB2 p.E770_A771insAYVM	192.38	0.00	
	KRAS p.G12D	168.83	0.00	
	KRAS p.Q61K	202.67	0.00	
	KRAS p.A146T	234.32	0.01	
	PIK3CA p.C420R	124.40	0.04	
	PIK3CA p.E542K	261.14	0.00	
	PIK3CA p.E545A	287.98	0.75	
	PIK3CA p.E545D	186.97	0.02	
	PIK3CA p.E545G	258.19	0.00	
	PIK3CA p.E545K	168.94	0.00	
	PIK3CA p.Q546E	310.48	0.06	
	PIK3CA p.Q546R	316.41	0.00	
	PIK3CA p.H1047L	224.68	0.03	
	PIK3CA p.H1047R	240.19	0.00	
	PIK3CA p.H1047Y	232.52	0.04	
	EGFR p.G719S	199.33	0.00	
	EGFR p.E746_A750delELREA	209.71	0.00	
	EGFR p.S752_I759delSPKANKEI	129.94	0.00	
	EGFR p.S768I	166.71	0.02	
	EGFR p.V769_D770insASV	179.00	0.00	
	EGFR p.T790M	195.89	0.02	
	EGFR p.L858R	192.57	0.00	
	EGFR p.L861Q	247.81	0.00	
	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: 11.03.2023

Signature batch release: Björn Nowack

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