

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	00738
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · Manufactured and sealed in class 2 safety cabinet · 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	24.06.2024
EXPIRY DATE	23.06.2026
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	20 μl
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: 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		
	Fragmentation	Fragment length analysis: Agilent D5000 ScreenTape System (Agilent Technologies)		
	Quantification	dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		
	Allele frequency	Allele frequency analysis: ddPCR (BioRad QX200™)		
RESULTS OF ANALYSIS	Quality control	Result		
	Fragmentation	172 bp		
	Quantification	21.2 ng/μl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		AKT1 p.E17K	0.01	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	0.01	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	0.01	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	
EGFR p.G719S	0.00	PASS		
EGFR p.E746_A750delELREA	0.00	PASS		
EGFR p.S752_I759delSPKANKEI	0.00	PASS		
EGFR p.S768I	0.00	PASS		
EGFR p.V769_D770insASV	0.00	PASS		
EGFR p.T790M	0.00	PASS		
EGFR p.L858R	0.00	PASS		
EGFR 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		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng	CN mut/ng
	AKT1 p.E17K	210.92	0.03
	BRAF p.V600E	179.38	0.00
	ERBB2 p.E770_A771insAYVM	303.93	0.00
	KRAS p.G12D	445.05	0.00
	KRAS p.Q61K	310.68	0.01
	KRAS p.A146T	365.01	0.00
	PIK3CA p.C420R	191.24	0.02
	PIK3CA p.E542K	451.87	0.00
	PIK3CA p.E545A	527.95	0.00
	PIK3CA p.E545D	305.61	0.00
	PIK3CA p.E545G	498.69	0.00
	PIK3CA p.E545K	387.23	0.04
	PIK3CA p.Q546E	544.90	0.00
	PIK3CA p.Q546R	582.90	0.00
	PIK3CA p.H1047L	397.59	0.00
	PIK3CA p.H1047R	360.88	0.00
	PIK3CA p.H1047Y	377.00	0.00
	EGFR p.G719S	348.66	0.00
	EGFR p.E746_A750delELREA	398.72	0.00
	EGFR p.S752_I759delSPKANKEI	211.61	0.00
	EGFR p.S768I	116.86	0.00
	EGFR p.V769_D770insASV	304.77	0.00
	EGFR p.T790M	398.19	0.00
	EGFR p.L858R	160.33	0.00
	EGFR p.L861Q	372.41	0.00
	wt: wildtype; mut: mutation		
<p><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></p>			

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

Björn Nowack, Managing Director

Date of batch release: 28.06.2024

Signature batch release: Björn Nowack

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