

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	Ashkenazim son cfDNA (human) AF: 0% in Plasma
DESCRIPTION	Human proteins in common plasma concentrations, electrolytes, EDTA and cfDNA / ctDNA in common plasma concentrations
CATALOG NUMBER	SID-000002
BATCH NUMBER	00025
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • Bottled with qualified liquid handling workstation and dispenser tool • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
PACKAGE SIZE AND TYPE	
DATE OF MANUFACTURE	12.11.2019
EXPIRY DATE	11.11.2020
CONCENTRATION	80 ng/ml
QUANTITY	400 ng
NOMINAL VOLUME	5 ml
MUTATION	<p>p.G719S (COSM6252*, COSV51767289*, substitution, c.2155G>A, Exon 18)</p> <p>p.E746_A750delELREA (COSM6225*, COSV51765066*, deletion, c.2236_2250del15, Exon 19)</p> <p>p.S752_I759delSPKANKEI (COSM6256*, COSV51774879*, deletion, c.2254_2277del24, Exon 19)</p> <p>p.S768I (COSM6241*, COSV51768106* substitution, c.2303G>T, Exon 20)</p> <p>p.V769_D770insASV (COSM20884*, COSV51850427* Insertion, c.2303_2304insTGTGGCCAG, Exon 20)</p> <p>p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C>T, Exon 20)</p> <p>p.L858R (COSM6224*, COSV51765161*, substitution, c.2573T>G, Exon 21)</p> <p>p.L861Q (COSM6213*, COSV51766344*, substitution, c.2582T>A, Exon 21)</p> <p><small>* GRCh38 COSMIC v90</small></p>
ALLELIC FREQUENCY	0,0%
QUALITY	Quantity traceable to internationally certified reference material ¹
STORAGE CONDITIONS	+ 2-8 °C

¹ERM-AD442k
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MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany				
TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method		Acceptance criteria	
	Fragmentation	Fragment Length Analysis ² Agilent High Sensitivity DNA Kit (Agilent Techn.)		peak size 167 bp ± 10% (151 bp – 181 bp)	
	Quantification	Spectrophotometry ssDNA [ng/μl] = (A260- A320)*38 ^{3,4}		18,5 – 21,5 ng/μl	
	Allelic Frequency	dPCR Analysis ⁵ using BioRad QX200™ System		AF 0,0% (0,00-0,00%)	
RESULTS OF ANALYSIS			Result	PASS/FAIL	
	Fragmentation		167,0 bp	PASS	
	Quantification		20 ng/μl	PASS	
	Allelic Frequency		Mutation	AF in %	PASS
			L858R	0,0	
			L861Q	0,0	
			S768I	0,0	
			E746_A750delELREA	0,0	
T790M			0,0		
G719S			0,0		
V769_D770insASV	0,0				
S752_I759delSPANKEI	0,0				
COMMENTS/REMARKS		-			

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

Mr. Björn Nowack

Date of batch release: 20 Dec. 2018

Signature batch release: Björn Nowack

This document was created electronically and is valid without a signature.

² Measured after extraction

³ Protocol NK603 – Community Reference Laboratory for GM Food and Feed

⁴ measured cfDNA conc. before spiking in

⁵ Measured after spiking in