

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	Ashkenazim son cfDNA (EGFR)
DESCRIPTION	Ashkenazim son cfDNA (EGFR) is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-0003
BATCH NUMBER	00004
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in clean ISO 5 safety cabinet • Bottled with qualified liquid handling workstation • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
PACKAGE SIZE AND TYPE	
DATE OF MANUFACTURE	26 Nov 2018
EXPIRY DATE	26 Nov 2019
CONCENTRATION	20 ng/μl
QUANTITY	400 ng
NOMINAL VOLUME	20 μl
MUTATION	<p>p.G719S (COSM6252*, substitution, c.2155G>A, Exon 18)</p> <p>p.E746_A750delELREA (COSM6225*, deletion, c.2236_2250del15, Exon 19)</p> <p>p.S752_I759delSPKANKEI (COSM6256*, deletion, c.2254_2277del24, Exon 19)</p> <p>p.S768I (COSM6241*, substitution, c.2303G>T, Exon 20)</p> <p>p.V769_D770insASV (COSM20884*, Insertion, c.2303_2304insTGTGGCCAG, Exon 20)</p> <p>p.T790M (COSM6240*, substitution, c.2369C>T, Exon 20)</p> <p>p.L858R (COSM6224*, substitution, c.2573T>G, Exon 21)</p> <p>p.L861Q (COSM6213*, substitution, c.2582T>A, Exon 21)</p> <p>* GRCh38 COSMIC v88</p>
ALLELIC FREQUENCY	0,0%
QUALITY	Quantity traceable to internationally certified reference material ¹ sterile
STORAGE CONDITIONS	+ 2-8 °C
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

¹ERM-AD442k

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 – 183 bp)	
	Quantification	Spectrophotometry ssDNA [ng/μl] = (A260–A320)*38 ³		18,0 – 22,0 ng/μl	
	Allelic Frequency	dPCR Analysis ⁴ using BioRad QX200™ System		AF 0,0% (0,00–0,00%)	
RESULTS OF ANALYSIS			Result	PASS/FAIL	
	Fragmentation		170,0 bp	PASS	
	Quantification		20,1 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: 28 Nov. 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 after spiking in