

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 1% AF cfDNA in Plasma
DESCRIPTION	Human proteins in common plasma concentrations, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations
CATALOG NUMBER	SID-000016
BATCH NUMBER	00028
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • Bottled with qualified liquid handling workstation • At room temperature
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	12.11.2019
EXPIRY DATE	11.11.2021
CONCENTRATION	80 ng/ml (ds DNA)
QUANTITY	400 ng (ds DNA)
NOMINAL VOLUME	19.2 µl in 5 ml plasma
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	1%
QUALITY	<p>DNA quantity metrologically traceable to internationally certified reference material¹</p> <p>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.</p>

¹ ERM_AD442K
Phone: +49 (0) 381 377 182 01

STORAGE CONDITIONS	+ 2–8 °C			
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 Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)	
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/μl] = (A260–A320)*38 ^{2,3} dsDNA measurement ² : Qubit dsDNA BR Assay Kit (Invitrogen)	ssDNA: n.a. ⁴ dsDNA: n.a. ⁴	
	Allelic Frequency	dPCR Analysis ² using BioRad QX200™ System	AF 1% ±40% (0.6–1.4%)	
RESULTS OF ANALYSIS		Result	PASS/FAIL	
	Fragmentation	181 bp	PASS	
	Quantity	22.3 ng/μl (total DNA) 31.6 ng/μl (dsDNA)		
	Allelic Frequency	Mutation	AF in %	PASS
		L858R	1.0	
L861Q		1.3		
S768I		0.9		
E746_A750delELREA		0.9		
T790M		0.9		
G719S		0.9		
V769_D770insASV	0.9			
S752_I759delSPANKEI	1.0			
COMMENTS/REMARKS	Additional information: Copy numbers (CN) of the respective measurements <i>Table 1 indicates the values of the QC assays performed by SensID GmbH with an DNA input of ~40 ng. The value for the respective mutation results from the mean value of three measured replicates (CN values are rounded). CN concentration values per microliter (μl), 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.</i>			

² Measured before spiking in

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

⁴ not applicable

Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.

Mutation	CN wt⁵/μl	CN mut⁶/μl
L858R	3498	37
L861Q	4929	64
S768I	3382	30
E746_A750delELREA	3798	35
T790M	4389	44
G719S	3890	36
V769_D770insASV	3513	32
S752_I759delSPANKEI	2624	27

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

Mr. Björn Nowack, Managing Director

Date of batch release: 12.11.2019

Signature batch release: Björn Nowack

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

⁵ Wild Type

⁶ Mutation