

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 0.1% AF cfDNA in Plasma AKT1/BRAF/ERBB2/KRAS/PIK3CA
DESCRIPTION	Human proteins in common plasma concentrations, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations
CATALOG NUMBER	SID-000088
BATCH NUMBER	00023
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	11.11.2020
CONCENTRATION	80 ng/ml (ds DNA)
QUANTITY	400 ng (ds DNA)
NOMINAL VOLUME	17.1 µl in 5 ml plasma
MUTATION	AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G>A, Exon 2) BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T>A, Exon 15) ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSM20959*/ COSM404915*, COSV54062409*, insertion, c.2313_2324dup/ c.2310_2311ins12, Exon 19) KRAS p.G12D (COSM521*, COSV55497369*, substitution, c.35G>A, Exon 1) KRAS p.Q61K (COSM549*, COSV55502066*, substitution, c.181C>A, Exon 2) KRAS p.A146T (COSM19404*, COSV55501778*, substitution, c.436G>A, Exon 3) PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A>G, Exon 20) PIK3CA p.E545K (COSM763*, COSV55873239* substitution, c.1633G>A, Exon 9) <small>* GRCh38 COSMIC v90</small>
ALLELIC FREQUENCY	0.1%
QUALITY	DNA quantity metrological traceable to internationally certified reference material ¹ 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

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

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: 17.5 – 23.5 ng/μl																		
	Allelic Frequency	dPCR Analysis ² using BioRad QX200™ System	AF 0.1% ±60% (0.04–0.16%)																		
RESULTS OF ANALYSIS		Result	PASS/FAIL																		
	Fragmentation	181 bp	PASS																		
	Quantity	26.8 ng/μl (total DNA) 23.5 ng/μl (dsDNA)	PASS																		
	Allelic Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> </tr> </thead> <tbody> <tr> <td>AKT1 E17K</td> <td>0.05</td> </tr> <tr> <td>BRAF V600E</td> <td>0.06</td> </tr> <tr> <td>ERBB2 E770_A771insAYVM (Y772_A775dup)</td> <td>0.09</td> </tr> <tr> <td>KRAS G12D</td> <td>0.04</td> </tr> <tr> <td>KRAS Q61K</td> <td>0.09</td> </tr> <tr> <td>KRAS A146T</td> <td>0.1</td> </tr> <tr> <td>PIK3CA H1047R</td> <td>0.1</td> </tr> <tr> <td>PIK3CA E545K</td> <td>0.1</td> </tr> </tbody> </table>	Mutation	AF in %	AKT1 E17K	0.05	BRAF V600E	0.06	ERBB2 E770_A771insAYVM (Y772_A775dup)	0.09	KRAS G12D	0.04	KRAS Q61K	0.09	KRAS A146T	0.1	PIK3CA H1047R	0.1	PIK3CA E545K	0.1	PASS
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COMMENTS/REMARKS	<p>Additional information:</p> <p>Copy numbers (CN) of the respective measurements</p> <p><i>Table 1 indicates the values of the QC assays performed by SensID GmbH with an DNA input of ~80 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></p>																				

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 wt ⁵ /μl	CN mut ⁶ /μl
AKT1 E17K	2094	1
BRAF V600E	1720	1
ERBB2 E770_A771insAYVM (Y772_A775dup)	2895	3
KRAS G12D	2548	2
KRAS Q61K	3034	3
KRAS A146T	3428	4
PIK3CA H1047R	3676	4
PIK3CA E545K	2429	3

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

Mr. Björn Nowack

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