Batch Certificate
For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 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-000089
BATCH NUMBER	00027
MANUFACTURING CONDITIONS	• Manufactured and sealed in class 2 safety cabinet • Bottled with qualified liquid handling workstation • At room temperature
PACKAGE SIZE AND TYPE	• 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	20.1 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) * GRCh38 COSMIC v90
ALLELIC FREQUENCY	1%
QUALITY	DNA quantity metrologically 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

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	30.2 ng/µl (total DNA) 19.9 ng/µl (dsDNA)	
Allelic Frequency	see table below	PASS

Mutation	AF in %
AKT1 E17K	1.1
BRAF V600E	0.9
ERBB2 E770_A771insAYVM (Y772_A775dup)	1.1
KRAS G12D	1.1
KRAS Q61K	1.1
KRAS A146T	1.0
PIK3CA H1047R	1.0
PIK3CA E545K	0.8

COMMENTS/REMARKS

Additional information:

Copy numbers (CN) of the respective measurements

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.

[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	2152	25
BRAF V600E	1805	17
ERBB2 E770_A771insAYVM (Y772_A775dup)	3055	34
KRAS G12D	2821	33
KRAS Q61K	3180	37
KRAS A146T	3946	39
PIK3CA H1047R	3748	38
PIK3CA E545K	2401	21

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