Batch Certificate

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 0,1% AF cfDNA BRAF/KRAS/PIK3CA/AKT1/ERBB2
DESCRIPTION	5-Gene-Multiplex 0,1% AF cfDNA BRAF/KRAS/PIK3CA/AKT1/ERBB2 is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000092
BATCH NUMBER	00019
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	02.09.2019
EXPIRY DATE	01.09.2020
CONCENTRATION	20 ng/µl (ds DNA)
QUANTITY	400 ng (ds DNA)
NOMINAL VOLUME	21,5 µl
MUTATION	BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T>A, Exon 15) PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A>G, Exon 20) PIK3CA p.E545K (COSM763*, COSV55873239* substitution, c.1633G>A, Exon 9) 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) AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G>A, Exon 2) ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSM20959*/ COSM404915*, COSV54062409*, insertion, c.2313_2324dup/ c.2310_2311ins12, Exon 19) * GRCh38 COSMIC v90
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.

[1] ERM_AD442K

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SensID GmbH, Schillingallee 68, 18057 Rostock, Germany

VAT No: DE305142405, district court: Rostock HRB 14621
CEO: Björn Nowack

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 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] dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	ssDNA: n.a.[3] dsDNA: 18,5 – 22,5 ng/µl
Allelic Frequency	dPCR Analysis using BioRad QX200™ System	AF 0,1% ±60% (0,04-0,16%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	181 bp	PASS
Quantity	33,2 ng/µl (total DNA) 19,5 ng/µl (dsDNA)	PASS
Allelic Frequency	see table below	PASS

Mutation	AF in %
BRAF V600E	0,06
PIK3CA H1047R	0,06
PIK3CA E545K	0,10
KRAS G12D	0,08
KRAS Q61K	0,10
KRAS A146T	0,12
AKT1 E17K	0,13
ERBB2 E770_A771insAYVM (Y772_A775dup)	0,09

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 ~80 ng. The value for the respective mutation results from the mean value of three measured repetitions of QC Pool of 7 QC samples (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

[2] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[3] not applicable

depending on the assay used. 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[4]/µl	CN mut[5]/µl
BRAF V600E	1999	1
PIK3CA H1047R	4489	3
PIK3CA E545K	2649	3
KRAS G12D	2742	3
KRAS Q61K	3329	3
KRAS A146T	3957	6
AKT1 E17K	2348	3
ERBB2 E770_A771insAYVM (Y772_A775dup)	3177	3

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

Mr. Björn Nowack

Date of batch release: **20.09.2019**

Signature batch release: Björn Nowack

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

[4] Wild Type
[5] Mutation

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