Batch Certificate
For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 5% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA
DESCRIPTION	5-Gene-Multiplex 5% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000094
BATCH NUMBER	00017
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	01.09.2021
CONCENTRATION	20 ng/µl (ds DNA)
QUANTITY	400 ng (ds DNA)
NOMINAL VOLUME	20.0 µl
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
ALLELE FREQUENCY	5%
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

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 Techn.)	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
	Allele Frequency	dPCR Analysis using BioRad QX200™ System	AF 5% ±30% (3.5–6.5%)

RESULTS OF ANALYSIS		Result	PASS/FAIL
	Fragmentation	180 bp	PASS
	Quantity	35.15 ng/µl (total DNA) 21.80 ng/µl (dsDNA)	PASS

		Mutation	AF in %	
	Allele Frequency	AKT1 E17K	6.5	PASS
		BRAF V600E	5.2	
		ERBB2 E770_A771insAYVM (Y772_A775dup)	4.9	
		KRAS G12D	4.9	
		KRAS Q61K	5.7	
		KRAS A146T	5.5	
		PIK3CA H1047R	6.0	
		PIK3CA E545K	6.5	

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

---

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

Phone: +49 (0) 381 377 182 01   Net: www.sens-id.com   Mail: support@sens-id.com
SensID GmbH, Schillingallee 68, 18057 Rostock, Germany

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

Mutation	CN wt[4]/µl	CN mut[5]/µl
AKT1 E17K	2605	180
BRAF V600E	2182	120
ERBB2 E770_A771insAYVM (Y772_A775dup)	3545	184
KRAS G12D	3055	159
KRAS Q61K	3547	215
KRAS A146T	4102	239
PIK3CA H1047R	4409	282
PIK3CA E545K	3245	226

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

Mr. Björn Nowack, Managing Director

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