

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	00021
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • 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	26.02.2020
EXPIRY DATE	25.02.2022
CONCENTRATION	20 ng/μl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 μl; (553 ng)
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>
ALLELE FREQUENCY	5%
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
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

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

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 ^{2,3} dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a. ⁴ dsDNA: 17.5 – 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	178 bp	PASS																											
	Quantity	24.8 ng/μl (total DNA) 22.1 ng/μl (dsDNA)	PASS																											
	Allele Frequency	<table border="1"> <thead> <tr> <th data-bbox="831 1115 1098 1149">Mutation</th> <th data-bbox="1098 1115 1270 1149">AF in %</th> <th data-bbox="1270 1115 1442 1149">PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td data-bbox="831 1149 1098 1182">AKT1 E17K</td> <td data-bbox="1098 1149 1270 1182">6.0</td> <td data-bbox="1270 1149 1442 1182">PASS</td> </tr> <tr> <td data-bbox="831 1182 1098 1216">BRAF V600E</td> <td data-bbox="1098 1182 1270 1216">5.4</td> <td data-bbox="1270 1182 1442 1216">PASS</td> </tr> <tr> <td data-bbox="831 1216 1098 1249">PIK3CA H1047R</td> <td data-bbox="1098 1216 1270 1249">5.0</td> <td data-bbox="1270 1216 1442 1249">PASS</td> </tr> <tr> <td data-bbox="831 1249 1098 1283">PIK3CA E545K</td> <td data-bbox="1098 1249 1270 1283">5.9</td> <td data-bbox="1270 1249 1442 1283">PASS</td> </tr> <tr> <td data-bbox="831 1283 1098 1373">ERBB2 E770_A771insAYVM (Y772_A775dup)</td> <td data-bbox="1098 1283 1270 1373">5.3</td> <td data-bbox="1270 1283 1442 1373">PASS</td> </tr> <tr> <td data-bbox="831 1373 1098 1406">KRAS G12D</td> <td data-bbox="1098 1373 1270 1406">5.1</td> <td data-bbox="1270 1373 1442 1406">PASS</td> </tr> <tr> <td data-bbox="831 1406 1098 1440">KRAS Q61K</td> <td data-bbox="1098 1406 1270 1440">7.1</td> <td data-bbox="1270 1406 1442 1440">FAIL</td> </tr> <tr> <td data-bbox="831 1440 1098 1473">KRAS A146T</td> <td data-bbox="1098 1440 1270 1473">5.7</td> <td data-bbox="1270 1440 1442 1473">PASS</td> </tr> </tbody> </table>		Mutation	AF in %	PASS/FAIL	AKT1 E17K	6.0	PASS	BRAF V600E	5.4	PASS	PIK3CA H1047R	5.0	PASS	PIK3CA E545K	5.9	PASS	ERBB2 E770_A771insAYVM (Y772_A775dup)	5.3	PASS	KRAS G12D	5.1	PASS	KRAS Q61K	7.1	FAIL	KRAS A146T	5.7	PASS
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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 ~20 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 Protocol NK603 – Community Reference Laboratory for GM Food and Feed

³ Measured before filling in product tube

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
AKT1 E17K	1937	124
BRAF V600E	1951	112
PIK3CA H1047R	4554	238
PIK3CA E545K	3101	196
ERBB2 E770_A771insAYVM (Y772_A775dup)	3894	216
KRAS G12D	2863	154
KRAS Q61K	3485	267
KRAS A146T	4428	266

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

Mr. Björn Nowack, Managing Director

Date of batch release: 28.02.2020

Signature batch release: Björn Nowack

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

⁵ Wild Type
⁶ Mutation