

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	00136
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	09.12.2020
EXPIRY DATE	08.12.2022
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 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*, COSV54062409*, insertion, c.2313_2324dup, 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 v91</small>
ALLELE FREQUENCY	5.0%
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
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 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}	Total DNA: n.a. ⁴																																							
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	dsDNA: 17.5 – 22.5 ng/μl																																							
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 5% ±30% (3.5–6.5%)																																							
RESULTS OF ANALYSIS	<table border="1"> <thead> <tr> <th></th> <th>Result</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>Fragmentation</td> <td>177 bp</td> <td>PASS</td> </tr> <tr> <td>Quantity</td> <td>36.4 ng/μl (total DNA) 19.7 ng/μl (dsDNA)</td> <td>PASS</td> </tr> <tr> <td>Allele Frequency</td> <td colspan="2"> <table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>AKT1 E17K</td> <td>3.9</td> <td>PASS</td> </tr> <tr> <td>BRAF V600E</td> <td>4.3</td> <td>PASS</td> </tr> <tr> <td>ERBB2 E770_A771insAYVM (new: Y772_A775dup)</td> <td>4.4</td> <td>PASS</td> </tr> <tr> <td>KRAS G12D</td> <td>4.8</td> <td>PASS</td> </tr> <tr> <td>KRAS Q61K</td> <td>4.9</td> <td>PASS</td> </tr> <tr> <td>KRAS A146T</td> <td>5.6</td> <td>PASS</td> </tr> <tr> <td>PIK3CA H1047R</td> <td>5.0</td> <td>PASS</td> </tr> <tr> <td>PIK3CA E545K</td> <td>3.8</td> <td>PASS</td> </tr> </tbody> </table> </td> </tr> </tbody> </table>				Result	PASS/FAIL	Fragmentation	177 bp	PASS	Quantity	36.4 ng/μl (total DNA) 19.7 ng/μl (dsDNA)	PASS	Allele Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>AKT1 E17K</td> <td>3.9</td> <td>PASS</td> </tr> <tr> <td>BRAF V600E</td> <td>4.3</td> <td>PASS</td> </tr> <tr> <td>ERBB2 E770_A771insAYVM (new: Y772_A775dup)</td> <td>4.4</td> <td>PASS</td> </tr> <tr> <td>KRAS G12D</td> <td>4.8</td> <td>PASS</td> </tr> <tr> <td>KRAS Q61K</td> <td>4.9</td> <td>PASS</td> </tr> <tr> <td>KRAS A146T</td> <td>5.6</td> <td>PASS</td> </tr> <tr> <td>PIK3CA H1047R</td> <td>5.0</td> <td>PASS</td> </tr> <tr> <td>PIK3CA E545K</td> <td>3.8</td> <td>PASS</td> </tr> </tbody> </table>		Mutation	AF in %	PASS/FAIL	AKT1 E17K	3.9	PASS	BRAF V600E	4.3	PASS	ERBB2 E770_A771insAYVM (new: Y772_A775dup)	4.4	PASS	KRAS G12D	4.8	PASS	KRAS Q61K	4.9	PASS	KRAS A146T	5.6	PASS	PIK3CA H1047R	5.0	PASS	PIK3CA E545K	3.8	PASS
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² Protocol NK603 – Community Reference Laboratory for GM Food and Feed

³ Measured before filling in product tube

⁴ Not applicable

COMMENTS/REMARKS

ADDITIONAL INFORMATION:

Copy numbers (CN) of the respective measurements

Mutation	CN wt ⁵ /μl	CN mut ⁶ /μl
AKT1 E17K	2143	86
BRAF V600E	1985	90
ERBB2 E770_A771insAYVM (new: Y772_A775dup)	3166	147
KRAS G12D	2722	138
KRAS Q61K	3194	163
KRAS A146T	3724	222
PIK3CA H1047R	4058	214
PIK3CA E545K	3318	132

Table 1 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~40 ng. The value for the respective mutation results from the mean value of five 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. Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.

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

Mr. Björn Nowack, Managing Director

Date of batch release: 16.12.2020

Signature batch release: Björn Nowack

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

⁵ Wild Type
⁶ Mutation