

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 1% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA
DESCRIPTION	5-Gene-Multiplex 1% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000093
BATCH NUMBER	00018
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • Bottled with qualified liquid handling workstation • 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	02.09.2019
EXPIRY DATE	01.09.2020
CONCENTRATION	20 ng/μl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	21.6 μl
MUTATION	<p>AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G>A, Exon 2)</p> <p>BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T>A, Exon 15)</p> <p>ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSM20959*/ COSM404915*, COSV54062409*, insertion, c.2313_2324dup/ c.2310_2311ins12, Exon 19)</p> <p>KRAS p.G12D (COSM521*, COSV55497369*, substitution, c.35G>A, Exon 1)</p> <p>KRAS p.Q61K (COSM549*, COSV55502066*, substitution, c.181C>A, Exon 2)</p> <p>KRAS p.A146T (COSM19404*, COSV55501778*, substitution, c.436G>A, Exon 3)</p> <p>PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A>G, Exon 20)</p> <p>PIK3CA p.E545K (COSM763*, COSV55873239* substitution, c.1633G>A, Exon 9)</p> <p><small>* GRCh38 COSMIC v90</small></p>
ALLELIC FREQUENCY	1%
QUALITY	<p>DNA quantity metrological traceable to internationally certified reference material¹</p> <p>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.</p>
STORAGE CONDITIONS	+ 2-8 °C

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

<p>MANUFACTURING AND QUALITY CONTROL SITES</p>	<p>SensID GmbH Schillingallee 68, 18057 Rostock, Germany</p>																														
<p>TEST METHOD AND ACCEPTANCE CRITERIA</p>	<p>Quality Control</p>	<p>Test Method</p>	<p>Acceptance criteria</p>																												
	<p>Fragmentation</p>	<p>Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Technologies)</p>	<p>peak size 167 bp ± 10% (151 bp – 181 bp)</p>																												
	<p>Quantification</p>	<p>Total DNA measurement: Spectrophotometry ssDNA [ng/μl] = (A260-A320)*38² dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)</p>	<p>ssDNA: n.a.³ dsDNA: 18.5 – 22.5 ng/μl</p>																												
	<p>Allelic Frequency</p>	<p>dPCR Analysis using BioRad QX200™ System</p>	<p>AF 1% ±40% (0.6–1.4%)</p>																												
<p>RESULTS OF ANALYSIS</p>	<table border="1"> <thead> <tr> <th></th> <th>Result</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>Fragmentation</td> <td>175 bp</td> <td>PASS</td> </tr> <tr> <td>Quantity</td> <td>28.91 ng/μl (total DNA) 19.7 ng/μl (dsDNA)</td> <td>PASS</td> </tr> <tr> <td rowspan="8">Allelic Frequency</td> <td>Mutation</td> <td>AF in %</td> </tr> <tr> <td>AKT1 E17K</td> <td>0.9</td> </tr> <tr> <td>BRAF V600E</td> <td>0.6</td> </tr> <tr> <td>ERBB2 E770_A771insAYVM (Y772_A775dup)</td> <td>1.0</td> </tr> <tr> <td>KRAS G12D</td> <td>0.8</td> </tr> <tr> <td>KRAS Q61K</td> <td>1.1</td> </tr> <tr> <td>KRAS A146T</td> <td>1.1</td> </tr> <tr> <td>PIK3CA H1047R</td> <td>1.0</td> </tr> <tr> <td>PIK3CA E545K</td> <td>0.8</td> </tr> </tbody> </table>				Result	PASS/FAIL	Fragmentation	175 bp	PASS	Quantity	28.91 ng/μl (total DNA) 19.7 ng/μl (dsDNA)	PASS	Allelic Frequency	Mutation	AF in %	AKT1 E17K	0.9	BRAF V600E	0.6	ERBB2 E770_A771insAYVM (Y772_A775dup)	1.0	KRAS G12D	0.8	KRAS Q61K	1.1	KRAS A146T	1.1	PIK3CA H1047R	1.0	PIK3CA E545K	0.8
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<p>COMMENTS/REMARKS</p>	<p>Additional information: Copy numbers (CN) of the respective measurements</p> <p><i>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.</i></p>																														

² Protocol NK603 – Community Reference Laboratory for GM Food and Feed

³not applicable

Mutation	CN wt ⁴ /μl	CN mut ⁵ /μl
AKT1 E17K	2316	21
BRAF V600E	2028	12
ERBB2 E770_A771insAYVM (Y772_A775dup)	3347	35
KRAS G12D	2903	26
KRAS Q61K	3211	37
KRAS A146T	3664	43
PIK3CA H1047R	3975	42
PIK3CA E545K	2682	23

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