

## Batch Certificate For Research Use Only

### PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 0.1% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA
DESCRIPTION	5-Gene-Multiplex 0.1% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000092
BATCH NUMBER	00019
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> <li>• Manufactured and sealed in class 2 safety cabinet</li> <li>• Bottled with qualified liquid handling workstation</li> <li>• At room temperature</li> </ul>
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> <li>• 2D barcoded tube with screw cap</li> <li>• Material: Polypropylen (PP)</li> </ul>
DATE OF MANUFACTURE	02.09.2019
EXPIRY DATE	01.09.2021
CONCENTRATION	20 ng/μl (ds DNA)
QUANTITY	400 ng (ds DNA)
NOMINAL VOLUME	21.5 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) <small>* GRCh38 COSMIC v90</small>
ALLELE FREQUENCY	0.1%
QUALITY	DNA quantity metrological traceable to internationally certified reference material <sup>1</sup>  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

<sup>1</sup> 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 <sup>2</sup> dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	ssDNA: n.a. <sup>3</sup>  dsDNA: 18.5 – 22.5 ng/μl																														
	Allele Frequency	dPCR Analysis using BioRad QX200™ System	AF 0.1% ±60% (0.04–0.16%)																														
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>181 bp</td> <td>PASS</td> </tr> <tr> <td>Quantity</td> <td>33.2 ng/μl (total DNA) 19.5 ng/μl (dsDNA)</td> <td>PASS</td> </tr> <tr> <td>Allele Frequency</td> <td> <table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> </tr> </thead> <tbody> <tr> <td>AKT1 E17K</td> <td>0.13</td> </tr> <tr> <td>BRAF V600E</td> <td>0.06</td> </tr> <tr> <td>ERBB2 E770_A771insAYVM (Y772_A775dup)</td> <td>0.09</td> </tr> <tr> <td>KRAS G12D</td> <td>0.08</td> </tr> <tr> <td>KRAS Q61K</td> <td>0.10</td> </tr> <tr> <td>KRAS A146T</td> <td>0.12</td> </tr> <tr> <td>PIK3CA H1047R</td> <td>0.06</td> </tr> <tr> <td>PIK3CA E545K</td> <td>0.10</td> </tr> </tbody> </table> </td> <td>PASS</td> </tr> </tbody> </table>				Result	PASS/FAIL	Fragmentation	181 bp	PASS	Quantity	33.2 ng/μl (total DNA) 19.5 ng/μl (dsDNA)	PASS	Allele Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> </tr> </thead> <tbody> <tr> <td>AKT1 E17K</td> <td>0.13</td> </tr> <tr> <td>BRAF V600E</td> <td>0.06</td> </tr> <tr> <td>ERBB2 E770_A771insAYVM (Y772_A775dup)</td> <td>0.09</td> </tr> <tr> <td>KRAS G12D</td> <td>0.08</td> </tr> <tr> <td>KRAS Q61K</td> <td>0.10</td> </tr> <tr> <td>KRAS A146T</td> <td>0.12</td> </tr> <tr> <td>PIK3CA H1047R</td> <td>0.06</td> </tr> <tr> <td>PIK3CA E545K</td> <td>0.10</td> </tr> </tbody> </table>	Mutation	AF in %	AKT1 E17K	0.13	BRAF V600E	0.06	ERBB2 E770_A771insAYVM (Y772_A775dup)	0.09	KRAS G12D	0.08	KRAS Q61K	0.10	KRAS A146T	0.12	PIK3CA H1047R	0.06	PIK3CA E545K	0.10	PASS
	Result	PASS/FAIL																															
Fragmentation	181 bp	PASS																															
Quantity	33.2 ng/μl (total DNA) 19.5 ng/μl (dsDNA)	PASS																															
Allele Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> </tr> </thead> <tbody> <tr> <td>AKT1 E17K</td> <td>0.13</td> </tr> <tr> <td>BRAF V600E</td> <td>0.06</td> </tr> <tr> <td>ERBB2 E770_A771insAYVM (Y772_A775dup)</td> <td>0.09</td> </tr> <tr> <td>KRAS G12D</td> <td>0.08</td> </tr> <tr> <td>KRAS Q61K</td> <td>0.10</td> </tr> <tr> <td>KRAS A146T</td> <td>0.12</td> </tr> <tr> <td>PIK3CA H1047R</td> <td>0.06</td> </tr> <tr> <td>PIK3CA E545K</td> <td>0.10</td> </tr> </tbody> </table>	Mutation	AF in %	AKT1 E17K	0.13	BRAF V600E	0.06	ERBB2 E770_A771insAYVM (Y772_A775dup)	0.09	KRAS G12D	0.08	KRAS Q61K	0.10	KRAS A146T	0.12	PIK3CA H1047R	0.06	PIK3CA E545K	0.10	PASS													
Mutation	AF in %																																
AKT1 E17K	0.13																																
BRAF V600E	0.06																																
ERBB2 E770_A771insAYVM (Y772_A775dup)	0.09																																
KRAS G12D	0.08																																
KRAS Q61K	0.10																																
KRAS A146T	0.12																																
PIK3CA H1047R	0.06																																
PIK3CA E545K	0.10																																
COMMENTS/REMARKS	Additional information:  <b>Copy numbers (CN) of the respective measurements</b>  <i>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</i>																																

<sup>2</sup> Protocol NK603 – Community Reference Laboratory for GM Food and Feed

<sup>3</sup>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 <sup>4</sup> /μl	CN mut <sup>5</sup> /μl
AKT1 E17K	2348	3
BRAF V600E	1999	1
ERBB2 E770_A771insAYVM (Y772_A775dup)	3177	3
KRAS G12D	2742	1
KRAS Q61K	3329	3
KRAS A146T	3957	4
PIK3CA H1047R	4489	2
PIK3CA E545K	2649	2

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.

<sup>4</sup> Wild Type

<sup>5</sup> Mutation