

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 0% AF cfDNA BRAF/KRAS/PIK3CA/AKT1/ERBB2
DESCRIPTION	5-Gene-Multiplex 0% AF cfDNA BRAF/KRAS/PIK3CA/AKT1/ERBB2 is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000003
BATCH NUMBER	00020
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	01.09.2019
CONCENTRATION	20 ng/μl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	20 μl
MUTATION	<p>BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T>A, Exon 15)</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>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>AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G>A, Exon 2)</p> <p>ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSM20959*/ COSM404915*, COSV54062409*, insertion, c.2313_2324dup/ c.2310_2311ins12, Exon 19)</p> <p><small>* GRCh38 COSMIC v90</small></p>
ALLELIC FREQUENCY	0%
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>

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

STORAGE CONDITIONS MANUFACTURING AND QUALITY CONTROL SITES	+ 2-8 °C 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] 0 (A260-A280)*38 ² dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	ssDNA: n.a. ³ dsDNA: 18,5 – 22,5 ng/μl																														
	Allelic Frequency	dPCR Analysis using BioRad QX200™ System	AF 0,0% (0,00-0,04%)																														
RESULTS OF ANALYSIS	<table border="1"> <thead> <tr> <th data-bbox="549 987 815 1066"></th> <th data-bbox="815 987 1294 1066">Result</th> <th data-bbox="1294 987 1498 1066">PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td data-bbox="549 1066 815 1122"> Fragmentation </td> <td data-bbox="815 1066 1294 1122">179 bp</td> <td data-bbox="1294 1066 1498 1122">pass</td> </tr> <tr> <td data-bbox="549 1122 815 1234"> Quantification </td> <td data-bbox="815 1122 1294 1234"> 35,18 ng/μl (total DNA) 20,7 ng/μl (dsDNA) </td> <td data-bbox="1294 1122 1498 1234">pass</td> </tr> <tr> <td data-bbox="549 1234 815 1570" rowspan="9"> Allelic Frequency </td> <td data-bbox="815 1234 1174 1267"> <table border="1"> <thead> <tr> <th data-bbox="815 1234 1174 1267">Mutation</th> <th data-bbox="1174 1234 1294 1267">AF in %</th> </tr> </thead> <tbody> <tr> <td data-bbox="815 1267 1174 1301">BRAF V600E</td> <td data-bbox="1174 1267 1294 1301">0,00</td> </tr> <tr> <td data-bbox="815 1301 1174 1335">PIK3CA H1047R</td> <td data-bbox="1174 1301 1294 1335">0,01</td> </tr> <tr> <td data-bbox="815 1335 1174 1368">PIK3CA E545K</td> <td data-bbox="1174 1335 1294 1368">0,01</td> </tr> <tr> <td data-bbox="815 1368 1174 1402">KRAS G12D</td> <td data-bbox="1174 1368 1294 1402">0,04</td> </tr> <tr> <td data-bbox="815 1402 1174 1435">KRAS Q61K</td> <td data-bbox="1174 1402 1294 1435">0,00</td> </tr> <tr> <td data-bbox="815 1435 1174 1469">KRAS A146T</td> <td data-bbox="1174 1435 1294 1469">0,02</td> </tr> <tr> <td data-bbox="815 1469 1174 1503">AKT1 E17K</td> <td data-bbox="1174 1469 1294 1503">0,02</td> </tr> <tr> <td data-bbox="815 1503 1174 1570">ERBB2 E770_A771insAYVM (Y772_A775dup)</td> <td data-bbox="1174 1503 1294 1570">0,01</td> </tr> </tbody> </table> </td> <td data-bbox="1294 1234 1498 1570" rowspan="9">pass</td> </tr> </tbody> </table>				Result	PASS/FAIL	Fragmentation	179 bp	pass	Quantification	35,18 ng/μl (total DNA) 20,7 ng/μl (dsDNA)	pass	Allelic Frequency	<table border="1"> <thead> <tr> <th data-bbox="815 1234 1174 1267">Mutation</th> <th data-bbox="1174 1234 1294 1267">AF in %</th> </tr> </thead> <tbody> <tr> <td data-bbox="815 1267 1174 1301">BRAF V600E</td> <td data-bbox="1174 1267 1294 1301">0,00</td> </tr> <tr> <td data-bbox="815 1301 1174 1335">PIK3CA H1047R</td> <td data-bbox="1174 1301 1294 1335">0,01</td> </tr> <tr> <td data-bbox="815 1335 1174 1368">PIK3CA E545K</td> <td data-bbox="1174 1335 1294 1368">0,01</td> </tr> <tr> <td data-bbox="815 1368 1174 1402">KRAS G12D</td> <td data-bbox="1174 1368 1294 1402">0,04</td> </tr> <tr> <td data-bbox="815 1402 1174 1435">KRAS Q61K</td> <td data-bbox="1174 1402 1294 1435">0,00</td> </tr> <tr> <td data-bbox="815 1435 1174 1469">KRAS A146T</td> <td data-bbox="1174 1435 1294 1469">0,02</td> </tr> <tr> <td data-bbox="815 1469 1174 1503">AKT1 E17K</td> <td data-bbox="1174 1469 1294 1503">0,02</td> </tr> <tr> <td data-bbox="815 1503 1174 1570">ERBB2 E770_A771insAYVM (Y772_A775dup)</td> <td data-bbox="1174 1503 1294 1570">0,01</td> </tr> </tbody> </table>	Mutation	AF in %	BRAF V600E	0,00	PIK3CA H1047R	0,01	PIK3CA E545K	0,01	KRAS G12D	0,04	KRAS Q61K	0,00	KRAS A146T	0,02	AKT1 E17K	0,02	ERBB2 E770_A771insAYVM (Y772_A775dup)	0,01	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 ~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>																																

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

³not applicable

Mutation	CN wt ⁴ /μl	CN mut ⁵ /μl
BRAF V600E	2110	0
PIK3CA H1047R	4216	1
PIK3CA E545K	2907	0
KRAS G12D	3045	1
KRAS Q61K	3644	0
KRAS A146T	3900	1
AKT1 E17K	2481	0
ERBB2 E770_A771insAYVM (Y772_A775dup)	3393	0

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