

## 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	00125
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	<ul style="list-style-type: none"> <li>• Manufactured and sealed in class 2 safety cabinet</li> <li>• At room temperature</li> <li>• 2D barcoded tube with screw cap</li> <li>• Material: Polypropylen (PP)</li> </ul>
DATE OF MANUFACTURE	10.11.2020
EXPIRY DATE	09.11.2022
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 <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

<b>MANUFACTURING AND QUALITY CONTROL SITES</b>	SensID GmbH Schillingallee 68, 18057 Rostock, Germany																													
<b>TEST METHOD AND ACCEPTANCE CRITERIA</b>	<b>Quality Control</b>	<b>Test Method</b>	<b>Acceptance Criteria</b>																											
	<b>Fragmentation</b>	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)																											
	<b>Quantification</b>	Total DNA measurement: Spectrophotometry ssDNA [ng/μl] = (A260- A320)*38 <sup>2,3</sup>	Total DNA: n.a. <sup>4</sup>																											
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	dsDNA: 17.5 – 22.5 ng/μl																											
<b>Allele Frequency</b>	ddPCR Analysis using BioRad QX200™ System		AF 5% ±30% (3.5–6.5%)																											
<b>RESULTS OF ANALYSIS</b>	<b>Result</b>		<b>PASS/FAIL</b>																											
	<b>Fragmentation</b>	177 bp		PASS																										
	<b>Quantity</b>	35.9 ng/μl (total DNA) 20.5 ng/μl (dsDNA)		PASS																										
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<sup>2</sup> Protocol NK603 – Community Reference Laboratory for GM Food and Feed

<sup>3</sup> Measured before filling in product tube

<sup>4</sup> Not applicable

## COMMENTS/REMARKS

## ADDITIONAL INFORMATION:

**Copy numbers (CN) of the respective measurements**

Mutation	CN wt <sup>5</sup> /μl	CN mut <sup>6</sup> /μl
AKT1 E17K	2265	121
BRAF V600E	1954	97
PIK3CA H1047R	4268	217
PIK3CA E545K	2998	160
ERBB2 E770_A771insAYVM (new: Y772_A775dup)	3350	166
KRAS G12D	2916	141
KRAS Q61K	3336	184
KRAS A146T	3929	202

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: 30.11.2020

Signature batch release: Björn Nowack

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

<sup>5</sup> Wild Type  
<sup>6</sup> Mutation