

**Batch Certificate**  
For Research Use Only

**PRODUCT INFORMATION AND QUALITY CONTROL**

<b>NAME OF PRODUCT</b>	5-Gene-Multiplex 5% AF cfDNA BRAF/KRAS/PIK3CA/AKT1/ERBB2
<b>DESCRIPTION</b>	5-Gene-Multiplex 5% AF cfDNA BRAF/KRAS/PIK3CA/AKT1/ERBB2 is highly characterized human DNA from cell lines.
<b>CATALOG NUMBER</b>	SID-000094
<b>BATCH NUMBER</b>	00017
<b>MANUFACTURING CONDITIONS</b>	<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>
<b>PACKAGE SIZE AND TYPE</b>	<ul style="list-style-type: none"> <li>• 2D barcoded tube with screw cap</li> <li>• Material: Polypropylen (PP)</li> </ul>
<b>DATE OF MANUFACTURE</b>	02.09.2019
<b>EXPIRY DATE</b>	01.09.2020
<b>CONCENTRATION</b>	20 ng/μl (ds DNA)
<b>QUANTITY</b>	400 ng (ds DNA)
<b>NOMINAL VOLUME</b>	20,0 μl
<b>MUTATION</b>	<p>BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T&gt;A, Exon 15)</p> <p>PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A&gt;G, Exon 20)</p> <p>PIK3CA p.E545K (COSM763*, COSV55873239* substitution, c.1633G&gt;A, Exon 9)</p> <p>KRAS p.G12D (COSM521*, COSV55497369*, substitution, c.35G&gt;A, Exon 1)</p> <p>KRAS p.Q61K (COSM549*, COSV55502066*, substitution, c.181C&gt;A, Exon 2)</p> <p>KRAS p.A146T (COSM19404*, COSV55501778*, substitution, c.436G&gt;A, Exon 3)</p> <p>AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G&gt;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>
<b>ALLELIC FREQUENCY</b>	5%
<b>QUALITY</b>	<p>DNA quantity metrological traceable to internationally certified reference material<sup>1</sup></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>

<sup>1</sup> ERM\_AD442K  
Phone: +49 (0) 381 377 182 01

<b>STORAGE CONDITIONS</b>	+ 2-8 °C			
<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 Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)	
	<b>Quantification</b>	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	
	<b>Allelic Frequency</b>	dPCR 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>	180 bp	PASS	
	<b>Quantity</b>	35,15 ng/μl (total DNA) 21,80 ng/μl (dsDNA)	PASS	
	<b>Allelic Frequency</b>	<b>Mutation</b>	<b>AF in %</b>	PASS
		BRAF V600E	5,2	
PIK3CA H1047R		6,0		
PIK3CA E545K		6,5		
KRAS G12D		5,0		
KRAS Q61K		5,7		
KRAS A146T		5,5		
AKT1 E17K		6,5		
ERBB2 E770_A771insAYVM (Y772_A775dup)	4,9			
<b>COMMENTS/REMARKS</b>	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 ~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>			

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

<sup>3</sup>not applicable

Mutation	CN wt <sup>4</sup> /μl	CN mut <sup>5</sup> /μl
BRAF V600E	2182	120
PIK3CA H1047R	4409	283
PIK3CA E545K	3023	212
KRAS G12D	3055	161
KRAS Q61K	3547	215
KRAS A146T	4102	241
AKT1 E17K	2605	181
ERBB2 E770_A771insAYVM (Y772_A775dup)	3545	184

**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.

<sup>4</sup> Wild Type<sup>5</sup> Mutation