

## 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	00094
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	01.09.2020
EXPIRY DATE	31.08.2022
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	1.0%
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  
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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>2,3</sup>  dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a. <sup>4</sup>  dsDNA: 17.5 – 22.5 ng/μl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 1% ±40% (0.6-1.4%)

  

RESULTS OF ANALYSIS	Result	PASS/FAIL	
	Fragmentation	172 bp	PASS
	Quantity	30.6 ng/μl (total DNA) 22.1 ng/μl (dsDNA)	PASS

  

Allele Frequency	Mutation	AF in %	PASS/FAIL
	AKT1 E17K	0.8	PASS
	BRAF V600E	0.9	PASS
	PIK3CA H1047R	0.7	PASS
	PIK3CA E545K	1.0	PASS
	ERBB2 E770_A771insAYVM (new: Y772_A775dup)	1.2	PASS
	KRAS G12D	1.1	PASS
	KRAS Q61K	1.0	PASS
	KRAS A146T	1.1	PASS

<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:

Wildtype copies (wt) or mutant copies (mut) of the respective measurements

Mutation	wt <sup>5</sup> /μl	mut <sup>6</sup> /μl
AKT1 E17K	2105	17
BRAF V600E	1795	16
PIK3CA H1047R	3845	28
PIK3CA E545K	2710	28
ERBB2 E770_A771insAYVM (new: Y772_A775dup)	3081	38
KRAS G12D	2617	28
KRAS Q61K	3025	32
KRAS A146T	3634	40

*Table 1 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~20 ng. The value for the respective mutation results from the mean value of five measured replicates (values are rounded). The wt/mut 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 wt/mut may vary depending on the assay used. Therefore, due to assay properties, there may be deviations in the observed number of wt/mut 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: 04<sup>th</sup> September 2020

Signature batch release: Björn Nowack

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

<sup>5</sup> Wildtype

<sup>6</sup> Mutation