# Batch Certificate
For Research Use Only

## PRODUCT INFORMATION AND QUALITY CONTROL

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|---|---|
| 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 | 00018 |
| MANUFACTURING CONDITIONS | • Manufactured and sealed in class 2 safety cabinet<br>• Bottled with qualified liquid handling workstation<br>• At room temperature |
| PACKAGE SIZE AND TYPE | • 2D barcoded tube with screw cap<br>• Material: Polypropylen (PP) |
| DATE OF MANUFACTURE | 02.09.2019 |
| EXPIRY DATE | 01.09.2021 |
| CONCENTRATION | 20 ng/µl (dsDNA) |
| QUANTITY | 400 ng (dsDNA) |
| NOMINAL VOLUME | 21.6 µl |
| MUTATION | AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G>A, Exon 2)<br>BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T>A, Exon 15)<br>ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSM20959*/ COSM404915*, COSV54062409*, insertion, c.2313_2324dup/ c.2310_2311ins12, Exon 19)<br>KRAS p.G12D (COSM521*, COSV55497369*, substitution, c.35G>A, Exon 1)<br>KRAS p.Q61K (COSM549*, COSV55502066*, substitution, c.181C>A, Exon 2)<br>KRAS p.A146T (COSM19404*, COSV55501778*, substitution, c.436G>A, Exon 3)<br>PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A>G, Exon 20)<br>PIK3CA p.E545K (COSM763*, COSV55873239* substitution, c.1633G>A, Exon 9)<br>* GRCh38 COSMIC v90 |
| ALLELE FREQUENCY | 1% |
| QUALITY | DNA quantity metrological traceable to internationally certified reference material[1]<br>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 |

[1] ERM_AD442K

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|---|---|
| MANUFACTURING AND QUALITY CONTROL SITES | SensID GmbH<br>Schillingallee 68, 18057 Rostock, Germany |

**TEST METHOD AND ACCEPTANCE CRITERIA**

| Quality Control | Test Method | Acceptance criteria |
|---|---|---|
| Fragmentation | Fragment Length Analysis<br>Agilent High Sensitivity DNA Kit<br>(Agilent Technologies | peak size<br>167 bp ± 10%<br>(151 bp – 181 bp) |
| Quantification | Total DNA measurement:<br>Spectrophotometry<br>ssDNA [ng/µl] = (A260-A320)*38[2]<br>dsDNA measurement: Qubit<br>dsDNA BR Assay Kit (Invitrogen) | ssDNA:<br>n.a.[3]<br><br>dsDNA:<br>18.5 – 22.5 ng/µl |
| Allele Frequency | dPCR Analysis<br>using BioRad QX200™ System | AF 1% ±40%<br>(0.6-1.4%) |

**RESULTS OF ANALYSIS**

| | Result | PASS/FAIL |
|---|---|---|
| Fragmentation | 175 bp | PASS |
| Quantity | 28.91 ng/µl (total DNA)<br>19.7 ng/µl (dsDNA) | PASS |
| Allele Frequency | | PASS |

| Mutation | AF in % |
|---|---|
| AKT1 E17K | 0.9 |
| BRAF V600E | 0.6 |
| ERBB2 E770_A771insAYVM (Y772_A775dup) | 1.0 |
| KRAS G12D | 0.8 |
| KRAS Q61K | 1.1 |
| KRAS A146T | 1.1 |
| PIK3CA H1047R | 1.0 |
| PIK3CA E545K | 0.8 |

**COMMENTS/REMARKS**

Additional information:

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

*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.*

[2] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[3] not applicable

| Mutation | CN wt[4]/µl | CN mut[5]/µl |
|---|---|---|
| AKT1 E17K | 2316 | 20 |
| BRAF V600E | 2028 | 12 |
| ERBB2 E770_A771insAYVM (Y772_A775dup) | 3347 | 34 |
| KRAS G12D | 2903 | 23 |
| KRAS Q61K | 3211 | 37 |
| KRAS A146T | 3664 | 41 |
| PIK3CA H1047R | 3975 | 41 |
| PIK3CA E545K | 2682 | 22 |

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.

[4] Wild Type
[5] Mutation