

## Batch Certificate For Research Use Only

### PRODUCT INFORMATION AND QUALITY CONTROL

|                          |  |
|--------------------------|--|
| NAME OF PRODUCT          | cfDNA (human) AF: 0% Ashkenazim Son  |
| DESCRIPTION              | cfDNA (human) AF: 0% Ashkenazim Son is highly characterized human DNA from cell lines.   |
| CATALOG NUMBER           | SID-000003   |
| BATCH NUMBER             | 00063  |
| MANUFACTURING CONDITIONS | <ul style="list-style-type: none"> <li>• Manufactured and sealed in class 2 safety cabinet</li> <li>• At room temperature</li> </ul>   |
| PACKAGE SIZE AND TYPE    | <ul style="list-style-type: none"> <li>• 2D barcoded tube with screw cap</li> <li>• Material: Polypropylen (PP)</li> </ul>   |
| DATE OF MANUFACTURE      | 04.05.2020   |
| EXPIRY DATE              | 03.05.2022   |
| CONCENTRATION            | 20 ng/μl (dsDNA)   |
| QUANTITY                 | 400 ng (dsDNA)   |
| NOMINAL VOLUME           | 25 μl; (480 ng)  |
| MUTATION                 | <p>AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G&gt;A, Exon 2)</p> <p>BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T&gt;A, Exon 15)</p> <p>ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSM20959*, COSV54062409*, insertion, c.2313_2324dup, Exon 19)</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>PIK3CA p.C420R (COSM757*, COSV55874020* substitution, c.1258T&gt;C, Exon 7)</p> <p>PIK3CA p.E542K (COSM760*, COSV55873227*, substitution, c.1624G&gt;A, Exon 9)</p> <p>PIK3CA p.E545A (COSM12458*, COSV55873209*, substitution, c.1634A&gt;C, Exon 9)</p> <p>PIK3CA p.E545D (COSM765*, COSV55874040*, substitution, c.1635G&gt;T, Exon 9)</p> <p>PIK3CA p.E545G (COSM764*, COSV55873220*, substitution, c.1634A&gt;G, Exon 9)</p> <p>PIK3CA p.E545K (COSM763*, COSV55873239* substitution, c.1633G&gt;A, Exon 9)</p> <p>PIK3CA p.Q546E (COSM6147*, COSV55882350* substitution, c.1636C&gt;G, Exon 9)</p> <p>PIK3CA p.Q546R (COSM12459*, COSV55876869* substitution, c.1637A&gt;G, Exon 9)</p> <p>PIK3CA p.H1047L (COSM776*, COSV55873401* substitution, c.3140A&gt;T, Exon 20)</p> <p>PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A&gt;G, Exon 20)</p> <p>PIK3CA p.H1047Y (COSM774*, COSV55876499* substitution, c.3139C&gt;T, Exon 20)</p> <p>p.G719S (COSM6252*, COSV51767289*, substitution, c.2155G&gt;A, Exon 18)</p> <p>p.E746_A750delELREA (COSM6225*, COSV51765066*, deletion, c.2236_2250del15, Exon 19)</p> <p>p.S752_I759delSPKANKEI (COSM6256*, COSV51774879*, deletion, c.2254_2277del24, Exon 19)</p> |

**ALLELE FREQUENCY**

**QUALITY**

**STORAGE CONDITIONS**

**MANUFACTURING AND**

**QUALITY CONTROL**

**SITES**

p.S768I (COSM6241\*, COSV51768106\* substitution, c.2303G>T, Exon 20)  
 p.V769\_D770insASV (new: p.A767\_V769dup) (COSM20884\*, COSV51850427\* Insertion, c.2303\_2304insTGTGGCCAG, Exon 20)  
 p.T790M (COSM6240\*, COSV51765492\*, substitution, c.2369C>T, Exon 20)  
 p.L858R (COSM6224\*, COSV51765161\*, substitution, c.2573T>G, Exon 21)  
 p.L861Q (COSM6213\*, COSV51766344\*, substitution, c.2582T>A, Exon 21)

\* GRCh38 COSMIC v91

0%

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.

+ 2-8 °C

SensID GmbH

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| 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 167 bp ± 10%<br>(151 bp – 181 bp)                        |
|                                     | Quantification   | Total DNA measurement:<br>Spectrophotometry<br>ssDNA [ng/μl] = (A260-A320)*38 <sup>2,3</sup><br><br>dsDNA measurement: Qubit<br>dsDNA BR Assay Kit (Invitrogen) | Total DNA:<br>n.a. <sup>4</sup><br><br>dsDNA:<br>17.5 – 22.5 ng/μl |
|                                     | Allele Frequency | ddPCR Analysis<br>using BioRad QX200™ System  | AF 0.00%<br>(≤0.03%) <sup>5</sup>                                  |

<sup>1</sup> ERM\_AD442K

<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

<sup>5</sup> With the exception of PIK3CA E545A where it is ≤0.7%

| RESULTS OF ANALYSIS |  |                |                  |
|---------------------|--|----------------|------------------|
|                     | Result                                       | PASS/FAIL      |                  |
| Fragmentation       | 172 bp                                       | PASS           |                  |
| Quantity            | 33.5 ng/μl (total DNA)<br>19.2 ng/μl (dsDNA) | PASS           |                  |
| Allele<br>Frequency | <b>Mutation</b>                              | <b>AF in %</b> | <b>PASS/FAIL</b> |
|                     | AKT1 E17K                                    | 0.00           | PASS             |
|                     | BRAF V600E                                   | 0.00           | PASS             |
|                     | ERBB2<br>E770_A771insAYVM<br>(Y772_A775dup)  | 0.00           | PASS             |
|                     | KRAS G12D                                    | 0.00           | PASS             |
|                     | KRAS Q61K                                    | 0.00           | PASS             |
|                     | KRAS A146T                                   | 0.00           | PASS             |
|                     | PIK3CA C420R                                 | 0.00           | PASS             |
|                     | PIK3CA E542K                                 | 0.00           | PASS             |
|                     | PIK3CA E545A <sup>6</sup>                    | 0.59           | PASS             |
|                     | PIK3CA E545D                                 | 0.00           | PASS             |
|                     | PIK3CA E545G                                 | 0.00           | PASS             |
|                     | PIK3CA E545K                                 | 0.00           | PASS             |
|                     | PIK3CA Q546E                                 | 0.00           | PASS             |
|                     | PIK3CA Q546R                                 | 0.00           | PASS             |
|                     | PIK3CA H1047L                                | 0.00           | PASS             |
|                     | PIK3CA H1047R                                | 0.00           | PASS             |
|                     | PIK3CA H1047Y                                | 0.00           | PASS             |
|                     | EGFR L858R                                   | 0.00           | PASS             |
|                     | EGFR L861Q                                   | 0.00           | PASS             |
|                     | EGFR S768I                                   | 0.00           | PASS             |
|                     | EGFR<br>E746_A750delELREA                    | 0.00           | PASS             |
|                     | EGFR T790M                                   | 0.00           | PASS             |
|                     | EGFR G719S                                   | 0.00           | PASS             |
|                     | EGFR<br>V769_D770insASV                      | 0.00           | PASS             |
|                     | EGFR<br>S752_I759delSPANKEI                  | 0.00           | PASS             |

<sup>6</sup> A BLAST sequence analysis shows 98% homology of PIK3CA E545A mutation sequence to genome locus Homo sapiens chromosome 22, GRCh38.p13. Therefore, a higher false positive rate is expected and measured, most likely due to a cross reaction of gene probe to genome locus Homo sapiens chromosome 22, GRCh38.p13.

## COMMENTS/REMARKS

## ADDITIONAL INFORMATION:

Copy numbers (CN) of the respective measurements

| Mutation                              | CN wt <sup>7</sup> /μl | CN mut <sup>8</sup> /μl |
|---------------------------------------|------------------------|-------------------------|
| AKT1 E17K                             | 1155                   | 0                       |
| BRAF V600E                            | 1012                   | 0                       |
| ERBB2 E770_A771insAYVM (Y772_A775dup) | 1763                   | 0                       |
| KRAS G12D                             | 1554                   | 0                       |
| KRAS Q61K                             | 1759                   | 0                       |
| KRAS A146T                            | 2004                   | 0                       |
| PIK3CA C420R                          | 1119                   | 0                       |
| PIK3CA E542K                          | 2593                   | 0                       |
| PIK3CA E545A <sup>6</sup>             | 3185                   | 19                      |
| PIK3CA E545D                          | 1790                   | 0                       |
| PIK3CA E545G                          | 2619                   | 0                       |
| PIK3CA E545K                          | 1462                   | 0                       |
| PIK3CA Q546E                          | 2961                   | 0                       |
| PIK3CA Q546R                          | 3173                   | 0                       |
| PIK3CA H1047L                         | 2348                   | 0                       |
| PIK3CA H1047R                         | 2276                   | 0                       |
| PIK3CA H1047Y                         | 2236                   | 0                       |
| EGFR L858R                            | 2053                   | 0                       |
| EGFR L861Q                            | 2909                   | 0                       |
| EGFR S768I                            | 1600                   | 0                       |
| EGFR E746_A750delELREA                | 2228                   | 0                       |
| EGFR T790M                            | 2247                   | 0                       |
| EGFR G719S                            | 2634                   | 0                       |
| EGFR V769_D770insASV                  | 1831                   | 0                       |
| EGFR S752_I759delSPANKEI              | 1282                   | 0                       |

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 eight 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

Date of batch release: 07.05.2020

Signature batch release: Björn Nowack

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

<sup>7</sup> Wild Type

<sup>8</sup> Mutation