

## Batch Certificate For Research Use Only

### PRODUCT INFORMATION AND QUALITY CONTROL

|   |   |
|---|---|
| NAME OF PRODUCT                         | PIK3CA-E545G 50%AF FFPE Reference Standard  |
| DESCRIPTION                             | Human FFPE Reference Standard (curl)  |
| CATALOG NUMBER                          | SID-000106  |
| BATCH NUMBER                            | 00083   |
| MANUFACTURING CONDITIONS                | <ul style="list-style-type: none"> <li>• Manufactured and sealed according to internal quality standards related to EN ISO 13485</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                     | 16.07.2020  |
| EXPIRY DATE                             | 15.07.2022  |
| FORMAT                                  | 10 µm section / 1 curl  |
| MUTATION                                | PIK3CA p.E545G (COSM764*, COSV55873220*, substitution, c.1634A>G, Exon 9)<br><small>* GRCh38 COSMIC v91</small>   |
| ALLELIC FREQUENCY                       | 50.0%   |
| QUALITY                                 | <p>DNA quantity metrologically 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 ration 1 and International System of Units (SI) derived units of volume.</p> |
| STORAGE CONDITIONS                      | + 2-8 °C  |
| MANUFACTURING AND QUALITY CONTROL SITES | SensID GmbH<br>Schillingallee 68, 18057 Rostock, Germany  |

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

| TEST METHOD AND ACCEPTANCE CRITERIA | Quality Control   | Test Method  | Acceptance criteria                               |
|-------------------------------------|-------------------|--|---|
|                                     | Cell Density      | Visual   | > 60 %  |
|                                     | Quality           | Agarose gel electrophoresis <sup>2</sup><br>1% Gel with fluorescent DNA stain in 1 % TAE buffer  | Bright band of high-molecular-weight gDNA ≥ 20 kb |
|                                     | Quantification    | dsDNA measurement <sup>2</sup> : Qubit dsDNA BR Assay Kit (Invitrogen)<br>RNA measurement <sup>2</sup> : Qubit RNA BR Assay Kit (Invitrogen) | dsDNA:<br>> 400 ng<br>RNA:<br>> 400 ng            |
|                                     | Allelic Frequency | ddPCR Analysis <sup>2</sup><br>using BioRad QX200™ System  | AF 50.0 %<br>(45.0-55.0 %)                        |

| RESULTS OF ANALYSIS | Result   |          | PASS/FAIL |              |      |  |      |
|---------------------|--|----------|-----------|--------------|------|--|------|
|                     |  |          |           |              |      |  |      |
| Cell Density        | Visual: > 60 %   |          | PASS      |              |      |  |      |
| Quality             | Bright band of high-molecular-weight gDNA ≥ 20 kb  |          | PASS      |              |      |  |      |
| Quantity            | 1092.7 ng (dsDNA)<br>1369.1 ng (RNA)   |          | PASS      |              |      |  |      |
| Allelic Frequency   | <table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> </tr> </thead> <tbody> <tr> <td>PIK3CA E545G</td> <td>50.4</td> </tr> </tbody> </table> | Mutation | AF in %   | PIK3CA E545G | 50.4 |  | PASS |
| Mutation            | AF in %  |          |           |              |      |  |      |
| PIK3CA E545G        | 50.4   |          |           |              |      |  |      |

| COMMENTS/REMARKS   |  |   |   |              |     |     |
|--|--|---|---|--------------|-----|-----|
| <p>Additional information:</p> <p>Theoretical DNA yield from 1 curl under the assumption of a diploid chromosome set:</p> <p>3,164 ng (dsDNA)</p> <p>Copy numbers (CN) of the respective measurements</p> <p><i>Table 1 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~10 ng. The value for the respective mutation results from the mean value of eight measured replicates (CN values are rounded). CN values per nanogram extracted DNA, 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></p> <table border="1"> <thead> <tr> <th>Mutation</th> <th>CN wt<sup>3</sup>/<br/>ng extracted DNA</th> <th>CN mut<sup>4</sup>/<br/>ng extracted DNA</th> </tr> </thead> <tbody> <tr> <td>PIK3CA E545G</td> <td>141</td> <td>143</td> </tr> </tbody> </table> | Mutation                                 | CN wt <sup>3</sup> /<br>ng extracted DNA  | CN mut <sup>4</sup> /<br>ng extracted DNA | PIK3CA E545G | 141 | 143 |
| Mutation   | CN wt <sup>3</sup> /<br>ng extracted DNA | CN mut <sup>4</sup> /<br>ng extracted DNA |   |              |     |     |
| PIK3CA E545G   | 141                                      | 143                                       |   |              |     |     |

<sup>2</sup> Measured after extraction with Qiagen AllPrep DNA/RNA FFPE Kit

<sup>3</sup> Wild Type

<sup>4</sup> Mutation



Bringing Precision to MD<sub>x</sub>

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Version 01

**Page 3/3**

Name and position/title of Person authorising the batch release:

Mr. Björn Nowack, Managing Director

Date of batch release: 01.08.2020

Signature batch release: Björn Nowack

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

Phone: +49 (0) 381 377 182 01

Net: [www.sens-id.com](http://www.sens-id.com)  
SensID GmbH, Schillingallee 68, 18057 Rostock, Germany

Mail: [support@sens-id.com](mailto:support@sens-id.com)

VAT No: DE305142405, district court: Rostock HRB 14621  
CEO: Björn Nowack