# BATCH CERTIFICATE

For Research Use Only

## PRODUCT INFORMATION AND QUALITY CONTROL

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|---|---|---|---|
| NAME OF PRODUCT | ESR1 Reference Vial 1 1 % AF cfDNA | | |
| DESCRIPTION | ESR1 Reference Vial 1 1 % AF cfDNA is part of ESR1 Reference Set 1 % AF cfDNA (SID-000144). It consists of highly characterized human DNA from cell line containing ESR1 p.L536H and ESR1 p.Y537C. | | |
| CATALOG NUMBER | SID-000145 | | |
| **BATCH NUMBER** | **01011** | | |
| MANUFACTURING CONDITIONS | · Manufactured and sealed in class 2 safety cabinet<br>· Manufactured according to DIN EN ISO 13485:2016 | | |
| PACKAGE SIZE AND TYPE | · 2D barcoded tube with screw cap<br>· Material: Polypropylen (PP) | | |
| DATE OF MANUFACTURE | 23.10.2025 | | |
| EXPIRY DATE | 22.10.2027 | | |
| TARGET CONCENTRATION | 10 ng/µl (dsDNA) | | |
| TARGET QUANTITY | 250 ng (dsDNA) | | |
| NOMINAL VOLUME | 25 µl | | |
| VARIANT | ESR1 p.L536H c.1607T>A (ENSG00000091831, 6:152098785-152098785 (GRCh38.p13))<br>ESR1 p.Y537C c.1610A>G (ENSG00000091831, 6:152098788-152098788 (GRCh38.p13)) | | |
| ALLELE FREQUENCY | 1.00 % | | |
| QUALITY | Digital PCR (dPCR) is an SI-traceable method for copy number (CN) determination (see comments and remarks). The copy number values are metrologically traceable to the natural units count 1 and ratio 1 and to International System of Units (SI) derived units of volume. | | |
| CERTIFICATION | DIN EN ISO 13485:2016, Registration-No.: SX 1652079-1, TÜV Rheinland® | | |
| STORAGE CONDITIONS | + 2-8 °C | | |
| MANUFACTURING SITE | SensID GmbH<br>Schillingallee 68, 18057 Rostock, Germany | | |
| TEST METHOD AND ACCEPTANCE CRITERIA | Quality control | Test method | Acceptance criteria |
| | Fragmentation | Fragment length analysis: Agilent D5000 ScreenTape System (Agilent Technologies) | Peak size: 167 bp ± 15 % (142 bp – 192 bp) |
| | Quantification | dsDNA measurement: Qubit™ 1X dsDNA HS Assay-Kit (Invitrogen) | dsDNA: 10.0 ng/µl ± 15 % (8.5 – 11.5 ng/µl) |
| | Allele frequency | Allele frequency analysis: dPCR (QIAGEN® QIAcuity Four) | AF 1.00 % ± 40 % (0.60 – 1.40 %) |

<table>
<tr><td rowspan="5">RESULTS OF ANALYSIS</td><td>Quality control</td><td colspan="2">Result</td><td>PASS / FAIL</td></tr>
<tr><td>Fragmentation</td><td colspan="2">168 bp</td><td>PASS</td></tr>
<tr><td>Quantification</td><td colspan="2">10.5 ng/µl (dsDNA)</td><td>PASS</td></tr>
<tr><td rowspan="3">Allele frequency</td><td>Variant</td><td>AF in %</td><td>PASS / FAIL</td></tr>
<tr><td>ESR1 p.L536H</td><td>1.03</td><td>PASS</td></tr>
<tr><td>ESR1 p.Y537C</td><td>0.97</td><td>PASS</td></tr>
<tr><td>COMMENTS / REMARKS</td><td colspan="4">Whale, Alexandra S., et al. "Assessment of digital PCR as a primary reference measurement procedure to support advances in precision medicine." Clinical chemistry 64.9 (2018): 1296-1307.<br>Whale et al. (2018) validated dPCR as an SI-traceable reference measurement procedure based on enumeration and demonstrates how it can be applied for assignment of copy number concentration and fractional abundance values to DNA reference materials in an aqueous solution. High-accuracy measurements using dPCR will support the implementation and traceable standardization of molecular diagnostic procedures needed for advancements in precision medicine.</td></tr>
<tr><td rowspan="6">MEASUREMENT OF COPY NUMBER</td><td colspan="4">Additional information: Measurement of copy number</td></tr>
<tr><td>Variant</td><td>CN wt/ng</td><td colspan="2">CN mut/ng</td></tr>
<tr><td>ESR1 p.L536H</td><td>285.70</td><td colspan="2">2.96</td></tr>
<tr><td>ESR1 p.Y537C</td><td>287.09</td><td colspan="2">2.81</td></tr>
<tr><td colspan="4">wt: wildtype; mut: mutation</td></tr>
<tr><td colspan="4">The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of 1 ng. The value for the respective mutation results from the mean value of QC samples based on ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per nanogram (ng) are based on digital (dPCR) assay counts and dilution factors. 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.</td></tr>
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Name and position/title of person authorising the batch release:

Björn Nowack, Managing Director

Date of batch release: 30.10.2025

Signature batch release: Björn Nowack

This document has been created electronically and is valid without signature.