

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

| | |
|--------------------------|--|
| NAME OF PRODUCT | ESR1 Reference Vial 2 1% AF cfDNA |
| DESCRIPTION | ESR1 Reference Vial 2 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.L536P and ESR1 p.Y537S. |
| CATALOG NUMBER | SID-000146 |
| BATCH NUMBER | 00732 |
| MANUFACTURING CONDITIONS | <ul style="list-style-type: none"> · Manufactured and sealed in class 2 safety cabinet · Manufactured according to DIN EN ISO 13485:2016 |
| PACKAGE SIZE AND TYPE | <ul style="list-style-type: none"> · 2D barcoded tube with screw cap · Material: Polypropylen (PP) |
| DATE OF MANUFACTURE | 21.06.2024 |
| EXPIRY DATE | 20.06.2026 |
| TARGET CONCENTRATION | 10 ng/μl (dsDNA) |
| TARGET QUANTITY | 250 ng (dsDNA) |
| NOMINAL VOLUME | 25 μl |
| MUTATION | ESR1 p.L536P (COSV52782930*, substitution, c.1607T>C, Exon 8) |
| * GRCh38 COSMIC v99 | ESR1 p.Y537S (COSV52783938*, substitution, c.1610A>C, Exon 8) |
| ALLELE FREQUENCY | 1.00% |
| QUALITY | 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 |
| MANUFACTURING SITE | SensID GmbH 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 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%) |
| RESULTS OF ANALYSIS | Quality control | Result | | PASS / FAIL |
| | Fragmentation | 168 bp | | PASS |
| | Quantification | 10.6 ng/μl (dsDNA) | | PASS |
| | Allele frequency | Mutation | AF in % | PASS / FAIL |
| | | ESR1 p.L536P | 1.14 | PASS |
| ESR1 p.Y537S | | 0.94 | PASS | |
| COMMENTS / REMARKS | Additional information: Measurement of copy number | | | |
| MEASUREMENT OF COPY NUMBER | Mutation | CN wt/ng | CN mut/ng | |
| | ESR1 p.L536P | 396.65 | 4.56 | |
| | ESR1 p.Y537S | 394.47 | 3.73 | |
| | wt: wildtype; mut: mutation | | | |
| | <i>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 according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per nanogram (ng) are based on digital (dPCR) 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> | | | |

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

Björn Nowack, Managing Director

Date of batch release: 02.07.2024

Signature batch release: Björn Nowack

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