# QUALITY CERTIFICATE

## Selenotest ELISA Kit Version 4, CE

Colorimetric enzyme immunoassay for the quantitative measurement of human selenoprotein P in serum

Certificate valid for: LOT STE.16001

Product code: STE

Recommended storage: +2°C … +8°C

Expiry date: 6 month after delivery

TEST KIT COMPOSITION:

| No. | Identifier | Description | Product code | Lot No. | Packed |
|---|---|---|---|---|---|
| 1 | SORB AB | Assay plate | STE1 | LOT STE1.16001 | ☐ |
| 2 | CAL 1 2 3 4 5 6 7 8 | Calibrator 1, 2, 3, 4, 5, 6, 7, 8 | STE2 | LOT STE2.16001 | ☐ |
| 3 | CONTROL L M H | Control L, M, H | STE3 | LOT STE3.16001 | ☐ |
| 4 | CONTROL B | Control B | STE4 | LOT STE4.16001 | ☐ |
| 5 | CONJ AB | Detection antibody | STE5 | LOT STE5.16001 | ☐ |
| 6 | CONJ EN | Enzyme conjugate | STE6 | LOT STE6.16001 | ☐ |
| 7 | BUF RCNS | Reconstitution buffer | STE7 | LOT STE7.16001 | ☐ |
| 8 | DIL AB | Detection antibody diluent | STE8 | LOT STE8.16001 | ☐ |
| 9 | DIL EN | Enzyme conjugate diluent | STE9 | LOT STE9.16001 | ☐ |
| 10 | DIL SPE | Sample dilution buffer | STE10 | LOT STE10.16001 | ☐ |
| 11 | BUF WASH 10× | 10× Washing buffer | STE11 | LOT STE11.16001 | ☐ |
| 12 | SUBS TMB | TMB substrate | STE12 | LOT STE12.16001 | ☐ |
| 13 | SOLN STOP | Stop solution | STE13 | LOT STE13.16001 | ☐ |
| 14 | ./. | Plate cover foil | STE14 | LOT 16/151 | ☐ |
| 15 | ./. | Instructions for use | ./. | IFUv4_20170131_EN | ☐ |
| 16 | ./. | Product specification sheet | ./. | PSS_STE.16001_EN | ☐ |
| 17 | ./. | This certificate | ./. | QCC_STE.16001_EN | ☐ |

TEST KIT PACKED BY: _____

DATE: _____

QC testing: The quality testing was performed according to recommendations from the referred guidelines. Detailed results on page 2.

APPROVAL: The quality testing results meet the defined product specifications.

DATE: 2016-12-22

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## QUALITY TESTING RESULTS:

STANDARDS AND CONTROLS

| CALIBRATOR/ CONTROL | Valid $E_{450\ nm}$ range | Testing result $E_{450\ nm}$ | Valid concentration range SELENOP [ng/mL] | Testing result SELENOP [ng/mL] | Conclusion |
|---|---|---|---|---|---|
| CONTROL L | 0.1066 – 0.1980 | 0.1523 ± 0.0122 | 16.1 – 21.7 | 19.0 ± 1.1 | comply |
| CONTROL M | 0.5486 – 1.0188 | 0.7837 ± 0.0651 | 63.2 – 85.6 | 75.1 ± 2.2 | comply |
| CONTROL H | 1.3553 – 2.5170 | 1.9362 ± 0.0792 | 233.0 – 315.2 | 271.8 ± 12.3 | comply |
| CONTROL B | 0.0306 – 0.0568 | 0.0437 ± 0.0008 | n/a | N/A | comply |
| CAL 1 | 0.0416 – 0.0773 | 0.0594 ± 0.0035 | 5.0 – 9.2 | 7.3 ± 1.0 | comply |
| CAL 2 | 0.0675 – 0.1254 | 0.0965 ± 0.0069 | 10.4 – 14.1 | 12.7 ± 0.6 | comply |
| CAL 3 | 0.1653 – 0.3069 | 0.2361 ± 0.0196 | 23.1 – 31.2 | 27.2 ± 1.0 | comply |
| CAL 4 | 0.3915 – 0.7270 | 0.5592 ± 0.0466 | 46.7 – 63.2 | 55.1 ± 0.9 | comply |
| CAL 5 | 0.7682 – 1.4267 | 1.0975 ± 0.0781 | 91.0 – 123.2 | 107.8 ± 1.3 | comply |
| CAL 6 | 1.1954 – 2.2201 | 1.7078 ± 0.0879 | 174.9 – 236.6 | 206.1 ± 3.6 | comply |
| CAL 7 | 1.5237 – 2.8297 | 2.1767 ± 0.0964 | 341.2 – 461.6 | 390.6 ± 16.7 | comply |
| CAL 8 | 1.6770 – 3.1144 | 2.3957 ± 0.1025 | 435.2 – 808.2 | 645.7 ± 57.9 | comply |

ANALYTICAL PERFORMANCE PARAMETERS

| PERFORMANCE PARAMETER | Specification | Testing result | Conclusion |
|---|---|---|---|
| Serum samples, accuracy, 4-PL | RE ± 25 % | +2.5 ± 11.3 % | comply |
| Serum samples, precision, intra-assay, 4-PL | RSD ≤ 20 % | 8.3 ± 4.6 % | comply |
| Serum samples, precision, inter-assay, 4-PL | RSD ≤ 25 % | 15.9 ± 1.8 % | comply |
| Serum samples, precision, inter-batch, 4-PL | RSD ≤ 30 % | 20.4 ± 8.3 % | comply |
| Lower limit of detection, LLOD | < 1 mg/L | 0.2 mg/L | comply |
| Upper limit of detection, ULOD | > 10 mg/L | 20.5 mg/L | comply |
| Lower limit of quantitation, LLOQ | < 1 mg/L | 0.4 mg/L | comply |
| Upper limit of quantitation, ULOQ | > 10 mg/L | 13.2 mg/L | comply |
| Calibration curve, regression model, 4-PL | $r$ > 0.970 | 0.993 ± 0.003 | comply |
| Calibration curve, regression model, 5-PL | $r$ > 0.970 | 0.995 ± 0.002 | comply |
| Calibration curve, Calibrators and Controls, accuracy, 4-PL | RE ± 25 % | +1.2 ± 5.2 % | comply |
| Calibration curve, Calibrators and Controls, precision, 4-PL | RSD ≤ 25 % | 5.9 ± 5.3 % | comply |

REFERENCES: **[1]** US DEPARTMENT OF HEALTH AND HUMAN SERVICES, FDA, CDER and CVM. Guidance for the Industry: Bioanalytical Method Validation. Washington, DC, 2001; **[2]** INTERNATIONAL CONFERENCE OF HARMONIZATION (ICH) OF TECHNICAL REQUIREMENTS FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE. ICH Harmonised Tripartite Guideline. Validation of Analytical Procedures: Text and Methodology. Q2(R1). 2005; **[3]** DESILVA B., W. SMITH, R. WEINER, M. KELLEY, J. SMOLEC, B. LEE, M. KHAN, R. TACEY, H. HILL and A. CELNIKER. Recommendations for the bioanalytical method validation of ligand-binding assays to support pharmacokinetic assessments of macromolecules. *Pharm Res*. 2003, **20** (11), 1885-1900

IMPORTANT NOTES: Do not mix or interchange reagents from different Selenotest ELISA kit batches and do not use other reagents than provided by the kit or recommended by the instructions for use. Reagents from different Selenotest ELISA kits of the same batch can be mixed within the specified shelf life. Reagents from the same Selenotest ELISA kit batch were harmonised in order to ensure high reproducibility and optimal assay performance.