selenomed

QUALITY CERTIFICATE

selenotest ELISA CE

Version 4

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

Certificate valid for: LOT STE.18001

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.
1	SORB AB	Assay plate	STE1	LOT STE1.18001
2	CAL 1 2 3 4 5 6 7 8	Calibrator 1, 2, 3, 4, 5, 6, 7, 8	STE2	LOT STE2.18001
3	CONTROL L M H	Control L, M, H	STE3	LOT STE3.18001
4	CONTROL B	Control B	STE4	LOT STE4.18001
5	CONJ AB	Detection antibody	STE5	LOT STE5.18001
6	CONJ EN	Enzyme conjugate	STE6	LOT STE6.18001
7	BUF RCNS	Reconstitution buffer	STE7	LOT STE7.18001
8	DIL AB	Detection antibody diluent	STE8	LOT STE8.18001
9	DIL EN	Enzyme conjugate diluent	STE9	LOT STE9.18001
10	DIL SPE	Sample dilution buffer	STE10	LOT STE10.18001
11	BUF WASH 10×	10× Washing buffer	STE11	LOT STE11.18001
12	SUBS TMB	TMB substrate	STE12	LOT STE12.18001
13	SOLN STOP	Stop solution	STE13	LOT STE13.18001
14	./.	Plate cover foil	STE14	LOT 16/151
15	./.	Instructions for use	STE15	IFU_20180914_EN
16	./.	Product specification sheet	STE16	PSS_STE.18001_EN
17	./.	This certificate	STE17	QCC_STE.18001_EN

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.

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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	0.1477 – 0.2744	0.2110 ± 0.0410	15.9 – 21.6	18.4 ± 0.7	comply
CONTROL M	0.7108 – 1.3201	1.0155 ± 0.1881	63.2 – 85.5	71.6 ± 3.7	comply
CONTROL H	1.5971 – 2.9660	2.2816 ± 0.2204	213.1 – 288.3	250.5 ± 20.5	comply
CONTROL B	0.0306 – 0.0568	0.0437 ± 0.0031	N/A	N/A	comply
CAL 1	0.0528 – 0.0981	0.0755 ± 0.0089	4.0 – 12.1	8.2 ± 0.4	comply
CAL 2	0.1049 – 0.1947	0.1498 ± 0.0243	11.3 – 16.9	14.1 ± 0.6	comply
CAL 3	0.2272 – 0.4220	0.3246 ± 0.0613	22.4 – 30.2	25.9 ± 0.7	comply
CAL 4	0.5356 – 0.9946	0.7651 ± 0.1429	45.7 – 61.8	54.0 ± 1.9	comply
CAL 5	0.9854 – 1.8300	1.4077 ± 0.2063	88.9 – 120.3	105.0 ± 4.1	comply
CAL 6	1.4533 – 2.6990	2.0762 ± 0.2185	170.3 – 230.4	198.8 ± 13.6	comply
CAL 7	1.7976 – 3.3384	2.5680 ± 0.2128	291.5 – 437.3	376.4 ± 46.8	comply
CAL 8	1.9604 – 3.6408	2.8006 ± 0.1221	371.3 – 1113.8	778.9 ± 195.8	comply

ANALYTICAL PERFORMANCE PARAMETERS

PERFORMANCE PARAMETER	Specification	Testing result	Conclusion
Serum samples, accuracy, intra-assay, 4-PL	RE ± 15 %	+4.4 ± 9.9 %	comply
Serum samples, accuracy, inter-assay, 4-PL	RE ± 20 %	+9.0 ± 10.3 %	comply
Serum samples, accuracy, inter-batch, 4-PL	RE ± 25 %	+1.0 ± 4.3 %	comply
Serum samples, precision, intra-assay, 4-PL	RSD ≤ 15 %	4.9 ± 0.7 %	comply
Serum samples, precision, inter-assay, 4-PL	RSD ≤ 20 %	9.6 ± 2.2 %	comply
Serum samples, precision, inter-batch, 4-PL	RSD ≤ 25 %	2.5 ± 1.8 %	comply
Lower limit of detection, LLOD	< 1 mg/L	0.3 ± 0.0 mg/L	comply
Upper limit of detection, ULOD	> 10 mg/L	24.5 ± 6.9 mg/L	comply
Lower limit of quantitation, LLOQ	< 1 mg/L	0.5 ± 0.0 mg/L	comply
Upper limit of quantitation, ULOQ	> 10 mg/L	12.0 ± 1.4 mg/L	comply
Calibration curve, regression model, 4-PL	r > 0.970	0.984 ± 0.006	comply
Calibration curve, Calibrators and Controls, accuracy, intra-assay, 4-PL	RE ± 15 %	+0.3 ± 2.4 %	comply
Calibration curve, Calibrators and Controls, accuracy, inter-assay, 4-PL	RE ± 20 %	+0.3 ± 2.4 %	comply
Calibration curve, Calibrators and Controls, precision, intra-assay, 4-PL	RSD ≤ 15 %	7.1 ± 7.1 %	comply
Calibration curve, Calibrators and Controls, precision, inter-assay, 4-PL	RSD ≤ 20 %	7.8 ± 6.4 %	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.