

ANALYTICAL PERFORMANCE FOR ERBA XL-200 UIBC

Cat. No.	Pack Name	Packaging (Content)
XSYS0050	UIBC 125	R1: 4 × 25 mL, R2: 4 × 6.5 mL, R3 standard: 1 × 4 mL, RFID tag, instruction for use

EN

CE 2797 IVD

Data contained within this section is representative for performance on ERBA XL-200 automatic system. Data obtained in your laboratory may differ from these values.

Limit of quantification: 10.5 µg/dL

Limit of quantification represents the lowest measurable analyte level. It is calculated as the determined activity of diluted sample to have CV <20 % (n = 30)

Linearity: 830 µg/dL

Linearity is the highest measured activity with recovery within ±10 % from theoretical value.

Precision

Precision was determined by using controls in an internal protocol with repeatability (n = 20) and intermediate precision (2 aliquots per run, 2 run per day, 20 days). The following results were obtained:

Repeatability	Mean (µg/dL)	SD (µg/dL)	CV (%)
Sample 1	127	3.3	2.62
Sample 2	185	3.2	1.74

Intermediate precision	Mean (µg/dL)	SD (µg/dL)	CV (%)
Sample 1	136	2.7	1.99
Sample 2	184	3.1	1.68

Accuracy

Two different validated control materials were used. Determined bias is and -22.2 % at the target value 55.7 µg/dL and -12.5 % at the target value 131 µg/dL.

Comparison

A comparison between XL-200 automatic system UIBC (y) and a commercially available test (x) using 119 samples gave following results:

Linear regression:

$$y = 0.991x + 16.914 \text{ µg/dL} \quad r = 0.990$$

Passing-Bablok¹:

$$y = 0.995x + 15.058 \text{ µg/dL} \quad r = 0.991$$

Interferences

Criterion: Recovery within ±10 % of initial value of UIBC concentration in the sample without interfering substance.

Following substances do not interfere: haemoglobin interferes (higher haemoglobin concentrations lead to artificially decreased values due to contamination of the sample with haemoglobin-bound iron), bilirubin min. up to 50 mg/dL, triglycerides up to 2350 mg/dL.

REFERENCES

1. Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. J Clin Chem Clin Biochem, Nov;26(11): 783-790, 1988.



ANALYTICAL PERFORMANCE FOR ERBA XL-640 UIBC

Cat. No.	Pack Name	Packaging (Content)
XSYS0050	UIBC 125	R1: 4 × 25 mL, R2: 4 × 6.5 mL, R3 standard: 1 × 4 mL, RFID tag, instruction for use

EN

CE₂₇₉₇ IVD

Data contained within this section is representative for performance on ERBA XL-640 automatic system. Data obtained in your laboratory may differ from these values.

Limit of quantification: 10.0 µg/dL

Limit of quantification represents the lowest measurable analyte level. It is calculated as the determined activity of diluted sample to have CV <20 % (n = 30)

Linearity: 830 µg/dL

Linearity is the highest measured activity with recovery within ±10 % from theoretical value.

Precision

Precision was determined by using controls in an internal protocol with repeatability (n = 20) and intermediate precision (2 aliquots per run, 2 run per day, 20 days). The following results were obtained:

Repeatability	Mean (µg/dL)	SD (µg/dL)	CV (%)
Sample 1	153	3.4	2.22
Sample 2	216	4.7	2.17

Intermediate precision	Mean (µg/dL)	SD (µg/dL)	CV (%)
Sample 1	155	5.8	3.76
Sample 2	214	6.8	3.20

Accuracy

Two different validated control materials were used. Determined bias is and 16.8 % at the target value 55.7 µg/dL and 4.2 % at the target value 131 µg/dL.

Comparison

A comparison between XL-640 automatic system UIBC (y) and a commercially available test (x) using 119 samples gave following results:

Linear regression:

$$y = 1.045x + 10.827 \text{ µg/dL} \quad r = 0.993$$

Passing-Bablok¹:

$$y = 1.048x + 10.189 \text{ µg/dL} \quad r = 0.991$$

Interferences

Criterion: Recovery within ±10 % of initial value of UIBC concentration in the sample without interfering substance.

Following substances do not interfere: haemoglobin interferes (higher haemoglobin concentrations lead to artificially decreased values due to contamination of the sample with haemoglobin-bound iron), bilirubin min. up to 50 mg/dL, triglycerides min. up to 2600 mg/dL.

REFERENCES

1. Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. J Clin Chem Clin Biochem, Nov;26(11): 783-790, 1988.



ANALYTICAL PERFORMANCE FOR ERBA XL-1000 UIBC

Cat. No.	Pack Name	Packaging (Content)
XSYS0050	UIBC 125	R1: 4 × 25 mL, R2: 4 × 6.5 mL, R3 standard: 1 × 4 mL, RFID tag, instruction for use

EN

CE 2797 IVD

Data contained within this section is representative for performance on ERBA XL-1000 automatic system. Data obtained in your laboratory may differ from these values.

Limit of quantification: 10.1 µg/dL

Limit of quantification represents the lowest measurable analyte level. It is calculated as the determined activity of diluted sample to have CV <20 % (n = 30)

Linearity: 830 µg/dL

Linearity is the highest measured activity with recovery within ±10 % from theoretical value.

Precision

Precision was determined by using controls in an internal protocol with repeatability (n = 20) and intermediate precision (2 aliquots per run, 2 run per day, 20 days). The following results were obtained:

Repeatability	Mean (µg/dL)	SD (µg/dL)	CV (%)
Sample 1	169	3.9	2.30
Sample 2	217	4.2	1.92

Intermediate precision	Mean (µg/dL)	SD (µg/dL)	CV (%)
Sample 1	151	3.6	2.37
Sample 2	205	5.3	2.58

Accuracy

Two different validated control materials were used. Determined bias is and 9.6 % at the target value 55.7 µg/dL and -5.6 % at the target value 131 µg/dL.

Comparison

A comparison between XL-1000 automatic system UIBC (y) and a commercially available test (x) using 119 samples gave following results:

Linear regression:

$$y = 1.018x + 8.642 \text{ µg/dL} \quad r = 0.999$$

Passing-Bablok¹:

$$y = 1.016x + 8.329 \text{ µg/dL} \quad r = 0.998$$

Interferences

Criterion: Recovery within ±10 % of initial value of UIBC concentration in the sample without interfering substance.

Following substances do not interfere: haemoglobin interferes (higher haemoglobin concentrations lead to artificially decreased values due to contamination of the sample with haemoglobin-bound iron), bilirubin min. up to 50 mg/dL, triglycerides up to 1350 mg/dL.

REFERENCES

1. Bablok W, Passing H, Bender R, et al. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry, Part III. J Clin Chem Clin Biochem, Nov;26(11): 783-790, 1988.

