Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-200
CHLORIDE

Cat. No.	Pack Name	Packaging (Content)
XSYS0008	CL 120	R1: 10 × 12 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: 0.38 mmol/L
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: 190 mmol/L
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 (serum)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	108.7	2.29	2.10
Sample 2	119.7	1.61	1.35

Intermediate precision (serum)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	106.0	2.99	2.82
Sample 2	113.8	3.35	2.95

Repeatability (urine)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	91.6	0.93	1.01
Sample 2	115.8	1.37	1.18

Intermediate precision (urine)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	120.0	4.75	3.96
Sample 2	150.2	5.54	3.69

Accuracy
Two different validated control materials for serum were used. Determined bias is 2.5 % at the target value 112 mmol/L and -3.0 % at the target value 131 mmol/L.

Comparison
A comparison between XL-200 automatic system CHLORIDE (y) and a commercially available test (x) using 101 samples (serum) gave following results:

Linear regression
y = 1.033x - 5.784 mmol/L r = 0.931

Passing-Bablok[1]:
y = 1.131x - 15.960 mmol/L r = 0.920

Interferences
Criterion: Recovery within ±10 % of initial value of chloride concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 12.5 g/L, bilirubin up to 12 mg/dL, triglycerides up to 850 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 1988 Nov; 26(11): 783-790.

QUALITY SYSTEM CERTIFIED ISO 13485, IVDR

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CC/AP/041/26/A Date of revision: 9. 4. 2026

Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-640
CHLORIDE

Cat. No.	Pack Name	Packaging (Content)
XSYS0008	CL 120	R1: 10 × 12 mL, RFID tag, instruction for use

EN

CE 2797 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: 0.43 mmol/L
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: 200 mmol/L
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 (serum)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	110.1	0.79	0.71
Sample 2	119.6	0.87	0.73

Intermediate precision (serum)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	109.6	2.64	2.41
Sample 2	119.5	2.35	1.96

Repeatability (urine)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	91.3	1.06	1.16
Sample 2	120.1	1.09	0.91

Intermediate precision (urine)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	122.1	2.07	1.70
Sample 2	142.4	3.17	2.23

Accuracy
Two different validated control materials for serum were used. Determined bias is 4.1 % at the target value 112 mmol/L and -2.4 % at the target value 131 mmol/L.

Comparison
A comparison between XL-640 automatic system CHLORIDE (y) and a commercially available test (x) using 145 samples (serum) gave following results:

Linear regression
y = 0.912x + 0.955 mmol/L r = 0.968

Passing-Bablok[1]:
y = 0.956x + 5.156 mmol/L r = 0.964

Interferences
Criterion: Recovery within ±10 % of initial value of chloride concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 12.5 g/L, bilirubin up to 12 mg/dL, triglycerides up to 850 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 1988 Nov; 26(11): 783-790.

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Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-1000
CHLORIDE

Cat. No.	Pack Name	Packaging (Content)
XSYS0008	CL 120	R1: 10 × 12 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: 0.31 mmol/L
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: 200 mmol/L
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 (serum)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	112.2	1.37	1.22
Sample 2	123.7	0.91	0.74

Intermediate precision (serum)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	108.7	2.53	2.33
Sample 2	121.0	2.53	2.09

Repeatability (urine)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	89.0	1.38	1.55
Sample 2	122.0	0.95	0.78

Intermediate precision (urine)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	117.7	2.00	1.70
Sample 2	151.1	1.49	0.99

Accuracy
Two different validated control materials for serum were used. Determined bias is 5.7 % at the target value 112 mmol/L and 0.8 % at the target value 131 mmol/L.

Comparison
A comparison between XL-1000 automatic system CHLORIDE (y) and a commercially available test (x) using 146 samples (serum) gave following results:

Linear regression
y = 1.068x - 4.177 mmol/L r = 0.964

Passing-Bablok[1]:
y = 1.136x - 11.268 mmol/L r = 0.958

Interferences
Criterion: Recovery within ±10 % of initial value of chloride concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 12.5 g/L, bilirubin up to 8 mg/dL, triglycerides up to 850 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 1988 Nov; 26(11): 783-790.

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