Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-200
CALCIUM

Cat. No.	Pack Name	Packaging (Content)
XSYS0007	CA 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:
Serum / plasma 0.19 mg/dL
Urine 1.70 mg/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:
Serum / plasma 20 mg/dL
Urine 60 mg/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 (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	8.71	0.059	0.68
Sample 2	11.04	0.081	0.73

Intermediate precision (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	8.00	0.298	3.73
Sample 2	10.61	0.262	2.47

Repeatability (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	22.3	0.79	3.55
Sample 2	33.3	0.83	2.50

Intermediate precision (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	18.5	0.63	3.39
Sample 2	32.4	1.13	3.50

Accuracy
Two different validated control materials for serum and urine were used. Determined bias is 7.9 % at the target value 11.7 mg/dL, 7.7 % at the target value 12.1 mg/dL for serum, 12.9 % at the target value 8.2 mg/dL and 9.5 % at the target value 12.2 mg/dL for urine.

Comparison
A comparison between XL-200 automatic system CALCIUM (y) and a commercially available test (x) using 62 samples (serum) gave following results:

Linear regression
y = 1.002x + 0.139 mg/dL r = 0.959

Passing-Bablok[1]:
y = 1.087x - 0.870 mg/dL r = 0.943

Interferences
Criterion: Recovery within ±10 % of initial value of calcium concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 12.5 g/L, bilirubin up to 40 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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Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-640
CALCIUM

Cat. No.	Pack Name	Packaging (Content)
XSYS0007	CA 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:
Serum / plasma 0.45 mg/dL
Urine 4.43 mg/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:
Serum / plasma 20 mg/dL
Urine 60 mg/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 (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	8.22	0.130	1.58
Sample 2	10.41	0.076	0.73

Intermediate precision (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	8.28	0.206	2.49
Sample 2	10.76	0.164	1.53

Repeatability (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	13.8	0.52	3.76
Sample 2	28.9	0.90	3.11

Intermediate precision (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	23.1	1.02	4.43
Sample 2	32.5	1.36	4.19

Accuracy
Two different validated control materials for serum and urine were used. Determined bias is 2.0 % at the target value 11.7 mg/dL, 2.0 % at the target value 12.1 mg/dL for serum, 5.5 % at the target value 8.2 mg/dL and 8.6 % at the target value 12.2 mg/dL for urine.

Comparison
A comparison between XL-640 automatic system CALCIUM (y) and a commercially available test (x) using 90 samples (serum) gave following results:

Linear regression
y = 0.936x + 0.765 mg/dL r = 0.981
Passing-Bablok[1]:
y = 0.947x + 0.629 mg/dL r = 0.973

Interferences
Criterion: Recovery within ±10 % of initial value of calcium concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 12.5 g/L, bilirubin up to 40 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
CALCIUM

Cat. No.	Pack Name	Packaging (Content)
XSYS0007	CA 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:
Serum / plasma 0.22 mg/dL
Urine 0.75 mg/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:
Serum / plasma 20 mg/dL
Urine 60 mg/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 (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	8.43	0.119	1.41
Sample 2	10.99	0.142	1.29

Intermediate precision (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	8.30	0.248	2.99
Sample 2	10.93	0.359	3.28

Repeatability (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	33.4	0.67	1.99
Sample 2	38.2	0.83	2.18

Intermediate precision (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	24.4	0.64	2.62
Sample 2	35.7	0.82	2.31

Accuracy
Two different validated control materials for serum and urine were used. Determined bias is 5.0 % at the target value 11.7 mg/dL, 5.6 % at the target value 12.1 mg/dL for serum, 9.8 % at the target value 8.2 mg/dL and 3.5 % at the target value 12.2 mg/dL for urine.

Comparison
A comparison between XL-1000 automatic system CALCIUM (y) and a commercially available test (x) using 56 samples (serum) gave following results:

Linear regression
y = 0.917x + 0.636 mg/dL r = 0.992

Passing-Bablok[1]:
y = 0.941x + 0.417 mg/dL r = 0.992

Interferences
Criterion: Recovery within ±10 % of initial value of calcium concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 12.5 g/L, bilirubin up to 40 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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