XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-200
BICARBONATE

Cat. No.	Pack Name	Packaging (Content)
XSYS0100	CO2	R1: 4 × 34 mL, R2 standard: 1 × 3 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: 0.60 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: 50 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	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	34.2	0.31	0.91
Sample 2	16.0	0.20	1.27

Intermediate precision	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	31.1	1.21	3.89
Sample 2	14.1	0.46	3.30

Accuracy
Two different validated control materials were used. Determined bias is and 0.2 % at the target value 20.0 mmol/L and 0.2 % at the target value 30.0 mmol/L.

Comparison
A comparison between XL-200 automatic system BICARBONATE (y) and a commercially available test (x) using 104 samples levels gave following results:
Linear regression:
y = 0.944x – 0.285 mmol/L r = 0.990
Passing-Bablok[1]:
y = 0.951x - 0.409 mmol/L r = 0.984

Interferences
Criterion: Recovery within ±10 % of initial value of CO_2 concentration in the sample (serum) without interfering substance. Following substances do not interfere: haemoglobin up to 7.0 g/L, bilirubin up to 45 mg/dL, triglycerides up to 1650 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

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XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-640
BICARBONATE

Cat. No.	Pack Name	Packaging (Content)
XSYS0100	CO2	R1: 4 × 34 mL, R2 standard: 1 × 3 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: 0.80 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: 50 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	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	32.2	0.19	0.60
Sample 2	15.5	0.16	1.02

Intermediate precision	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	29.9	0.96	3.23
Sample 2	14.3	0.42	2.91

Accuracy
Two different validated control materials were used. Determined bias is and 0.6 % at the target value 20.0 mmol/L and 1.7 % at the target value 30.0 mmol/L.

Comparison
A comparison between XL-640 automatic system BICARBONATE (y) and a commercially available test (x) using 6 concentration levels gave following results:
Linear regression:
y = 0.970x - 0.041 mmol/L r = 0.995
Passing-Bablok[1]:
y = 0.968x - 0.002 mmol/L r = 0.983

Interferences
Criterion: Recovery within ±10 % of initial value of CO_2 concentration in the sample (serum) without interfering substance. Following substances do not interfere: haemoglobin up to 3.5 g/L, bilirubin up to 35 mg/dL, triglycerides up to 1650 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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XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-1000
BICARBONATE

Cat. No.	Pack Name	Packaging (Content)
XSYS0100	CO2	R1: 4 × 34 mL, R2 standard: 1 × 3 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: 0.46 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: 50 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	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	29.9	0.96	3.23
Sample 2	14.3	0.42	2.91

Intermediate precision	Mean (mmol/L)	SD (mmol/L)	CV (%)
Sample 1	33.2	1.14	3.44
Sample 2	15.4	0.45	2.92

Accuracy
Two different validated control materials were used. Determined bias is and 1.9 % at the target value 20.0 mmol/L and 3.9 % at the target value 30.0 mmol/L.

Comparison
A comparison between XL-1000 automatic system BICARBONATE (y) and a commercially available test (x) using 104 samples gave following results:
Linear regression:
y = 0.997x - 0.583 mmol/L r = 0.990
Passing-Bablok[1]:
y = 1.018x - 1.020 mmol/L r = 0.985

Interferences
Criterion: Recovery within ±10 % of initial value of CO_2 concentration in the sample (serum) without interfering substance. Following substances do not interfere: haemoglobin up to 8.0 g/L, bilirubin up to 50 mg/dL, triglycerides up to 1650 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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