XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-200
GLUCOSE

Cat. No.	Pack Name	Packaging (Content)
XSYS0012	GLU 440	R1: 10 × 44 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: 1.24 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: 550 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	84.6	1.65	1.95
Sample 2	265.8	3.46	1.30

Repeatability (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	109.2	1.51	1.38
Sample 2	349.2	5.52	1.58

Intermediate precision (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	79.6	4.74	5.96
Sample 2	239.0	11.04	4.62

Intermediate precision (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	110.6	3.49	3.16
Sample 2	334.1	9.42	2.82

Accuracy
Two different validated control materials for serum and urine were used. Determined bias is 5.2 % at the target value 69.5 mg/dL, 3.5 % at the target value 211.4 mg/dL for serum, -4.0 % at the target value 27.7 mg/dL and 2.8 % at the target value 294.6 mg/dL for urine.

Comparison
A comparison between XL-200 automatic system GLUCOSE (y) and a commercially available test (x) using 146 samples (serum) gave following results:

Linear regression
y = 1.076x - 9.906 mg/dL r = 0.987

Passing-Bablok[1]:
y = 1.075x - 9.104 mg/dL r = 0.971

Interferences
Criterion: Recovery within ±10 % of initial value of glucose 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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CC/AP/023/26/A *Date of revision: 19. 1. 2026*

XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-640
GLUCOSE

Cat. No.	Pack Name	Packaging (Content)
XSYS0012	GLU 440	R1: 10 × 44 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: 0.96 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: 550 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	81.9	1.16	1.41
Sample 2	245.8	1.30	0.53

Repeatability (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	108.6	1.36	1.26
Sample 2	340.9	1.02	0.30

Intermediate precision (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	81.7	1.86	2.28
Sample 2	246.1	3.94	1.60

Intermediate precision (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	109.0	2.19	2.01
Sample 2	321.3	6.45	2.01

Accuracy
Two different validated control materials for serum and urine were used. Determined bias is 2.6 % at the target value 69.5 mg/dL, 0.9 % at the target value 211.4 mg/dL for serum, 2.1 % at the target value 27.7 mg/dL and 4.1 % at the target value 294.6 mg/dL for urine.

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

Linear regression
y = 1.027x - 7.500 mg/dL r = 0.982

Passing-Bablok[1]:
y = 1.025x - 7.560 mg/dL r = 0.963

Interferences
Criterion: Recovery within ±10 % of initial value of glucose 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
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Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-1000
GLUCOSE

Cat. No.	Pack Name	Packaging (Content)
XSYS0012	GLU 440	R1: 10 × 44 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: 2.45 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: 725 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	82.7	1.19	1.44
Sample 2	253.1	2.42	0.96

Repeatability (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	106.6	1.48	1.38
Sample 2	338.4	2.45	0.72

Intermediate precision (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	83.6	2.41	2.88
Sample 2	254.0	7.54	2.97

Intermediate precision (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	112.8	1.80	1.60
Sample 2	330.7	5.44	1.65

Accuracy
Two different validated control materials for serum and urine were used. Determined bias is 3.7 % at the target value 69.5 mg/dL, 2.4 % at the target value 211.4 mg/dL for serum, 4.5 % at the target value 27.7 mg/dL and 4.9 % at the target value 294.6 mg/dL for urine.

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

Linear regression
y = 1.003x - 7.281 mg/dL r = 0.986

Passing-Bablok[1]:
y = 0.991x - 5.622 mg/dL r = 0.969

Interferences
Criterion: Recovery within ±10 % of initial value of glucose 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 535 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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