

ANALYTICAL PERFORMANCE FOR ERBA XL-200

GLUCOSE HK

Cat. No.	Pack Name	Packaging (Content)
XSYS0095	GLU HK 330	R1: 6 × 44 mL, R2: 6 × 11 mL, RFID tag, instruction for use

EN

CE₂₇₉₇ 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: 0.91 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: 1000 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	82.1	1.77	2.16
Sample 2	251.5	4.41	1.75

Repeatability (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	113.4	1.41	1.25
Sample 2	346.5	3.46	1.00

Intermediate precision (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	77.9	2.59	3.32
Sample 2	236.1	9.17	3.88

Intermediate precision (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	109.6	3.67	3.35
Sample 2	327.6	12.94	3.95

Accuracy

Two different validated control materials for serum and urine were used. Determined bias is 2.5 % at the target value 69.5 mg/dL, 2.0 % at the target value 211.4 mg/dL for serum, -7.3 % at the target value 27.7 mg/dL and -1.6 % at the target value 294.6 mg/dL for urine.

Comparison

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

Linear regression:

$$y = 1.024x - 7.132 \text{ mg/dL} \quad r = 0.987$$

Passing-Bablok¹:

$$y = 1.016x - 6.169 \text{ mg/dL} \quad r = 0.974$$

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

- 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.



ANALYTICAL PERFORMANCE FOR ERBA XL-640 GLUCOSE HK

Cat. No.	Pack Name	Packaging (Content)
XSYS0095	GLU HK 330	R1: 6 × 44 mL, R2: 6 × 11 mL, RFID tag, instruction for use



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. Data are given below. Results obtained in different laboratories may vary.

Limit of quantification: 1.47 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: 1000 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	79.7	0.33	0.42
Sample 2	237.6	1.59	0.67

Repeatability (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	115.8	1.04	0.90
Sample 2	346.6	1.28	0.37

Intermediate precision (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	79.9	1.67	2.09
Sample 2	241.9	3.54	1.46

Intermediate precision (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	105.4	1.48	1.41
Sample 2	312.4	8.83	2.83

Accuracy

Two different validated control materials for serum and urine were used. Determined bias is -0.7 % at the target value 69.5 mg/dL, -1.4 % at the target value 211.4 mg/dL for serum, 3.7 % at the target value 27.7 mg/dL and 1.1 % at the target value 294.6 mg/dL for urine.

Comparison

A comparison between XL-640 automatic system GLUCOSE HK (y) and a commercially available test (x) using 146 samples (serum) gave following results:

Linear regression

$$y = 1.026x - 6.545 \text{ mg/dL} \quad r = 0.990$$

Passing-Bablok¹:

$$y = 1.029x - 6.901 \text{ mg/dL} \quad r = 0.982$$

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

- 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.



ANALYTICAL PERFORMANCE FOR ERBA XL-1000

GLUCOSE HK

Cat. No.	Pack Name	Packaging (Content)
XSYS0095	GLU HK 330	R1: 6 × 44 mL, R2: 6 × 11 mL, RFID tag, instruction for use



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: 1.56 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: 1000 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	82.2	0.97	1.18
Sample 2	252.5	1.81	0.72

Repeatability (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	112.7	1.81	1.60
Sample 2	338.1	2.47	0.73

Intermediate precision (serum)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	81.1	2.03	2.50
Sample 2	246.8	6.40	2.59

Intermediate precision (urine)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	112.2	2.30	2.05
Sample 2	326.9	6.22	1.90

Accuracy

Two different validated control materials for serum and urine were used. Determined bias is -4.3 % at the target value 69.5 mg/dL, -2.0 % at the target value 211.4 mg/dL for serum, -1.9 % at the target value 27.7 mg/dL and -3.8 % at the target value 294.6 mg/dL for urine.

Comparison

A comparison between XL-1000 automatic system GLUCOSE HK (y) and a commercially available test (x) using 144 samples (serum) gave following results:

Linear regression:

$$y = 1.033x - 9.229 \text{ mg/dL} \quad r = 0.986$$

Passing-Bablok¹:

$$y = 1.002x - 5.570 \text{ mg/dL} \quad r = 0.971$$

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

- 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.