Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-200
BILIRUBIN DIRECT

Cat. No.	Pack Name	Packaging (Content)
XSYS0028	BIL D 330	R1: 6 × 44 mL, R2: 6 × 11 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: 0.04 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: 20.5 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	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	0.60	0.011	1.86
Sample 2	1.59	0.029	1.85

Intermediate precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	0.55	0.022	3.96
Sample 2	1.54	0.038	2.45

Accuracy
Two different validated control materials were used. Determined bias is -3.0 % at the target value 0.35 mg/dL and -4.1 % at the target value 0.99 mg/dL.

Comparison
A comparison between XL-200 automatic system BILIRUBIN DIRECT (y) and a commercially available test (x) using 120 samples gave following results:

Linear regression
y = 0.967x + 0.118 mg/dL r = 0.993

Passing-Bablok[1]
y = 0.952x + 0.126 mg/dL r = 0.887

Interferences
Criterion: Recovery within ±10 % of initial value of direct bilirubin concentration in the sample without interfering substance.
Following substances do not interfere: haemoglobin up to 2 g/L, 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, Nov;26(11): 783-790, 1988.

QUALITY SYSTEM CERTIFIED
ISO 13485, IVDR

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erba.com, www.erba.com

CC/AP/053/25/A *Date of revision: 11. 11. 2025*

Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-640
BILIRUBIN DIRECT

Cat. No.	Pack Name	Packaging (Content)
XSYS0028	BIL D 330	R1: 6 × 44 mL, R2: 6 × 11 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: 0.04 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: 20.5 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	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	0.59	0.005	0.80
Sample 2	1.56	0.013	0.82

Intermediate precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	0.55	0.012	2.27
Sample 2	1.62	0.033	2.01

Accuracy
Two different validated control materials were used. Determined bias is 6.1 % at the target value 0.35 mg/dL and 7.9 % at the target value 0.99 mg/dL.

Comparison
A comparison between XL-640 automatic system BILIRUBIN DIRECT (y) and a commercially available test (x) using 120 samples gave following results:

Linear regression
y = 0.922x + 0.154 mg/dL r = 0.992

Passing-Bablok[1]
y = 0.933x + 0.134 mg/dL r = 0.882

Interferences
Criterion: Recovery within ±10 % of initial value of direct bilirubin concentration in the sample without interfering substance.
Following substances do not interfere: haemoglobin up to 3 g/L, 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, Nov;26(11): 783-790, 1988.

QUALITY SYSTEM CERTIFIED
ISO 13485, IVDR

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erba.com, www.erba.com

CC/AP/053/25/A *Date of revision: 11. 11. 2025*

XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-1000
BILIRUBIN DIRECT

Cat. No.	Pack Name	Packaging (Content)
XSYS0028	BIL D 330	R1: 6 × 44 mL, R2: 6 × 11 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: 0.05 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: 20.5 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	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	0.64	0.011	1.70
Sample 2	1.73	0.029	1.66

Intermediate precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	0.62	0.027	4.36
Sample 2	1.70	0.043	2.53

Accuracy
Two different validated control materials were used. Determined bias is 4.5 % at the target value 0.35 mg/dL and 7.5 % at the target value 0.99 mg/dL.

Comparison
A comparison between XL-1000 automatic system BILIRUBIN DIRECT (y) and a commercially available test (x) using 120 samples gave following results:

Linear regression
y = 0.927x + 0.164 mg/dL r = 0.993

Passing-Bablok[1]
y = 0.936x + 0.156 mg/dL r = 0.885

Interferences
Criterion: Recovery within ±10 % of initial value of direct bilirubin concentration in the sample without interfering substance.
Following substances do not interfere: haemoglobin up to 3 g/L, 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, Nov;26(11): 783-790, 1988.

QUALITY SYSTEM CERTIFIED ISO 13485, IVDR

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erba.com, www.erba.com

CC/AP/053/25/A *Date of revision: 11. 11. 2025*