Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-200
C-REACTIVE PROTEIN HIGH SENSITIVE

Cat. No.	Pack Name	Packaging (Content)
XSYS0084	CRP-HS	R1: 2 × 40 mL, R2: 2 × 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: 0.071 g/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: approx. 15 mg/dL
Linearity is given by concentration of the calibrator used for generating 6-point calibration curve.

Hook Effect: safety zone >225 mg/dL

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	2.22	0.023	1.02
Sample 2	4.10	0.028	0.70

Intermediate precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	2.10	0.043	2.04
Sample 2	3.90	0.088	2.27

Accuracy
Two different validated control materials were used. Determined bias is -3.9% at the target value 1.84 mg/dL and -4.6% at the target value 3.55 mg/dL.

Comparison
A comparison between XL-200 automatic system CRP-HS (y) and a commercially available test (x) using 150 samples gave following results:
Linear regression:
y = 1.024x - 0.416 mg/dL r = 0.996
Passing-Bablok[1]:
y = 0.986x - 0.283 mg/dL r = 0.991

Interferences
Criterion: Recovery within ±10% of initial value of CRP concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 13.3 g/L, bilirubin up to 5 mg/dL, triglycerides up to 1910 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
C-REACTIVE PROTEIN HIGH SENSITIVE

Cat. No.	Pack Name	Packaging (Content)
XSYS0084	CRP-HS	R1: 2 × 40 mL, R2: 2 × 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: 0.058 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: approx. 15 mg/dL
Linearity is given by concentration of the calibrator used for generating 6-point calibration curve.

Hook Effect: safety zone >225 mg/dL

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	2.13	0.022	1.02
Sample 2	3.90	0.029	0.75

Intermediate precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	2.14	0.056	2.64
Sample 2	3.90	0.083	2.12

Accuracy
Two different validated control materials were used. Determined bias is 11.5% at the target value 1.84 mg/dL and 7.2% at the target value 3.55 mg/dL.

Comparison
A comparison between XL-640 automatic system CRP-HS (y) and a commercially available test (x) using 150 samples gave following results:
Linear regression:
y = 1.013x - 0.075 mg/dL r = 0.996
Passing-Bablok[1]:
y = 1.009x - 0.050 mg/dL r = 0.994

Interferences
Criterion: Recovery within ±10% of initial value of CRP concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 13.3 g/L, bilirubin up to 5 mg/dL, triglycerides up to 1910 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

C-REACTIVE PROTEIN HIGH SENSITIVE

Cat. No.	Pack Name	Packaging (Content)
XSYS0084	CRP-HS	R1: 2 × 40 mL, R2: 2 × 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: 0.072 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: approx. 15 mg/dL
Linearity is given by concentration of the calibrator used for generating 6-point calibration curve.

Hook Effect: safety zone >225 mg/dL

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	2.22	0.028	1.27
Sample 2	3.90	0.033	0.85

Intermediate precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	2.02	0.037	1.85
Sample 2	3.73	0.087	2.34

Accuracy

Two different validated control materials were used. Determined bias is 2.9% at the target value 1.84 mg/dL and -7.9% at the target value 3.55 mg/dL.

Comparison

A comparison between XL-1000 automatic system CRP-HS (y) and a commercially available test (x) using 150 samples gave following results:
Linear regression:
y = 0.943x - 0.066 mg/dL r = 0.988
Passing-Bablok[1]:
y = 0.931x - 0.023 mg/dL r = 0.994

Interferences

Criterion: Recovery within ±10% of initial value of CRP concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 13.3 g/L, bilirubin up to 5 mg/dL, triglycerides up to 1910 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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