Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-200
TRIGLYCERIDES

Cat. No.	Pack Name	Packaging (Content)
XSYS0041	TG 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: 2.51 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: 1250 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	106.3	1.24	1.17
Sample 2	173.0	1.01	0.59

Repeatability	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	99.1	3.81	3.84
Sample 2	160.8	4.84	3.01

Accuracy
Two different validated control materials were used. Determined bias is 9.9% at the target value 91.3 mg/dL and 4.5% at the target value 156.7 mg/dL.

Comparison
A comparison between XL-200 automatic system TRIGLYCERIDES (y) and a commercially available test (x) using 149 samples gave following results:

Linear regression
y = 0.995x + 10.97 mg/dL r = 0.991

Passing-Bablok[1]:
y = 1.025x + 7.54 mg/dL r = 0.985

Interferences
Criterion: Recovery within ±10% of initial value of triglycerides concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 5 g/L, bilirubin up to 4 mg/dL.
Interference by N-acetylcysteine (NAC), acetoaminophen and metamizole causes falsely low results. To carry out the test, blood withdrawal should be performed prior to administration of drugs.

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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ANALYTICAL PERFORMANCE FOR ERBA XL-640
TRIGLYCERIDES

Cat. No.	Pack Name	Packaging (Content)
XSYS0041	TG 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: 1.64 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: 1250 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	106.4	3.13	2.94
Sample 2	168.7	0.94	0.56

Repeatability	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	105.2	3.34	3.17
Sample 2	167.2	3.78	2.26

Accuracy
Two different validated control materials were used. Determined bias is -0.8% at the target value 91.3 mg/dL and -1.5% at the target value 156.7 mg/dL.

Comparison
A comparison between XL-640 automatic system TRIGLYCERIDES (y) and a commercially available test (x) using 149 samples gave following results:

Linear regression
y = 0.997x + 16.64 mg/dL r = 0.994

Passing-Bablok[1]:
y = 1.025x + 13.99 mg/dL r = 0.993

Interferences
Criterion: Recovery within ±10% of initial value of triglycerides concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 5 g/L, bilirubin up to 8 mg/dL.
Interference by N-acetylcysteine (NAC), acetoaminophen and metamizole causes falsely low results. To carry out the test, blood withdrawal should be performed prior to administration of drugs.

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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ANALYTICAL PERFORMANCE FOR ERBA XL-1000
TRIGLYCERIDES

Cat. No.	Pack Name	Packaging (Content)
XSYS0041	TG 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: 2.21 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: 1250 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	104.8	1.79	1.71
Sample 2	169.1	2.19	1.29

Repeatability	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	107.5	4.24	3.95
Sample 2	172.5	6.28	3.64

Accuracy
Two different validated control materials were used. Determined bias is and 0.5% at the target value 91.3 mg/dL and -4.7% at the target value 156.7 mg/dL.

Comparison
A comparison between XL-1000 automatic system TRIGLYCERIDES (y) and a commercially available test (x) using 149 samples gave following results:

Linear regression
y = 0.986x + 17.00 mg/dL r = 0.994

Passing-Bablok[1]:
y = 0.996x + 15.83 mg/dL r = 0.994

Interferences
Criterion: Recovery within ±10% of initial value of triglycerides concentration in the sample (serum) without interfering substance.
Following substances do not interfere: haemoglobin up to 5 g/L, bilirubin up to 8 mg/dL.
Interference by N-acetylcysteine (NAC), acetoaminophen and metamizole causes falsely low results. To carry out the test, blood withdrawal should be performed prior to administration of drugs.

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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