Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-200
CREATINE KINASE

Cat. No.	Pack Name	Packaging (Content)
XSYS0022	CK 110	R1: 2 × 44 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: 5.04 U/L
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: 2340 U/L
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 (U/L)	SD (U/L)	CV (%)
Sample 1	144.3	1.24	0.86
Sample 2	344.3	2.75	0.80

Intermediate precision	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	148.6	3.12	2.10
Sample 2	352.7	6.15	1.74

Accuracy
Two different validated control materials were used. Determined bias is -1.1 % at the target value 208.1 U/L and -2.2 % at the target value 513.2 U/L.

Comparison
A comparison between XL-200 automatic system CK (y) and a commercially available test (x) using 50 samples gave following results:
Linear regression:
y = 1.007x - 13.45 U/L r = 0.988
Passing-Bablok[1]:
y = 1.029x - 5.85 U/L r = 0.985

Interferences
Criterion: Recovery within ±10 % of initial value of CK activity in the sample without interfering substance.
Following substances do not interfere: haemoglobin up to 7 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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Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-640
CREATINE KINASE

Cat. No.	Pack Name	Packaging (Content)
XSYS0022	CK 110	R1: 2 × 44 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: 5.12 U/L
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: 2340 U/L
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 (U/L)	SD (U/L)	CV (%)
Sample 1	133.0	0.86	0.64
Sample 2	313.3	0.86	0.27

Intermediate precision	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	143.1	2.99	2.09
Sample 2	333.3	6.05	1.81

Accuracy
Two different validated control materials were used. Determined bias is 2.1 % at the target value 208.1 U/L and -2.5 % at the target value 513.2 U/L.

Comparison
A comparison between XL-640 automatic system CK (y) and a commercially available test (x) using 51 samples gave following results:
Linear regression:
y = 0.975x - 8.47 U/L r = 0.991
Passing-Bablok[1]:
y = 0.992x - 4.00 U/L r = 0.990

Interferences
Criterion: Recovery within ±10 % of initial value of CK activity in the sample without interfering substance.
Following substances do not interfere: haemoglobin up to 7 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

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Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-1000
CREATINE KINASE

Cat. No.	Pack Name	Packaging (Content)
XSYS0022	CK 110	R1: 2 × 44 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: 5.19 U/L
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: 1737 U/L
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 (U/L)	SD (U/L)	CV (%)
Sample 1	130.6	2.79	2.13
Sample 2	306.4	2.28	0.74

Intermediate precision	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	143.0	2.90	2.03
Sample 2	334.3	7.58	2.27

Accuracy
Two different validated control materials were used. Determined bias is -0.2 % at the target value 208.1 U/L and -4.6 % at the target value 513.2 U/L.

Comparison
A comparison between XL-1000 automatic system CK (y) and a commercially available test (x) using 51 samples gave following results:
Linear regression:
y = 0.967x - 5.50 U/L r = 0.992
Passing-Bablok[1]:
y = 1.007x - 1.66 U/L r = 0.991

Interferences
Criterion: Recovery within ±10 % of initial value of CK activity in the sample without interfering substance.
Following substances do not interfere: haemoglobin up to 7 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

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