Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-200

MICROPROTEIN

Cat. No.	Pack Name	Packaging (Content)
XSYS0027	MP 120	R1: 10 × 12 mL, R2 standard: 1 × 5 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: 1.52 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: 210 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	20.5	0.37	1.81
Sample 2	73.6	1.02	1.39

Intermediate precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	22.3	1.09	4.86
Sample 2	65.8	2.23	3.39

Accuracy

Two different validated control materials were used. Determined bias is 6.3 % at the target value 18.9 mg/dL and -0.7 % at the target value 67.9 mg/dL.

Comparison

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

Linear regression:
y = 1.026x + 0.151 mg/dL r = 0.997

Passing-Bablok[1]:
y = 1.024x + 0.062 mg/dL r = 0.997

Interferences

In this method, some kinds of surface active agents may affect the color. Cationic surfactants, in general, give the same color as proteins. Because anions inhibit the color reaction, wash the equipment throughly, using distilled water, until no surface active agent remains. Then dry equipment completely before using it.
Haemoglobin interferes[2].
Small amounts of protein attached to the cuvette wall after measurement of certain other tests will cause an erroneously high measured value when the test solution is transferred to the cuvette. If this should occur, wash the cuvette completely and measure again.

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.
2. Yilmaz FM, Yücel D. Effect of Addition of Hemolysate on Urine and Cerebrospinal Fluid Assays for Protein. Clin Chem 52:152-153, 2006.

QUALITY SYSTEM CERTIFIED ISO 13485, IVDR

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Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-640

MICROPROTEIN

Cat. No.	Pack Name	Packaging (Content)
XSYS0027	MP 120	R1: 10 × 12 mL, R2 standard: 1 × 5 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: 1.57 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: 210 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	23.1	0.41	1.78
Sample 2	66.8	1.03	1.54

Intermediate precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	21.5	0.77	3.57
Sample 2	63.2	1.57	2.49

Accuracy

Two different validated control materials were used. Determined bias is and 8.9 % at the target value 18.9 mg/dL and 6.4 % at the target value 67.9 mg/dL.

Comparison

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

Linear regression:
y = 0.908x + 4.882 mg/dL r = 0.997

Passing-Bablok[1]:
y = 0.917x + 4.138 mg/dL r = 0.997

Interferences

In this method, some kinds of surface active agents may affect the color. Cationic surfactants, in general, give the same color as proteins. Because anions inhibit the color reaction, wash the equipment throughly, using distilled water, until no surface active agent remains. Then dry equipment completely before using it.
Haemoglobin interferes[2].
Small amounts of protein attached to the cuvette wall after measurement of certain other tests will cause an erroneously high measured value when the test solution is transferred to the cuvette. If this should occur, wash the cuvette completely and measure again.

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.
2. Yilmaz FM, Yücel D. Effect of Addition of Hemolysate on Urine and Cerebrospinal Fluid Assays for Protein. Clin Chem 52:152-153, 2006.

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Erba Mannheim
XL SysPack

ANALYTICAL PERFORMANCE FOR ERBA XL-1000

MICROPROTEIN

Cat. No.	Pack Name	Packaging (Content)
XSYS0027	MP 120	R1: 10 × 12 mL, R2 standard: 1 × 5 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: 0.87 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: 210 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	22.3	0.42	1.90
Sample 2	69.1	1.47	2.12

Intermediate precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Sample 1	20.0	0.78	3.92
Sample 2	63.8	1.43	2.24

Accuracy

Two different validated control materials were used. Determined bias is and 7.5 % at the target value 18.9 mg/dL and 4.2 % at the target value 67.9 mg/dL.

Comparison

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

Linear regression:
y = 1.036x - 3.854 mg/dL r = 0.996

Passing-Bablok[1]:
y = 1.022x - 2.896 mg/dL r = 0.996

Interferences

In this method, some kinds of surface active agents may affect the color. Cationic surfactants, in general, give the same color as proteins. Because anions inhibit the color reaction, wash the equipment throughly, using distilled water, until no surface active agent remains. Then dry equipment completely before using it.
Haemoglobin interferes[2].
Small amounts of protein attached to the cuvette wall after measurement of certain other tests will cause an erroneously high measured value when the test solution is transferred to the cuvette. If this should occur, wash the cuvette completely and measure again.

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.
2. Yilmaz FM, Yücel D. Effect of Addition of Hemolysate on Urine and Cerebrospinal Fluid Assays for Protein. Clin Chem 52:152-153, 2006.

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