Albumin FS*

Diagnostic reagent for quantitative in vitro determination of albumin in serum or plasma on Sysmex BX-Series

Order Information

Cat. No.	Kit size	Number of tests
1 0220 99 10 971	R1 3 x 16.5 mL	BX-3010 3 x 100 tests
		BX-4000 3 x 73 tests

Method

Photometric test using bromocresol green

Principle

In the presence of bromocresol green at a slightly acid pH, serum albumin produces a color change of the indicator from yellow-green to green-blue.

Reagents

Components and Concentrations

Citrate buffer	pH 4.2	30 mmol/L
Bromocresol green		0.26 mmol/L

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 25°C, protected from light and contamination is avoided. Do not freeze the reagent!

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results [6].
2. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
3. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent trays.

Specimen

Serum, heparin plasma or EDTA plasma

Stability [1]:

2.5 months	at	20 – 25°C
5 months	at	4 – 8°C
3 months	at	–20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. The assigned values of TruCal U have been made traceable to the reference material ERM-DA470. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range up to 6 g/dL (60 g/L) albumin (in case of higher concentrations re-measure samples after manual dilution with NaCl (9 g/L) solution or use rerun function)	
Limit of detection**	0.1 g/dL (1 g/L) albumin
On-board stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences < 10%	Analyte concentration
Ascorbate	up to 30 mg/dL	4.33 g/dL (43.3 g/L)
Hemoglobin	up to 300 mg/dL	4.29 g/dL (42.9 g/L)
Bilirubin, conjugated	up to 60 mg/dL	4.31 g/dL (43.1 g/L)
Bilirubin, unconjugated	up to 60 mg/dL	4.31 g/dL (43.1 g/L)
Lipemia (triglycerides)	up to 1200 mg/dL	3.97 g/dL (39.7 g/L)
For further information on interfering substances refer to Young DS [5].		

Precision (BX-4000)			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	3.51	4.13	4.92
Mean [g/L]	35.1	41.3	49.2
Coefficient of variation [%]	0.894	0.467	0.489
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	3.83	4.45	4.96
Mean [g/L]	38.3	44.5	49.6
Coefficient of variation [%]	0.872	0.419	0.848

Method comparison (n=109)	
Test x	Albumin FS (BioMajesty 6010C)
Test y	Albumin FS (BX-4000)
Slope	1.00
Intercept	0.000 g/dL (0.00 g/L)
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n = 20) of an analyte free specimen

Conversion factor

Albumin [g/dL] x 144.9 = Albumin [µmol/L]

Albumin [g/L] x 14.49 = Albumin [µmol/L]

Reference Range [2]

Adults: 3.5 – 5.2 g/dL (35 – 52 g/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
2. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvenu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
3. Johnson AM, Rohlfs EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER. editors. Tietz textbook of clinical chemistry. 3rd ed. Philadelphia: W. B. Saunders Company; 1999. p. 477-540.
4. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 652-6.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Assocation for Clinical Chemistry Press 2000.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Albumin FS

Chemistry Code 100 02

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	ALB	Reagent Name	Reagent (µL)	Water (µL)
Print Name	Albumin	MethodColor		R1	ALB	135
Sample Type	Serum			R2	Disable	
Unit	g/dL			Diluent	Disable	
Assay Type	End			Sample Ppt. Wash	Disable	

Measuring points — Start — End — Stirring Speed R1: Middle — R2:

	Start	End
1	7	9
2	Disable	

Wave Length — Prim. 600 — Sec. 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal Sample Volume (µL) Low	< Normal	< High	Diluted Sample (µL)	Diluent (µL)
☐ Diluent	0.0	1.5	0.0		
☐ Rerun (High/Prozone) Diluent	0.0	1.5	0.0		
☐ Rerun (Low) Diluent	0.0	1.5	0.0		

Technical Range (Conc) 0.1 – 6.0; (mAbs/10) * – *

Previous Result Comparison (%) * – * %

Abnormal Range (Conc) * – *

Panic Range (Conc) * – *

Decimal Point 1 — Profile SI Disable

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Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * — Method Name ALB — Sample Serum

Limit Checks

- ✓ Duplicate Limit: 100 mAbs/10
- ✓ Sensitivity Limit: 600 mAbs/10
- ☐ Linearity Limit: % ; (mAbs/10)/min
- ☐ Prozone Limit: Higher %
- SL1-S – SL1-F
- SL2-S – SL2-F
- Sensitivity: mAbs/10
- ✓ Absorbance Limit — Abs. in reaction: Increase — Limit: 25000 mAbs/10

Blank measurement

- Blank measurement: Disable reagent blank and C1 blank
- Measurement of Reagent Blank during Run: None
- Reagent blank measurement at calibration: Reagent blank (No sample)
- The number of measurement: Duplicate
- Reagent blank limit checks: ✓ Duplicate Limit: 30 mAbs/10

Instrument Factor

a 1.00 — b 0.00

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name ALB

Sample Type Serum

Replication Duplicate

Check Interval 42

Test without calibration

Disable

Calibration Type Linear

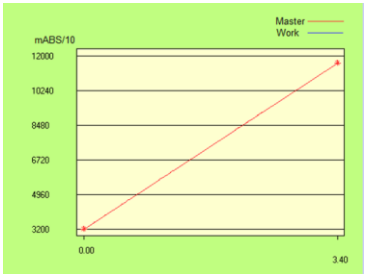
Reagent Lot New Add

Calibrator Name TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No. ☐ All
C1	0	Automatic entry	Automatic entry	*
C2	*	Automatic entry	Automatic entry	*
C3	*			
C4	*			
C5	*			
C6	*			
C7	*			

K Automatic entry ☐ C1 Blank
☐ Reagent Blank for C1

Reagent Lot No.
(R1) *
(R2) *
Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

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Albumin FS

Chemistry Code 100 02

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * | Name: ALB

Print Name: Albumin

Sample: Serum

Unit: g/dL

Assay Type: End

	Reagent Name	Reagent (µL)	Water (µL)
R1	ALB	189	
R2 ☐ Enable			
Diluent ☐ Enable			

Measuring points

	Start	End
1	11	13
☐ Enable 2		

Decimal Points: 1

Wave Length: Prim. 600 | Sec ☐ Disable 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Sampling	Sample (µL)	Diluent (µL)
Normal ☐ Dilution	2.1		
Rerun (High/Prozone) ☐ Dilution	2.1		
Rerun (Low) ☐ Dilution	2.1		

Technical Range

(Conc) 0.1 – 6.0

(mAbs/10) –

SPT Wash ☐ Enable — Reagent Name

Stirring Speed: R1 Middle | R2

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Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No.: * | Name: ALB | Sample: Serum

Limit Checks

✓ Duplicate Limit: 100 mAbs/10

✓ Sensitivity Limit: 600 mAbs/10

☐ Linearity Limit: % (mAbs/10)/min

☐ Prozone Limit: % Upper

SL1-S – SL1-F

SL2-S – SL2-F

Sensitivity: mAbs/10

✓ Absorbance Limit

Reaction: Increase

Limit: mAbs/10

Blank measurement

Blank measurement:
Disable reagent blank and S1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
✓ Duplicate Limit: 30 mAbs/10

Instrument Factor

a 1.00 b 0.00

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method * Name ALB

Sample Serum

Sampling Duplicate

Check Interval 42 days

Auto Change Lot Full Calibration

Auto Interval hours

Type Linear Lot New

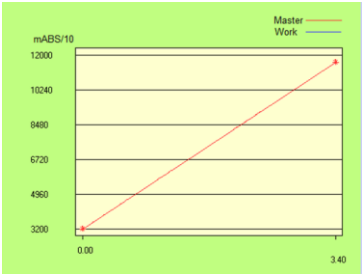
Material Name TruCal U

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1 * Last
R2 *



The calibration curve is lot-dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Type Conc.

Absorbance mAbs/10 Recalculation