Albumin FS*

Order Information

Cat. No.	Kit size		
1 0220 99 10 021	5 x	25 mL	+ 1 x 3 mL Standard
1 0220 99 10 026	6 x	100 mL	
1 0220 99 10 023	1 x	1000 mL	
1 0220 99 10 704	8 x	50 mL	
1 0220 99 10 917	10 x	60 mL	
1 0220 99 90 314	12 x	25 mL	

Intended Use

Diagnostic reagent for quantitative in vitro determination of albumin in serum or plasma on photometric systems.

Summary

Albumin is an important binding and transport protein for various substances in plasma and the main contributor to the plasma osmotic pressure. Measurement of albumin in serum is used for diagnosis and monitoring of liver diseases, e.g. liver cirrhosis. Furthermore, albumin levels indicate the health and nutritional status of an individual and, therefore, are used for detecting malnutrition and for prognosis in elderly hospitalized patients. [1,2]

Method

Photometric test using bromocresol green.

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
Standard	5 g/dL

Contains bovine serum albumin (5 – 10%)

Storage and Stability

The reagents and the standard are stable up to the date of expiry indicated on the kit, if stored at 2 – 25°C and contamination is avoided. Do not freeze the reagents and the standard and protect them from light.

Warnings and Precautions

1. The standard contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
2. In very rare cases, samples of patients with gammopathy might give falsified results [3].
3. 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.
4. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagent and the standard are ready to use.

Materials Required

General laboratory equipment

Specimen

Serum or heparin plasma

Stability [4]:

10 weeks	at	20 – 25°C
5 months	at	4 – 8°C
3 months	at	–20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Applications for automated systems are available on request.

Wavelength	Hg 546 nm, 540 – 600 nm
Optical path	1 cm
Temperature	20 – 25°C/37°C
Measurement	Against reagent blank

	Blank	Sample or standard
Sample or standard	-	10 µL
Dist. Water	10 µL	-
Reagent	1000 µL	1000 µL

Mix, incubate for approx. 10 min. and read the absorbance (A) against reagent blank within 60 min.

Calculation

With standard or calibrator

$$\text{Albumin [g/dL]} = \frac{\text{A Sample}}{\text{A Std / Cal}} \times \text{Conc. Std / Cal [g/dL]}$$

Conversion Factor

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

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. TruCal U calibrator values have been made traceable to the reference material ERM-DA470. Use DiaSys TruLab N and P for internal quality control. 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
Albumin Standard FS	1 0200 99 10 030	6 x 3 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 6 g/dL. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.
Limit of detection** 0.1 g/dL

Interfering substance	Interferences ≤ 10% up to
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	300 mg/dL
Lipemia (triglycerides)	1200 mg/dL
For further information on interfering substances refer to Young DS [5,6].	

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	3.26	4.03	4.48
CV [%]	1.00	0.63	1.02
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	3.96	4.53	2.46
CV [%]	0.73	0.98	1.42

Method comparison (n=100)	
Test x	Competitor Albumin (ALB)
Test y	DiaSys Albumin FS
Slope	0.987
Intercept	0.168 g/dL
Coefficient of correlation	0.997

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

Reference Range [7]

Adults: 3.5 – 5.2 g/dL 507 – 756 µmol/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. 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.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 652-6.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
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. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed on February 2021. Published by AACC Press and John Wiley and Sons, Inc.
7. 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.

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* Fluid Stable