Albumin (BCG)

DiaSystem Scandinavia AB

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

Order Information

Cat. No.	Kit size
01 00002 70 04 0125	R: 5x25 mL
01 00002 70 04 0600	R: 10x60 mL
01 00002 70 10 0160	R: 4x40 mL
CDT-Alb	R: 4x30 mL
01 00002 70 02 0240	R: 4 x 60 mL
06 00102 70 04 0018	Albumin Standard 6x3 mL

Summary [1,2]

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.

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 yellowgreen 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 Instructions and Reagent Stability

The reagent and the standard are stable up to the end of the indicated month of expiry, 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 [6].
3. Please refer to the safety data sheet 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

Please refer to local legal requirements.

Reagent Preparation

The reagent and the standard are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin plasma or EDTA plasma

Stability [3]:

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

Application sheets 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 against reagent blank within 60 min.

Calculation

With standard or calibrator

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

Conversion factor

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

Calibrators and Controls

For the calibration of automated photometric systems the DiaSystem UniCal CC calibrator is recommended. The assigned values of UniCal CC have been made traceable to the reference material ERM-DA470. For internal quality control DiaSystem UniLab N and DiaSystem UniLab controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
UniCal CC	06 00122 70 04 0018	6 x 3 mL
UniLab N	07 00123 70 05 0030	6 x 5 mL
UniLab P	07 00124 70 05 0030	6 x 5 mL

Albumin (BCG)

DiaSystem Scandinavia AB

Performance Characteristics

Measuring Range

The test has been developed to determine albumin concentrations within a measuring range from 0.2 – 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.

Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, hemoglobin up to 400 mg/dL and lipemia up to 500 mg/dL triglycerides. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection

The lower limit of detection is 0.2 g/dL.

Precision (at 25°C)

Intra-assay precision n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	3.52	0.03	0.91
Sample 2	4.50	0.05	1.12
Sample 3	6.89	0.12	1.79

Inter-assay precision n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	3.35	0.05	1.58
Sample 2	4.32	0.06	1.44
Sample 3	6.73	0.11	1.60

Method Comparison

A comparison of DiaSystem Albumin (BCG) (y) with a commercially available assay (x) using 59 samples gave following results: y = 1.00 x – 0.11 g/dL; r = 0.998.

Reference Range [4]

Adults: 3.5 – 5.2 g/dL
35 – 52 g/L
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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
4. 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.
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

DiaSystem Scandinavia AB
Datorgatan 3, Sweden – 561 33 Jönköping
Phone +46 36 126220 ▪ Fax +46 36 187730
info@diasystem.se ▪ www.diasystem.se

CE