ALBUMIN (BCG Method)

In-vitro Diagnostic reagent kit for quantitative determination of albumin (BCG Method) in serum/plasma sample on Photometric System.

Reagent
Reagent: BCG Reagent
Standard: Albumin (Conc. 3.5 g/dL)

Principle
Albumin binds with Bromocresol Green (BCG) dye in a buffered medium to produce green colored complex which is measured photometrically.

Summary
Albumin is a binding and important transport protein for different substances in plasma and the principle contributor of the osmotic pressure in plasma. Estimation of albumin in serum/plasma is utilized for the diagnosis and determination of liver related diseases, e.g. liver cirrhosis. Moreover, albumin levels demonstrate the wellbeing and nutritional status of an individual and, consequently, are utilized for identifying deteriorating health and for prognosis in hospitalized patients.

Storage instruction and reagent stability
The reagent and standard is stable up to the end of the indicated month of expiry, if stored at 2°C– 30°C, protected from direct light and contamination is avoided. Do not freeze the reagent and standard.

Components and Concentrations
Reagent: Citrate Buffer pH 4.2 - 30mmol/L, Bromocresol Green – 0.26mmol/L
Standard: Albumin -3.5 g/dL

Waste Management
Please refer to local, national / international regulatory 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 / EDTA Plasma
Stability: Serum @ 2°– 8°C: 1 month
@ -20°C: 3 months
Only freeze once!
Discard contaminated specimens.

Assay Procedure
Wavelength : 630 nm (600-640 nm)
Temperature : R.T°C
Measurement : Against reagent blank

	Blank	Standard or Sample
Standard or Sample	-	10 µL
Distilled water	-	-
Reagent	1000 µL	1000 µL
Mix & incubate for 5 min. at R.T°C.		

Calculation
With Standard or Calibrator (Cal)

$$\text{Albumin (g/dL)} = \frac{\text{Sample}}{\text{Std. /Cal}} \times 3.5 \text{ (Conc. of Std.) /Cal (g/dL)}$$

Quality Control
For internal quality, normal and abnormal controls of Human Matrix should be assayed with each batch of samples.

Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions
1. **The standard contains animal materials. Handle the products as potentially infections according to universal precautions and good clinical laboratory practices.**
2. **For diagnostic purposes, the results should always be assessed with the patient`s medical history, clinical & other findings.**
3. **Avoid direct contact with skin and do not swallow.**
4. **In very rare cases, samples of patients with gammopathy might give falsified results.**
5. **For Professional use only!**

Performance Characteristics
Measuring Range
This test has been developed to determine albumin concentrations within a measuring range from 0.20 – 8 g/dL. When values exceed this range, samples should be diluted 1+1 with NaCl solution (9 g/L) and the obtained result to be multiplied by 2.

Linearity/Limit of Maximum Detection
The higher limit of detection is 8.0 g/dL

Sensitivity/Limit of Detection
The lower limit of detection is 0.20 g/dL.

Specificity / Interferences
No interference was observed by Ascorbic acid up to 30 mg/dL, Bilirubin up to 40 mg/dL and Triglycerides up to 500 mg/dL.

Precision

Intra assay n=20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	3.61	0.06	1.54
Sample 2	4.91	0.04	0.75
Sample 3	5.80	0.05	0.81

Inter assay n=20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample1	3.29	0.03	0.98
Sample 2	4.63	0.05	1.07
Sample 3	5.64	0.06	0.02

Method Comparison
A comparison of Precision Biomed albumin (y) with commercially available assay (x) using 15 samples gave following results: y = 0.965 x – 0.185 g/dL; r = 0.986

Reference Range

Neonates	3.8 – 4.2 g/dL(38-42 g/L)
Adults	3.8 – 5.3 g/dL(38-44 g/L)

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

Quick Reference

Parameter	Albumin	
Mode	End Point	
Wavelength	630 (600-640nm)	
Path length	10 mm	
Standard	3.5 g/dl	
BCG solution	1000 µL	
Sample volume	10 µL	
Incubation time	5 min	
Temperature	R.T°C.	
Blank	Reagent Blank	
Normal range	Neonates	: 3.8 - 4.2g/dL
	Adults	: 3.8 – 5.3 g/dL
Linearity	8g/dL	
Sensitivity	0.20 g/dL	

Pack Size

Cat No.	Configuration	Pack
ALB00100	Reagent - 2 x 50mL Standard – 1 x 2mL	100mL
ALB01000	Reagent - 2 x 500mL Standard – 1 x 4mL	1000mL

Literature

1. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243
2. Johnson AM, Rohlfs EM, Silverman LM. Proteins In Burtis CA, Ashwood ER. 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 Biochem1996; 34:517-20.
5. Young DS. Effects of Drugs on Clinical LaboratoryTests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.

Version : ALB/00

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE

Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :

Precision Biomed Pvt. Ltd.

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