

ALBUMIN (BCG METHOD)

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

ORDER INFORMATION		
Cat no.	Kit Configuration	Pack
LG141-100	Reagent R1 : 2 X 50 mL Standard : 1 X 2 mL	100ML
LG141-1000	Reagent R1 : 2 X 500 mL Standard : 1 X 4 mL	1000ML

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.

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.

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°C–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)

Alb_u (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
- The standard contains animal materials. Handle the products as potentially infections according to universal precautions and good clinical laboratory practices.
 - For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical & other findings.
 - Avoid direct contact with skin and do not swallow.
 - In very rare cases, samples of patients with gammopathy might give falsified results.
 - 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 (%)
Sample 1	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
Normal range	Neonates : 3.8 - 4.2g/dL Adults : 3.8 - 5.3 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

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LITERATURE

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- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 14-5.
- 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 referene 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.
- Young DS. Effects of Drugs on Clinical LaboratoryTests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.

INDEX OF SYMBOLS

	International Organization or Standardization		Keep out of Sunlight
	Manufacturer		For invitro diagnostic use only
	Expiry date		Read product insert before use.
	Lot (batch) number		Do not use if package is damaged
	Store between 2-8°C		Keep Away From Moisture
ART/IFU/PRC-141-02			

Manufactured by:

LABGENE BIO-TECH PVT. LTD.

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