ARENA BioScien

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ALBUMIN - BCG

Diagnostic reagent for the in-vitro quantitative determination of Albumin in human serum or plasma on both manual and automated systems.

REF:BS.1/AL02.100.0200	200 test	REF:BS.1/AL01.250.0250	250 test
REF:BS.1/AL02.125.0250	250 test	REF:BS.1/AL01.500.0500	500 test

CLINICAL SIGNIFICANCE

Albumin is the major serum protein in normal individuals. It maintains the plasma colloidal osmotic pressure, binds and solubilizes many compounds such as calcium and bilirubin. Elevated serum albumin levels are usually the result of dehydration. Hyperalbuminemia is of little diagnostic significance. Hypoalbuminemia is very common in many diseases including malabsorption, liver diseases. kidney diseases, severe burns, infections, cancer and some genetic abnormalities. In severe hypoalbuminemia (less than 2.5 g/dl), the low plasma oncotic pressure allows water to move out of the blood capillaries into the tissues causing edema.

METHOD PRINCIPLE

Modified bromocresol green colorimetric method.
Measurement of albumin is based on its binding to the indicator dye bromocresol green (BCG) in pH 4.1 to form a blue-green colored complex. The intensity of the blue-green color is directly proportional to the concentration of albumin in the sample. It is determined by monitoring the increase in absorbance at 623 nm, or 578 nm.

Albumin + BCG —(PH 4.1)→ **Albumin – BCG Complex**

REAGENT COMPOSITION

R 1: Standard	- 4.0 g/dl
R 2: Reagent	
- Acetate Buffer	- 100 mmol/L
- Bromocresol green	- 0.27 mmol/L
- Detergent	- 5.0 mmol/L

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the Albumin reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Bioscien Albumin reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when properly stored refrigerated at 2–8˚C.

Deterioration
The ***Bioscien*** Albumin reagent is normally clear. Do not use Albumin reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

The only acceptable anticoagulants are heparin and EDTA. Use preferably fresh serum, Serum should be separated immediately from the clot. The biological half-life of albumin in blood is 3 weeks.
Stability: 1 day at 15 - 25°C, 4 weeks at 4 - 8°C, and 6 months at -20°C.

SYSTEM PARAMETERS

Wavelength	623 nm (578 nm)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample Reagent Ratio	1:100
e.g.: Reagent volume	1 ml
Sample volume	10 µl
Temperature	20– 25˚C
Incubation time	5 min. at 20–25˚
Zero adjustment	Reagent Blank
Sensitivity	1 g/dL
Linearity	7 g/dL

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes and automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Blank	*Standard*	*Specimen*
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard		10 µl	
Specimen			10 µl

Mix and incubate for 5 minutes at 20-25°C. Measure absorbance of specimen “A” and standard “A” against reagent blank within 60 minutes.

CALCULATION

$$\text{Albumin concentration (g/dl)} = \frac{(\text{A specimen}) \times 4}{(\text{A standard})}$$

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact ***Bioscien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	20	20	20	20
Mean g/dl	3.28	4.78	3.4	4.9
SD.	0.8	0.12	0.9	0.14
CV. %	2.66	2.68	3.1	2.9

The results of the performance characteristics depend on the analyzer used.

Accuracy (Methods Comparison)
Result obtained from ***Bioscien*** Albumin reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.97.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 1 g/dl.

Linearity
The reaction is linear up to Albumin concentration of 7 g/dl; specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result×2).

INTERFERING SUBSTANCES

Haemolysis
A haemoglobin level of 800 mg/dL results in 13 % positive bias.

Icterus
No significant interference from bilirubin up to levels of 40 mg/dl.

lipemia
No significant interference up to 1000 mg/dl.

EXPECTED VALUES

Serum or Plasma	***g/dl***	***g/L***
Adult		
18 – 60 years	3.5 - 5.5	35 - 50
>60 years	3.4 - 4.8	34 - 48
Children		
14 – 18 years	3.2 - 4.5	32 - 45
4 d – 14 years	3.8 - 5.4	38 - 54
Newborns		
0 – 4 days	2.8 - 4.4	28 - 44

DYNAMIC RANGE

1 - 7 g/dl.

REFERENCES

1. Doumas BT,Watson WA, Biggs HG. Albumin standard and the measurement of serum albumin with bromocresol green Clin Chim Acta. 1971; 31:87-96.
2. Grant GH, Silverman LM, Christenson RH. Amino acids and proteins. In:Tietz NW, ed. Fundamentals of Clinical Chemistry. 3 rd ed. Philadelphia: WB Saunders; 1987:291 345.
3. Tietz NW, ed. Clinical Guide to laboratory tests. 2 nd ed. Philadelphia: WB Saunders; 1990:26-29.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

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CE