Atlas Medical

ALBUMIN
Bromocresol green (BCG)

Quantitative determination of albumin

IVD *For In-Vitro diagnostic and professional use only*

Store at 2-8 °C

CE

INTENDED USE

For the determination of Albumin concentration in human serum or plasma.

INTRODUCTION

Albumin is the most abundant plasma protein in humans. It accounts for~60% of the total serum protein. Albumin plays important physiological roles, including maintenance of colloid osmotic pressure and binding of key substances such as long-chain fatty acids, bile acids, bilirubin, hematin, calcium, and magnesium. It has antioxidant and anticoagulant effects, acts as a carrier for nutritional factors and drugs, and is an effective plasma pH buffer. Serum albumin is a reliable prognostic indicator for morbidity and mortality, liver disease, nephritic syndrome, malnutrition, and protein-losing enteropathies. High levels are associated with dehydration.

PRINCIPLE

Albumin in the presence of bromocresol green at a slightly acid pH, produces a colour change of the indicator from yellow-green to green-blue. The intensity of the color formed is proportional to the albumin concentration in the sample.

MATERIALS PROVIDED

R	Bromocresol green pH 4.2 0.12 mmol/L
ALBUMIN STD	Albumin aqueous primary standard 5 g/dL

NOTE: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Spectrophotometer or colorimeter capable of measuring absorbance at 630 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

STORAGE AND STABILITY

- Store at 2-8 °C.
- Reagents are stable until the expiry date on the label.
- Protect the reagent from light.
- Signs of reagent deterioration :
  Presence of particales and turbidity.
  Blank absorbance (A) at 630 nm ≥0.40.

REAGENT PREPARATION

Reagent and Standard provided are ready to use.

SAMPLES

- Serum or plasma.
- Stability for 1 month at 2-8 °C or for 1 week at 15-25°C.

PROCEDURE

1. Assay conditions :
   Wavelength.....630 nm (600-650)
   Cuvette light path .....1 cm
   Temperature .....15-25 -37°C
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

TUBES	Blank	Sample	Standard
Reagent	1.0 mL	1.0 mL	1.0 mL
Sample	-	**5 µL**	-
Standard	-	-	**5 µL**

4. Mix and incubate for 10 minutes at room temperature (15-25^{0}C) or for 5 minutes at 37 °C.
5. Read the absorbance (A) of samples and standard, against blank.
   The color is stable for 60 minutes at room temperature.

CALCULATIONS

$$\frac{\text{(A) Sample - (A) Blank}}{\text{(A)Standard-(A)Blank}} \times 5 (\text{Standard conc}) = \text{g/dL albumin in the sample}$$

Conversion factor: g/dl X 144.9 **=** µmol/L.

REFERENCE VALUES

Normal range: 3.5 to 5.0 g/dl

These values are for orientation purposes; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range:

From detection limit of 0.0349 g/dL to linearity limit of 6 g/dL. If the results obtained were greater than linearity limit, dilute the sample to half with 9 NaCl g/L and multiply the result by 2.

Precision

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (g/dL)	5.00	3.71	4.56	3.07
SD	0.02	0.02	0.28	0.18
CV (%)	0.40	0.54	6.14	5.90

Sensitivity

1g/dL = 0.2003 (A).

Accuracy

Results obtained using ATLAS reagent (Y) did not show systemic differences when compared with other commercial reagents (X).

The results obtained using 50 samples were as follow:

Correlation coefficient $(R)^2$: 0.99169.

Regression equation: y=1.045x - 0.028

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

QUALITY CONTROL

- Control sera are recommended to monitor the performance of assay.
- If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

INTERFERENCES

Bilirubin up to 110 mg/L, hemoglobin up to 1 g/L and lipemic sera up to 10 g/L no interfere. A list of drugs and other substances interfering with albumin determination has been reported.

NOTES

- ALBUMIN STD: Proceed carefully with this product as, due its nature, it can get contaminated easily.
- Calibration with the aqueous Standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
- Use clean disposable pipette tips for its dispensation.

REFERENCES

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3. Tietz. N.W. Fundamentals of Clinical Chemistry, p. 940. W.B. Saunders Co. Philadelphia, PA. (1987).
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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry