

Intended Use:

Albumin Test reagent/kit is a medical device intended for estimation of Albumin in serum/plasma.

Clinical Significance

Albumin is a carbohydrate-free protein, which constitutes 55-65% of total plasma proteins in the body, the other major part being globulin. It is synthesized in the liver and maintains the oncotic plasma pressure in blood. Albumin also helps in the transportation of drugs, hormones and enzymes. Furthermore albumin is capable of binding toxic heavy metals ions as well as numerous pharmaceuticals, which is the reason why lower albumin concentrations in blood have a significant effect on pharmacokinetics.

Principle

Albumin + Bromocresol Green $\longrightarrow$ Green Albumin BCG Complex

Reagent Composition

R1 BCG Reagent	Succinate Buffer- 90 mmol/L
	Bromocresol Green - 0.26 mmol/L
Std Conc	4 g/dl

Working Reagent Preparation

Reagent is ready to use.

Stability and Storage

Store BCG Reagent at Room Temp or below 30°C. Store standard at 2-8°C

All the kit contents are stable until the expiry date stated on the label. Do not use reagents beyond the expiration date.

Store the vials tightly closed protected from light and prevent contaminations during the use.

Discard if signs of deterioration appear:

- Presence of particles and turbidity.

Materials required

- Photometer or spectrophotometer with a thermostat cell compartment set at 25/30/37°C, capable of reading at 630 nm.
- Stopwatch, strip-chart recorder or printer.
- Cuvettes with 1-cm path length
- Pipettes to measure reagent and samples.

Sample and Stability

Serum or plasma

Serum or heparinized plasma free of hemolysis.

Albumin in serum or plasma is stable for 6 days at 2-8°C.

Known Interfering Substances

- Lipemia (intralipid 20 g/L) do not interfere.
- Bilirubin (20 mg/dL) does not interfere.
- Hemoglobin (>2 g/L) may affect the results.

Assay Procedure

Pipette into clean dry test tubes labeled as Blank (B), Standard (S) and Test (T)

Addition Sequence	Blank	Std	Test
R1 BCG Reagent	1000 µl	1000 µl	1000 µl
Distilled water	10 µl	-	-
Albumin Standard (S)		10 µl	
Sample		-	10 µl

Mix well and incubate at Room Temp (<30°C) for 5 min. Measure absorbance of the standard (Abs. S) and Test Sample (Abs. T) Against the Blank at 630nm.

Calculation

$$\text{Albumin in g/dl} = \frac{\text{Abs. T}}{\text{Abs. S}} \times 4$$

$$\text{Globulin in g/dl} = \frac{(\text{Total Proteins}) - (\text{Albumin})}{(\text{in g/dl}) \quad (\text{in g/dl})}$$

$$\text{A/G Ratio} = \frac{\text{Albumin in g/dl}}{\text{Globulin in g/dl}}$$

Quality Control

To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

If the values are found outside of the defined range, check the instrument, reagents and procedure.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable result.

Linearity

The procedure is linear up to 8 g/dl. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Reference Values

Serum, Plasma (Albumin) :	3.7 – 5.3 g/dl
Globulin :	2.3 – 3.6 g/dl
A/G Ratio :	1.0 – 2.3

It is recommended that each laboratory establishes its own normal range representing its patient population.

General System Parameters

Mode	End Point
Reaction	Increasing
Wavelength	630 nm
Blank with	Reagent
Sample Volume	10 µl
Reagent Volume	1000 µl
Std Conc.	4 g/dl
Incub. Temp.	Room Temp (<30°C)
Incub. Time	5 min.
Delay Time	5 sec
Normal Range	3.7 g/dl To 5.3 g/dl
Linearity	Up to 8 g/dl
Unit	g/dl

Notes

1. Gross haemolysis, ampicillin and heparin interfere with the results. Elevated bilirubin and lipemic samples may have a slight effect on accuracy. For grossly lipemic samples run a sample blank by adding 0.02 ml sample in 2 ml distilled water. Read the absorbance against distilled water. and subtract the blank absorbance.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

Reference

1. Doumas, B.T. Watson, W.A., (1971) Clin. Chem. Acta. 31:87

For *in vitro* Diagnostic use only.