

# SBio ALBUMIN KIT

## (Bromocresol Green Method)

(For invitro diagnostic use only)

REF	90142150	90151000
Pack Size	2 x 150 ml	1000 ml



L1: Store at 15-30°C S: Store at 2-8°C	Manufacturer	In vitro Diagnostic Medical Device	L1 BCG Reagent	BCG
Use by (Last day of stated month)	Consult Instructions for use	This way up	Bromocresol Green Method	
Date of Manufacture	Catalogue Number	Batch Number	S Albumin Standard (4 g/dl)	EC REP Authorised Representative in the European Community

### INTENDED USE

Albumin Kit is used for the determination of Albumin in serum or plasma.

### PRINCIPLE OF THE TEST

Albumin binds with the dye Bromocresol Green in a buffered medium to form a green coloured complex. The intensity of the colour formed is directly proportional to the amount of albumin present in the sample.



### CLINICAL SIGNIFICANCE

Albumin consists of approximately 60% of the total proteins in the body, the other major part being globulin. It is synthesized in the liver and maintains the osmotic pressure in blood. Albumin also helps in the transportation of drugs, hormones and enzymes. Elevated levels are rarely seen and are usually associated with dehydration. Decreased levels are seen in liver diseases (Hepatitis, Cirrhosis). Malnutrition, kidney disorders, increased fluid loss during extensive burns and decreased absorption in gastro-intestinal diseases

PRESENTATION	2 x 150 ml	1000 ml
<b>Carton 1</b>		
L1 : BCG Reagent	2x 150 ml	1000 ml
<b>Carton 2</b>		
S : Albumin Standard (4 g/dl)	5 ml	5 ml

### COMPOSITION

Succinate Buffer 100 mM; pH 4.0.; Bromocresol Green 0.20 mM; Detergent.

### STORAGE / STABILITY

Carton 1: BCG Reagent is stable at R.T. (15-30°C) till the expiry mentioned on the label.

Carton 2: Albumin Standard is stable at 2-8°C till the expiry mentioned on the label.

### SAMPLE REQUIRED

Serum, EDTA plasma.

### REAGENT PREPARATION

Reagents are ready to use. Protect from bright light.

### SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.

This product requires the handling of human specimen. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.

Appropriate biosafety practices should be used for materials that

contain or are suspected of containing infectious agents. Handle specimen, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

### PROCEDURE

Wavelength / filter : 630 nm (Hg 623 nm) / Red  
Temperature : R.T.  
Light path : 1 cm

### MATERIALS REQUIRED BUT NOT PROVIDED

General laboratory instrumentation like Spectrophotometer/Analyzer, Thermostatic Cuvette holder, Cuvettes, Micropipettes, Test tubes, Stopwatch/Timer.

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

Addition Sequence	B (ml)	S (ml)	T (ml)
BCG Reagent (L1)	1.0	1.0	1.0
Distilled water	0.01	-	-
Albumin Standard (S)	-	0.01	-
Sample	-	-	0.01

Mix well and incubate at R.T. for 5 min. Measure absorbance of the Standard (Abs.S) and Test Sample (Abs.T) against the Blank.

### CALCULATIONS

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

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

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

### QUALITY CONTROL

The following process is recommended for QC during the assay of Albumin. \*Define and establish acceptable range for your laboratory.

- Two levels of control (Normal and Abnormal) are to be run on a daily basis.
- If QC results fall outside acceptance criteria, recalibration may be necessary.
- Review QC results and run acceptance criteria following a change of reagent/lot.

### SPECIFIC PERFORMANCE CHARACTERISTICS

#### Linearity:

The procedure is linear upto 7 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.

#### Limit of detection:

The limit of detection for Albumin is 0.1 g/dl.

#### Interferences:

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

#### Precision:

Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	4.61	1.65	4.73	4.10	9.34	5.75
Control 2	3.29	1.68	3.16	2.56	6.45	4.24

#### Method comparison:

Comparative studies were done to compare our reagent with another commercial Albumin Assay. No significant differences were observed. Details of the comparative study are available on request.

#### REFERENCE RANGE

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 establish its own normal range representing its patient population\*.

#### NOTE

Albumin is reported to be stable in the sample for 6 days at 2-8°C. 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 D.W. and subtract the blank absorbance from the test absorbance. The reagent may be used in several automated analyzers. Instructions are available on request. Do not use turbid, deteriorated or leaking reagents.

#### REFERENCES

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



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