台塑生醫科技股份有限公司
FORMOSA BIOMEDICAL TECHNOLOGY CORP.

ALBUMIN TEST

BCG Dye-Binding Method

INTENDED USE

For the quantitative determination of albumin in serum.

CLINICAL SIGNIFICANCE

Albumin is the most abundant individual protein in serum. It has several different functions. These include the maintenance of osmotic pressure, base balance, transport of large organic anions normally insoluble in aqueous fluids such as long-chain fatty acid and Bilirubin, binding of toxic heavy metal ions, and the transport of poorly soluble hormones such as cortisol, aldosterone and many other hormones in the body. Albumin also plays a "store" of nutritive structural protein in time of need.

Normal healthy adult contains about 35 to 50 g of albumin per liter, average about 4.5. The total globulins average about 29g/l, corresponding to an albumin/globulin ratio (A/G) of 1.3 to 1.8 average 1.6. The liver is the site of synthesis of albumin, so that chronic liver disease is one of the most common cause of decreased albumin levels. The liver diseases are often accompanied by a decrease of A/G ratio to 0.7 to 1.0. Many other conditions may also result in the decrease of albumin levels, such as congestive heart failure, malnutrition starvation, toxemia of pregnancy, acute or chronic glomerulonephritis, nephrosis, severe burns and leukemia. Significat decreases in serum albumin are also caused by protein loss through the intestinal tract.

Albumin levels may be elevated in dehydration, shock, hemoconcentration, or upon administration of large quantities of concentrated albumin intravenously.

PRINCIPLE

Bromcresol green (BCG), an anionic dye, binds tightly to albumin when added to serum. The albumin-BCG complex absorbs light much more intensely at pH 4.20 and 630 nm than BCG alone. The increase in light absorption is directly proportional to the albumin concentration. The reaction formula is as follows:

Albumin + BCG ——————→ green chromophore

SPECIMEN COLLECTION AND PREPARATION

Serum: Blood is drawn in the usual manner and allowed to clot. Serum is separated from cells by the conventional procedure, avoiding hemolysis. Albumin in serum is stable up to 1 week at room temperature, 1 month in refrigerator and longer when frozen.

Plasma: Plasma prepared with heparin or EDTA may be employed and will provide results identical to those obtained with serum.

REAGENT

Package:	R1:	3 ×100 ml	Common
		5 ×60 ml	Hitachi 7170
		5 ×80 ml	Hitachi 7060
		6 ×50 ml	Hitachi 7020
Component :	BCG	0.5 mmol/L	
	Succinate	75 mmol/L	
	Standard:	See Value on the Label.	

Store the reagent at 2~8℃.

PRECAUTIONS:

1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handed with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafetyin Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

PROCEDURE:

Wavelength: 630 nm; Cuvette: 1 cm light path; Incubation: 37℃

Reagents are ready-to-use.

	Blank	Standard	Test
Reagent ml	1	1	1
Water ml	0.01		
Serum ml			0.01
Standard iml		0.01	
Mix well. Wait for 5 minutes at 37℃ temperature, and read absorbance at 630nm against bland.			

If the albumin concentration exceeds 60 g/L, dilute the sample with normal saline and repeat the assay.
*The Hitachi reagents are used directly on Hitachi analyzers in accordant with Hitachi parameters.

RESULT CALCULATION

$$\text{Albumin (g/L)} = \frac{\text{Abs of Test}}{\text{Abs of Standard}} \times \text{concentration of standard}$$

A/G Ratio: After determination of Albumin and Total Protein, the A/G ratio may be calculated as follows:

$$\frac{\text{Albumin (g/L)}}{\text{Total protein (g/L)} - \text{Albumin (g/L)}}$$

LIMTATIONS OF THE METHOD

Care should be taken in specimen collection to avoid lipemia and gloss hemolysis since both will produce falsely elevated test results.

Standards and controls containing human albumin be employed with this procedure since the absorptivity of the dye-albumin complex differs for albumin obtained from different species.

EXPECTED VALUES:

Serum albumin: 35-52 g/L (3.5-2.2 g/dl)

PERFORMANCE:

Linearity: 60 g/L (6 g/dl) albumin.
Sensitivity: A change of absorbance of 0.001 in the range of linearity corresponds to 0.034 g/L of Albumin.
Precision:

	Within run		Between run	
Samples	Level Ⅰ	Level Ⅱ	Level Ⅰ	Level Ⅱ
Number n	20	20	20	20
Mean g/L	34	51	35	56
SD g/L	0.860	0.928	1.10	1.523
CV %	2.53	1.82	3.14	2.72

REFERENCES:

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