ANA BIO ISP Albumin

(Bromocresol Green Method)

For Miura Instruments

Intended Use

Albumin is a reagent kit used for the determination of Albumin in serum or plasma based on Bromocresol-Green (BCG) method. The reagents are for *in-vitro* diagnostic use.

Principle

Serum albumin in the presence of Bromocresol-green (BCG) under acidic condition forms a green colored complex. The intensity of the green colour complex is directly proportional to the albumin concentration in serum/plasma.

Albumin + BCG $\xrightarrow{\text{Acidic medium}}$ Albumin - BCG complex

Components & Concentration of Reagents

Reagent	Component	Concentration
Reagent	Succinate buffer pH 4.2	100 mmol/L
	Bromocresol green	0.15 mmol/L
	Stabilizers, excipients & surface active agents	

Reagent storage and stability

The kit should be stored at 15° - 25°C and is stable till the expiry date indicated on the label.

Reagent Preparation

Liquid reagents ready for use. After opening the reagent is stable for 30 days if closed, stored at 2° - 8°C, and protect from direct light and contamination. Do not mix different batches.

Specimen collection and preservation

Blood should be collected in a clean dry container. Avoid the use of plastic or siliconized container which may prolong clotting time. Serum is preferred but plasma can also be used. For plasma separation anticoagulants like EDTA or HEPARIN can be used. Avoid venous stasis while collecting blood. In absence of bacterial contamination, albumin is stable in sample for one week at room temperature and one month at 2° - 8°C.

Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.
All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration

For Calibration use the "Multicalibrator"

Calibration Stability

For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit

Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

Analyte Name	Albumin BCG	
Method Code	ALB	
Type	End-Point	
Unit	g/dl	
Filter F1	630 nm	
Blank in	Used	
Step	Reaction Volume	U.M.
Volume reagent R1	200	µl
Sample Volume	2	µl
Final Incubation	60	Sec.

Normal range

Guidance value : 3.2 - 5.5 g/dl

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

The reaction is linear up to 6 g/dl. For higher value, dilute sample with normal saline and perform the assay. Multiply the final result by dilution factor to get the real value.

Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery

Albumin added to a serum matrix containing known amounts of Albumin gave an average recovery of 96%.

Interference

The high dilution of the sample with the reagent reduces to a minimum the interference by lipids. Bilirubin below 26 mg/dl does not interfere in the reaction. Haemoglobin interferes at concentrations above 100 mg/dl. Above 100 mg/dl hemoglobin will represent an albumin increase of 0.1 gm/dl

Precision of the Method

Within-run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	g/dl	129.75	3.34	2.57	20
High	g/dl	205.85	3.50	1.70	20
Between run					
Range	U.M	Mean	S.D.	C.V.(%)	No. run
Low	g/dl	130.19	3.47	2.67	60
High	g/dl	204.45	3.71	1.82	60

Sensitivity

At 630 nm a concentration of 0.007 g/dl of Albumin can estimate.

References

1. Rodkey, F.L., Clin. Chem., 10 (1964) 606.
2. Doumas, B.T., Watson, W.A. and Biggs, H.G., Clin. Chem. Acta., 31 (1971) 87.
3. Gustafsson JE, Clin Chem 1976; 15: 1006 – 1008.

Symbols

IVD	In Vitro Diagnostics		Caution
LOT	Batch No.		Product Expiry Date
CONT	Content		Manufactured By
	Read Instructions		Date of Manufacture
	Storage Temperature		Keep Dry
REF	Catalogue No.		Fragile
			Keep away from sun light

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