ALBUMIN(BCG Dye Method-End Point)

Intended Use
The reagents are used for the quantitative determination of Albumin in serum or plasma . For in-vitro diagnostic use only.

Introduction
Albumin plays important physiological role in the body. In circulation of blood, 80% oncontic pressure is maintained by it. Albumin assists in the transportation of bilirubin, calcium, fatty acids, bile acids, and drugs. It sequesters the toxins entering in to the body fluid and delivers them to the liver for detoxification. Testing albumin levels in serum helps to assess a person's nutritional status and risk for malnutrition. The test helps in determining if a patient has liver disease or kidney disease, or if not enough protein is being absorbed by the body.

Method
Bromocresol green method (Dye Method- End point)

Principle
Albumin forms blue green colored complex with Bromocresol green in acidic medium. The color formed is directly proportional to the concentration of albumin present in the sample, intensity of color is measured at 620nm.

Reagent Composition

Reagent 1: BCG Reagent

Bromocresol green	0.15 mmol/l
Succinate buffer	75 mmol/l

Reagent 2:

Albumin Standard	3 g/dl

Precautions
Following precaution should be taken:
- Avoid ingestion, do not pipette by mouth.
- Avoid contact with skin and eyes. If spilled, thoroughly wash affected area with water.
- Flush with plenty of water while disposing.

Reagent Storage and Stability
Unopened Reagent 1 is stable till expiry mentioned on the label when stored at room temperature.

Standard Reagent R2 is stable till expiry mentioned on the label when stored at 2-8°C.

Note: On request, Reagent 3 (Albumin: 4 g/dl) & Reagent 4 (Albumin: 6 g/dl) can be provided for linearity check with Reagent 2 (Albumin: 3 g/dl-Standard) .

Reagent Preparation
Reagents are ready for use.

Reagent Deterioration
Reagents should be clear solutions. Turbidity and/or precipitation may be because of deterioration.

Sample Collection and Storage
Serum or plasma (EDTA, citrate or heparin) collected as per the standard procedures.
Albumin in serum is stable for 3 days at 2-8°C

General Assay Parameters

Mode	End Point
Wavelength (nm)	620
Wavelength Range Usable (nm)	570-650
Sample Volume (µl)	10
Reagent R1 (µl)	1000
Incubation Time (min.)	5
Incubation Temp. (°C)	RT
Normal Low (g/dl)	3.2
Normal High (g/dl)	5.0
Linearity (g/dl)	Upto 6
Concentration of Standard (g/dl)	3
Blank with	Reagent
Units	g/dl

Procedure
One reagent blank and one standard are sufficient for each assay series.
Pipette into test tubes:

	Blank	Standard	Sample
Reagent 1	1000µl	1000µl	1000µl
Dist. Water	10µl	-	-
Reagent 2	-	10µl	-
Sample	-	-	10µl

Mix well & incubate for 5 min at room temperature.

Measure the absorbance of standard (A std) and sample (A sample) against reagent blank at 620nm.

Calculation
Albumin concentration in the sample can be calculated using the following formula:

$$\text{Albumin (g/dl)} = \frac{\text{Absorbance of Sample}}{\text{Absorbance of Standard}} \times \text{Conc. of Std.}$$

Example: If the absorbance of sample is 0.200 and the absorbance of standard is 0.180. The calculation shall be:

$$\frac{0.200}{0.180} \times 3.0 = 3.33 \text{ g/dl}$$

If the albumin concentration exceeds 6 gm/dl, dilute the sample with normal saline and repeat the assay. Get the results by multiplying by dilution factor.

Expected values
Neonates: 3.8 – 4.2 gm/dl
Adult : 3.8 – 4.4 gm/dl

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

Limitations
1. Lipemic samples may give false elevated results. Lipemic samples should be reported with serum blank as below:
a) Add 10µl of serum sample to 1000µl of DI water and read absorbance at 620 nm.
b) Subtract the absorbance obtained as above from the absorbance of sample. Use this corrected absorbance for calculation.

2.The reagent and sample volumes can be altered proportionately so that the sample:reagent ratio remains same.
3. Calibration using aqueous standard provided in the kit may cause a matrix effect in some analyzers. In such a case it is recommended to use a serum based calibrator.

Quality Control
The patient results obtained for each batch can be validated by using normal and abnormal control sera with assayed values for albumin.

Performance
Linearity limit: 6 g/dl

Precision

Within run

Control	Control 1	Control 2
No. of samples	20	20
Mean (g/dl)	3.83	4.25
S.D.	0.05	0.04
C.V. %	1.29	0.84

Between run

Control	Control 1	Control 2
No. of samples	60	60
Mean (g/dl)	3.71	4.23
S.D.	0.07	0.06
C.V. %	1.75	1.36

References

1 Doumas B. T. , Arends R. L. , Pinto P. C. in standard Methods of Clinical Chemistry (1972) Vol. 7, p. 175-189, Academic Press Chicago.
2. Tietz N. W. (Ed.), Textbook of Clinical Chemistry, W. B. Saunders (1986) p. 589.
3. Young DS. Effects of drugs on CLinical Laboratory Tests, AACC Press, Washington DC, 5th edn. 2000.

Pack Presentation

Product Code/ Catalogue No.	Pack Size*	Reagent 1	Reagent 2
KGALB101.1.1	2x50ml	2x50ml	1x2ml
KGALB101.1.2	5x50ml	5x50ml	1x3ml

* Pack size may vary on market demand.

Revision No: (Ver: KGALB101.1/1)
Date of Issue:1st April 2010

Symbols
Following symbols are used in the labeling of KEE GAD kits:

REF	Catalogue No.	LOT	Batch No.
CE	CE Mark		Read instructions
IVD	In Vitro Diagnostics		Storage temperature
	Expiry Date	CONT	Content
ALBUMIN	Product Name		Manufactured By

Manufactured by:
KEE GAD Biogen Pvt. Ltd.
A-8, Third Floor, Naraina Industrial Area,
Phase-II, New Delhi-110028 (India)