ALBUMIN - LR

(BCG Method)

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INTENDED FOR USE:

The Albumin - LR is an *in vitro* assay for the quantitative determination of Albumin in serum, plasma.

CLINICAL SIGNIFICANCE:

Albumin and globulins are the most abundant serum proteins. Albumin made mainly in the liver and is important for tissue growth and healing. So decreased albumin levels are usually seen in terminal liver failure and also seen in renal disease where albumin is lost through kidneys. Albumin estimation help to determines the causes of swelling of the ankles (Pedal Odema) or Abdomen (Ascites). Albumin levels are decreased in malnutrition and starvation.

PRINCIPLE:

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.

Albumin + Bromocresol Green $\xrightarrow{\text{pH 3.8}}$ Green Colour Complex

REAGENT COMPOSITION:

R1 BCG Reagent	
Buffer (pH 3.8)	100 mmol /L
Bromo cresol Green	7 mmol /L
Surfactant	qs
Preservative	qs
R2 Albumin Standard	
Bovine Serum Albumin	3.5 gm/dL

REAGENT STORAGE:

BCG reagent is stable at room temperature (15-30°C) till the expiry and Albumin standard is stable at 2-8°C until the expiry date mentioned on the label. Reagents are ready to use and should be protected from direct light.

SAMPLE COLLECTION:

Unhemolyzed fresh serum, plasma with heparin or EDTA. Albumin is reported to be stable in the sample for 6 days at 2 - 8°C.

PRECAUTIONS & WARNING:

Avoid pipette with mouth. The preparation, according to current regulation, is classified as not dangerous. The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation. Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes. The samples must be handle as potentially infected from HIV or Hepatitis.

SYSTEM PARAMETERS:

Reaction Type	:	End Point Method
Wave Length	:	630 nm
Optical path length	:	1 cm
Abs max	:	≤ 1.0
Flow cell Temperature	:	37^0C
Blank	:	Reagent
Incubation Time	:	1 min
Reagent Volume	:	1000 uL
Sample Volume	:	10 uL
Standard Concentration	:	3.5
Reaction Slope	:	Increasing
Low Normal	:	3.8
High Normal	:	5.4
Linearity	:	8.0
Units	:	gm/dL

Note: Gross haemolysis, ampicillin and heparin interfere with the results. Elevated bilirubin and lipaemic samples may have a slight effect on accuracy. For grossly lipaemic 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 from the test absorbance. The reagent may be used in semi and fully automated analyzers.

ASSAY PROCEDURE:

Pipette into test tubes labeled Blank (B) Standard (S) and Test (T) as follows**:**

Addition Sequence	Blank (µL)	Standard (µL)	Test (µL)
R1 BCG Reagent	1000	1000	1000
R2 Albumin Standard	…	10	…
Sample	…	…	10

Mix well and Read absorbance of Standard (S) and Test (T) against Blank (B) at 630 nm or with red filter (600 – 640 nm).

CALCULATION:

1. Albumin in gm/dL = $\frac{\text{Abs. of T}}{\text{Abs. of S}} \times 3.5$

2. Globulin in gm/dL = Protein – Albumin

3. A/G Ratio = Albumin / Globulin

SENSITIVITY / LIMIT OF DETECTION:

The method will accurately measure Albumin level is 0.44 gm/dL.

LINEARITY:

The procedure is linearity up to 8 gm/dL. If values exceed this limit dilute the sample with normal saline and repeat the assay. Calculate the value using the proper dilution factor.

QUALITY CONTROL:

To ensure adequate quality control, the use of commercial reference control serum is recommended with each assay batch. Use of quality control material checks both the instrument and reagent function.

REFERENCE RANGE:

Adults **:** 3.8 – 5.4 gm/dL
Note: It is recommended that each laboratory establish its own normal range representing its patient population.

INTERFERENCE:

No interference was observed by up to hemoglobin 30 mg/dL, Triglycerides 300 mg/dL.

PRECISION:

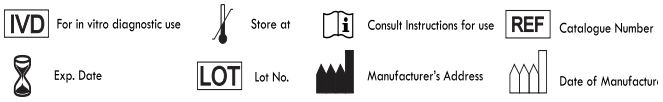
Precision studies were performed with two controls using NCCLS protocol EP5 –A. The result of the precision studies is shown below:

Sample	Within - Run		Between - Run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control-1	4.61	1.65	4.73	4.50	9.34	5.75
Control-2	3.29	1.68	3.16	2.16	6.45	4.24

REFERENCES:

1. Doumas, B.T, Watson, W.A., (1971) Clin Chem. Acta 31: 87.
2. Tietz, Clinical Chemistry, 2nd Ed, Saunders (1991), p:477- 540.
3. Clinical Chemistry, Principles, Procedures, Correlations, Michael L.
4. Bishop et. al., 5th Edition.

SYMBOLS USED ON THE LABELS:



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