

# LiquiMAX ALBUMIN -SLR

(BCG METHOD)

## ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVALB - 200	4 x 50 ml	Single Liquid Reagent
AVALB - 1000	2 x 500 ml	

## INTENDED USE:

LiquiMAX ALBUMIN is an in-vitro diagnostic kit for the quantitative determination of albumin in human serum and plasma.

## PRODUCT FEATURES:

1. Single Liquid Reagent.
2. One step End Point assay.
3. Superior over Methyl Orange and HABA dye methods
4. Linearity : 10 gm/dl.
5. Aqueous albumin standard provided
6. Can be used on any colorimeter, spectrophotometer, discrete semi automated and automated analyzers

## CLINICAL SIGNIFICANCE :

Hypoalbuminemia is found in any liver impairment (e.g. hepatitis), nephrosis, certain chronic diseases (e.g. rheumatoid arthritis), malnutrition, severe hemorrhage and pregnancy. Lowering of serum albumin usually results in lowering of A/G (Albumin/Globulin) ratio. Elevated serum albumin levels apart from indicating dehydration are generally of little significance.

## PRINCIPLE

Albumin binds with Bromocresol green (BCG) in a buffered medium to produce a green colored complex. The intensity of this color is proportional to the Albumin concentration.

## STORAGE & STABILITY

All the reagents are to be stored at 2-8°C and are stable till the expiry date mentioned on the label.

## KIT COMPONENTS

1. Albumin Reagent
2. Albumin Standard : Concentration as stated on the label

## COMPOSITION

Succinate Buffer (pH 4.20) 75 mmol/L

Bromocresol green 0.14 g/L

## REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

## MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

## REAGENT DETERIORATION

- Discard any turbid reagent if reagent absorbance exceeds 0.2 at 578 nm against distilled water.
- Keep the standard vial plugged after use, in order to avoid deterioration.

## WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP Guidelines.

## SPECIMEN & COLLECTION STORAGE

Use fresh unhemolysed serum or plasma should be separated from the cells as soon as possible. Use heparin or EDTA as anticoagulant. Serum/Plasma is stable for 7 days.

## SYSTEM PARAMETERS

Reaction type	:	END POINT
Reaction Slope	:	Increasing
Wave length	:	578 nm (570-630)
Flow cell Temp.	:	37°C
Sample volume	:	10 µl
Reagent volume	:	1000 µl
Standard concentration	:	4
Units	:	gm/dl
Blanking with	:	Reagent
Low normal	:	3.5
High normal	:	5.4
Linearity	:	10

## TEST PROCEDURE

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

Reagent	B	S	T
1. BCG Reagent	1.0 ml	1.0 ml	1.0 ml
2. Albumin Standard (Conc. 4 gm/dl)	-	10 µl	-
3. Specimen	-	-	10 µl

Mix well and read absorbance of Standard (S) and Test (T) against Blank (B) at 578 nm. (570-630).

## CALCULATIONS

$$1. \text{ Albumin (Ab) in gm/dl} = \frac{\text{Abs. of T}}{\text{Abs. of S}} \times 4$$

$$2. \text{ Globulin in gm/dl} = \text{TP-Ab}$$

$$3. \text{ A/G Ratio} = \frac{\text{Albumin in gm/dl}}{\text{Globulin in gm/dl}}$$

**Note :** To calculate Globulin and A/G Ratio user should estimate total protein concentration of the sample also using LiquiMAX Total Protein- SLR kit.

## EXPECTED VALUES

Albumin :	3.5–5.4 gm/dl
Globulin :	2.3–3.6 gm/dl
A/G Ratio :	1.0–2.3 gm/dl

It is recommended that laboratories establish their own normal range.

## QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:

- When using a new reagent or lot.
- When QC values are out of range.

## PERFORMANCE CHARACTERISTICS:

### 1. Linearity

The linearity upto 10 gm/d

### 2. Sensitivity/ Limit Of Detection (LOD)

Lower detection Limit is 0.1 g/dL

### 3. Interferences

No interference for, Ascorbic acid up to 50 mg/dL, Bilirubin up to 20 mg/dL, Haemoglobin up to 1000 mg/dL

### 4. PRECISION

	Intra-Assay (Sample)		Inter-Assay (Sample)	
	Sample 1	Sample 2	Sample 1	Sample 2
n	20	20	20	20
Mean (g/dL)	4.31	3.30	4.29	3.37
SD	0.02	0.01	0.03	0.03
CV (%)	0.35	0.40	0.65	0.96

## METHOD OF COMPARISON

A comparison study has been performed between Avecon reagent and another internationally available reagent yielded a correlation coefficient of  $r^2 = 0.955$  and a regression equation of  $y = 1.0034x$ .

## LIMITATION

Samples with values above 10 gm/dl should be diluted with 0.9% saline, re-run & result by dilution factor.

## WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.














## NOTES

- In Albumin assay, standard controls containing human Albumin are to be employed with this procedure, since the absorptivity of the BCG Albumin complex differs for Albumin of different species.
- If a large volume of reagent is required for absorbance reading, requisite volumes can be taken in multiples keeping the same ratio of reagents to specimen / standard.
- As with all the diagnostic procedures, the Physician should evaluate data obtained by the use of this kit in light of other clinical information.

## REFERENCES

- Doumas, B.T. (1971) Clin. ChemActa 31, 87.
- Doumas, B.T. (1978) Clin. ChemActa 23, 663
- Webster, O. (1977) Clin. Chem 21, 1159 N.

## Symbols Used on Pack

 REF	Catalogue Number		Warning/Caution
 LOT	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



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Plot No.: 338, Sector-2, Industrial Growth Centre, Saha, Ambala, Haryana (INDIA)-133104  
E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com  
Customer Care No. : +91 93065 12576, CIN No.: U24230HR2006PTC118875