

VDx ALBUMIN (BCG Method) Liquid Reagent

INTENDED USE:

This reagent kit is used for in-vitro quantitative determination of Albumin in serum and plasma.

TEST PRINCIPLE:

Under acidic conditions, albumin present in the serum sample binds to bromocresol green to form a green coloured albumin - BCG complex, which is photometrically measured at 628 nm. Intensity of the colour formed is directly proportional to albumin concentration in the sample.

KIT CONTENTS:

Reagent 1: BCG Reagent

Reagent 2: Calibrator (Conc. as indicated on the label)

Insert 01 No.

PREPARATION OF THE WORKING REAGENT:

VDx Albumin Liquid reagent is ready to use.

STORAGE AND STABILITY:



VDx Albumin Liquid reagent is stable till the expiry date indicated on the labels when stored at 2-8°C. All reagents must be brought to room temperature prior to use. All reagents must be returned back to refrigerator after use.

SPECIMEN COLLECTION & STORAGE:

Serum or heparinised plasma can be used. Samples should preferably be used on the same day. If necessary, may be preserved upto one week if stored at 2-8°C. Samples must be brought to room temperature prior to use.

PRECAUTIONS: /



- For in-vitro diagnostics use only. 1.
- 2. Do not inhale the reagent or pipette by mouth.
- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- 4. Before the assy bring all the reagents to room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust or debris.
- 7. Do not use the reagent if the reagent is hazy or cloudy.

PROCEDURE (Automated):



Refer to specific instrument application instructions.

TEST PROCEDURE (Manual):

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Pipette into Test Tube	Blank	Standard	Test	
BCG reagent	1.0 ml	1.0 ml	1.0 ml	
Calibrator	-	10 μΙ	-	
Sample	-	-	10 μΙ	
Distilled water	10 μΙ	-	-	

Mix and read the absorbance of the Test (A_{τ}) Calibrator (A_c) and Blank (A_B) after 1 min. and within 10 min. at 628 nm (600 to 650 nm) or with red filter against distilled water.

CALCULATIONS:

Albumin (gm/dl) = $\frac{A_T - A_B}{A_B}$ x Albumin conc. provided on Calibrator Label

EXPECTED VALUES*:

Albumin: 3.2 - 5.5 gm/dl

*It is recommended that each laboratory should establish its own normal range.

PERFORMANCE:

Linearity: 6 gm/dl

Comparison: r = 0.97

v=0.96x-0.2

Precision:

	V	Within Run		Run to Run		
	Mean	S.D.	C.V.%	Mean	S.D.	C.V.%
Low	3.1	0.2	1.6	3.1	0.3	3.1
High	4.1	0.3	3.1	4.1	0.2	2.1

Specificity: Ampicillin has been found to be highly interfered substance in BCG method. No interference upto 1 gm/l Haemoglobin & Bilirubin 30 mg/dl.

CLINICAL SIGNIFICANCE:

Elevated levels of serum albumin are associated with dehydration and stasis during venepuncture. Decreased levels of albumin are found during over hydration, excessive protein loss from kidney, skin or intestine, decreased synthesis due to dietary deficiency, liver disease or malnutrition and increased catabolism.

AUTOMATED APPLICATIONS:

VDx Albumin Liquid reagents can be used with Hitachi 700 series, 1000, 2000, XT, Express 550 plus, Syncron CX4, Lisa BTR 810/820/830, RA 50, Erbachem-5 plus etc. Application sheets for use on specific semi automatic/batch analyser and auto analysers are available on request. Input parameter for semi auto / auto analysers are given below:

INPUT PARAMETERS	VALUES	
Type of reaction	End Point	
Wavelength	628 nm	
Incubation time	1 Min.	
Calibrator concentration	as on label	
Units	gm/dl	
Upper Normal value	5.5 gm/dl	
Lower Normal value	3.2 gm/dl	
Reagent volume	1 ml	
Serum / Calibbrator Volume	10 μΙ	
Linearity	6 gm/dl	

QUALITY CONTROL:

For accuracy, it is necessary to run known serum controls with each assay.

REFERENCES:

- Kaplan, A. and Szabo, L.L. (1983): Clinical Chemistry. In Interpretation of techniques, 2nd edition. Lea and Febigei Philadelphia pp 403.
- Gustafsson, J.E.C. (1976) Clin Chem 22:616



