ACCUCARE®
ALBUMIN
Bromocresol Green Method

Quantitative determination of albumin in serum / plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
ALB 100	2 X 50 ML
ALB 200	2 X 100 ML

CLINICAL SIGNIFICANCE

An observation of serum albumin level is useful as an aid in diagnosing disease states of the liver and kidneys. Moderate to large changes in the concentration of albumin have significant effects on the relative amounts of the bound and free concentrations of the ligands it carries: because free ligands are those that interact with tissue receptor sites and that can be excreted, albumin levels have important influences on the metabolism of endogenous substances such as calcium, bilirubin, and fatty acids and on the effects of drugs and hormones. Hypoalbuminemia is very common in many illnesses and results in most instances from one or more of the following factors: 1) impaired synthesis, 2) increased catabolism, 3) reduced absorption of amino acids, 4) altered distribution which may sequester large amounts of albumin in an extravascular compartment, 5) protein loss by way of urine or feces.

METHOD

Photometric test using bromocresol green.

PRINCIPLE

Albumin in the presence of bromocresol green (BCG) at a slightly acid pH, produces a colour change of the indicator from yellow-green to green-blue. The intensity of the color formed is proportional to the albumin concentration in the sample.

REAGENT

Reagent I : BCG reagent
Albumin standard : 4 g/dL (store at 2-8°C)

REAGENT PREPARATION

The reagent supplied is ready to use. Protect from Bright Light.

REAGENT STORAGE AND STABILITY

BCG Reagent is stable at 2-8°C till the expiry mentioned on the label.
Albumin Standard is stable at 2-8°C till the expiry mentioned on the label.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum: Use non - haemolysed serum.
Plasma: Use heparin. Do not use EDTA, Oxalate or Fluoride.
Do not use hemolytic samples!
Stability:
7 Days at 4 – 8°C
2 Months at –20°C in case of immediate freezing.
Freeze only once! Discard contaminated specimens!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28°C, prior to analysis.

Automated Parameters	
Wavelength	620 nm
Cuvette	1 cm light path
Reaction Temperature	Room Temperature
Measurement	Against Reagent Blank
Reaction	End Point
Reaction Direction	Increasing
Sample Volume	5 µl
Reagent Volume	1000 µl
Incubation	5 minutes
Blank Abs. Limit	< 0.200
Low normal	3.5 g/dl
High Normal	5.2 g/dl
Linearity	8.0 g/dl

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	BLANK	STD	SAMPLE
Sample	-	-	5 µl
Standard	-	5 µl	-
Reagent	1000 µl	1000 µl	1000 µl

Mix well, and wait for 5 mins at Room Temperature. Measure the absorbance of the Sample (Abs. T) and Standard (Abs. S) against the reagent blank.

SAMPLE DILUTIONS

- If the Albumin concentration exceeds the reagents reportable dynamic range (Linearity) of 10gm/dl;
- Dilute 1part of serum/plasma with 1part of isotonic saline. e.g 10µl serum/plasma and 10µl isotonic saline. Pipette the required volume of sample for testing.
- Reanalyze.
- Multiply the result with dilution factor 2 to obtain an estimate the of the original samples albumin concentration.

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Art No.: IFU/BC/ALB
Effective Date: 20/09/2019
Revision No.: 01

CALCULATION

$$\text{Albumin (g/dl)} = \frac{\text{Abs. T}}{\text{Abs. S}} \times \text{Standard Value (4)}$$

Globulin (g/dl) = Total Proteins (g/dl) – Albumin (g/dl)

$$\text{A/G Ratio} = \frac{\text{Albumin (g/dl)}}{\text{Globulin (g/dl)}}$$

CLIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of **Albumin standard** have been made traceable to the reference material ERM-DA470.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Normal Level	4.74	0.07	1.56
High Level	3.33	0.10	3.11

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Normal Level	4.76	0.07	1.44
High Level	3.34	0.11	3.23

LINEARITY

The method is linear to a concentration of 8.0 g/dl

If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% saline solution and reassayed. Multiply the result by 2.

Limit of detection: The limit of detection for Albumin is 0.1 g/dl.

METHOD COMPARISON

A comparison of Accucare Albumin with a commercially available assay (x) using 59 samples gave following results: $R^2 = 0.991$

REFERENCE VALUES

Serum/Plasma(Albumin)	3.5 - 5.2 g/dl
Globulin	2.3 – 3.6 g/dl
A/G Ratio	1.0 – 2.3

The reference values are to be considered as indicative only.

Every Laboratory should establish its own normal ranges.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 27mg/dl.
- Hemoglobin: No interference found upto 350 mg/dL.
- Lipemia: No interference found upto 750 mg/dl.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

E.M. Gindler and J. O. Westgard Clin. Chem., (1973), 6,4.

J.O. Westgard, M.A. Poquette, Clin. Chem., (1973) 19, 647.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
Email: accucarediagnostics.com; Website: www.labcarediagnostics.com

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