Albumin Test Kit

REF	Pack Size	Reagent
ALBLMB01	2 x 70ml	2 x 70ml

INTENDED USE
Albumin kit is used for quantitative estimation of albumin concentration in human serum or plasma on automated clinical chemistry analyzer.

CLINICAL SIGNIFICANCE
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 on the relative amounts of the bound and free concentration of ligands it carries; because free ligands are those that interact with tissue receptor sides 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) reduce absorption of amino acids 4) altered distributions which may sequester large amounts of albumin in an extra vascular compartment 5) protein lost by way of urine or feces.

METHOD
End point method, Single reagent chemistry, Bromocresol green method (BCG Method)

TEST PRINCIPLE
Albumin forms complex with Bromocresol green in Acidic medium. The Intensity of the color solution formed after the reaction is directly proportional to the concentration of albumin present in respective samples.

KIT CONTENTS/COMPONENETS
Reagent: BCG Reagent

MATERIAL REQUIRED BUT NOT PROVIDED
Fully Auto Biochemistry Analyzer: LM1016-400TPH.
Calibrator
Controls.

REAGENT STORAGE, STABILITY AND HANDLING
BCG Reagent is ready to use & are stable up to expiry date mentioned on the pack.

ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

SPECIMEN
Serum (preferred) plasma (heparinase or EDTA). Venostasis shall be avoided in specimen collection because hemoconcentration increases the concentration of Albumin and other plasma proteins.

APPLICATION For LM1016-400 TPH

Method	End point
Blank	Reagent blank
Primary filter	620
Secondary filter	NO
R1 Volume	300
R1 Position	*
Incubation time (Sec)	270
R2 Volume	-
R2 Position	-
Incubation time (Sec)	-
Sample Volume	3
Read Time	27
Calibrator Concentration	As on the vial label
Mix speed set	Middle
Unit	gm/dl
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the albumin concentration of each sample.

NORMAL VALUES
Neonates: 3.8 – 4.2 gm/dl
Adult : 3.8 – 4.4 gm/dl

LIMITATIONS
If the value exceeds 6 gm / dL, dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not use the reagent after the expiration date printed on the kit.
3.Avoid reagents contamination.
4.These Reagent kits meant for laboratory/professional use only, not for Drug use.

QUALITY CONTROL AND CALIBRATION
It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result. Using the recommended multi calibrator, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run		Inter run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (gm/dl)	3.65	2.66	3.65	2.66
SD	0.11	0.058	0.115	0.053
CV (%)	0.03	0.02	0.03	0.02

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

REF	Catalog No.		Instruction for use
LOT	Batch No.	IVD	*In-vitro* Diagnostics
	Manufacturing Date		Storage temperature
	Expiry Date		Manufacturer

IFU/ALB/03 Rev.: 00; Rev Date.: 22/07/2024

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