GENESIS

Instructions For Use

ALBUMIN (BCG Method)

Cat no.	size
1101 101	2*100
1101 102	4*100

INTENDED USE
Albumin Reagent is intended for the in vitro Quantitative diagnostic determination of Albumin in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS
Albumin is the most abundant protein in human plasma.
It has three main functions:
1- It contributes towards maintaining the colloid oncotic pressure of plasma.
2 - It acts as non-specific transport vehicle for many nonpolar compounds.
3 -It is a source of endogenous amino acids.
Hyperalbuminemia: is of little diagnostic significance except in dehydration
Hypoalbuminemia: is found as a result of several factors as:
1. reduced synthesis caused by liver diseases.
2. Reduced absorption of amino acids due to malabsorption syndromes or malnutrition.
3. Abnormal losses caused by renal disease (nephrotic syndrome, diabetes mellitus,chronic glomerulonephritis, systemic lupus erythematosus).
4. Gastrointestinal tract disease (ulcerative colitis, Crohn's disease) or skin damage (exfoliative dermatitis, extensive burns); congenital absence of albumin or an albuminemia .

PRINCIPLE OF THE METHOD
Albumin in the sample reacts with bromocresol green in acid medium forming a coloured complex that can be measured by spectrophotometry.

$$\text{Albumin} + \text{BCG dye} \xrightarrow{\text{pH 4.3}} \text{Albumin-BCG Complex}$$

COMPOSITION

REAGENT(R)	
Citrate buffer	30 mmol/L
BCG dye	0.25 mmol/L
STANDARD(S)	4.0 g/dL

STORAGE.
Store at 2-8ºC.
Reagent and Standard are stable until the expiry date shown on the Vial label when stored tightly closed and if contaminations are prevented during their use.

REAGENT PREPARATION
Reagent and Standard are provided ready to use.

ADDITIONAL EQUIPMENT
− Analyzer, spectrophotometer able to read at 578 nm.

SPECIMEN
Serum, heparin or EDTA plasma.

Precautions and Warnings
Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by

PROCEDURE
1. Bring the Reagent to room temperature.
2. Pipette into labeled test tubes:

	Blank	Standard	Sample
REAGENT (R)	1.0 mL	1.0 mL	1.0 mL
STANDARD (S)	-	10 µL	-
SAMPLE	-	-	10 µL

3. Mix thoroughly and incubate the tubes for 5 minutes at room temperature (16-25ºC).
4.Measure the absorbance (A) of Standard and Sample at 578 nm against Blank. The color is stable for 1 hour.

CALCULATIONS
The Albumin concentration in the sample is calculated using the following general formula:

$$\frac{\text{A Sample}}{\text{A Standard}} \times \begin{matrix} 4.0 = \text{g/dL} & \text{Albumin} \\ 144.9 = \text{mmol /L} & \text{Albumin} \end{matrix}$$

REFERENCE VALUES

Newborn, 2 to 4 days	2.8 - 4.4 g/dL
4 days to 14 years	3.8 - 5.4 g/dL
Adult	3.5 - 5.0 g/dL
> 60 years	3.4 - 4.8 g/dL

QUALITY CONTROL
It is recommended to use the Control Serum level I And II to verify the performance of the measurement procedure.
Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS
− Detection limit: 0.11 g/dL.
− Linearity limit: 7.0 g/dL.
For higher values dilute sample with **1/2** physiological saline and repeat measurement.
− Repeatability (within run):

Mean Concentration	cv	n
2.57 g/dL	1.8 %	20
3.98 g/dL	1.5 %	20

− Reproducibility (run to run):

Mean Concentration	cv	n
2.57 g/dL	2.8 %	25
3.98 g/dL	2.0 %	25

INTERFERENCES
Bilirubin (>10 mg/dL), lipemia (triglycerides >7.5 g/L) and hemoglobin (>2.5 g/L) may affect the results.
Other drugs and substances may interfere.

BIBLIOGRAPHY
Doumas BT, Watson WA and Biggs HG. Albumin standards and the measurement of serum
albumin with bromocresol green. Clin Chim Acta 1971: 31: 87-96.

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IFU-ALB-01
Rev. (2) 17/09/2023