BioMed-Albumin

Colorimetric, Endpoint

REF: ALB100250 (1×250 ml)
ALB100240 (2×120 ml)
ALB100100 (2×50 ml)

INTENDED FOR USE:

For the quantitative determination of Albumin in serum.

PRINCIPLE:

Albumin is bound by the BCG dye to produce an increase in the blue green color in a pH 3.8 acid medium.
The color increase is proportional to the concentration of albumin present in the sample.
Albumin determination is useful in diagnoses of hepatic and renal pathologies.

SPECIMEN COLLECTION:

Non hemolyzed fresh serum, plasma with heparin.

Notes:
Albumin in serum or plasma is reported stable for one week at room temperature (+15-25°C), and approximately one year when stored in the refrigerator at -20°C and protected against evaporation. Shake and bring the samples at room temperature (+15-25°C) before using.

REAGENT COMPOSITIONS :

R1 Standard	Bovine Albumin	4.0 g/dl
R2 Color Reagent	Buffer pH 3.8 Bromocresol green	100mmol/L 7mmol/L

PACKAGE: Collection and storage.

Store in refrigerator **(+2-8°C).**
Stable until the expiration date reported upon the package.
After the unsealing and the taking of the reagent, it is advised to close up the bottle immediately in order to avoid evaporation, direct light exposure and bacterial contamination.

PRECAUTIONS & WARNING :

Avoid pipette with mouth.
The preparation, according to current regulation, is classified as not dangerous.
The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation.
Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes.
The samples must be handle as potentially infected from HIV or Hepatitis.

REAGENT PREPARATION & STABILITY :

Liquid reagents must be at room temperature (+15-25°C) before using.
The Reagent is limpid and yellow-green.
The reagent is ready for use.

REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations.

PROCEDURE:

Wavelength:	623nm (620-640)
Optical path:	1 cm light path
Temperature:	+25/30/37°C.
Reading:	Against reagent blank
Assay type:	End Point

Pipetting in tubes :

	BLANK	STANDARD	SAMPLE
Reagent (R2)	1000 µL	1000 µL	1000 µL
Distilled water	10 µL		
Standard		10 µL	
Sample			10 µL

Mix, incubate for **5** min at room temperature (+15-25°C.) Read the absorbance of standard and sample tubes.
Volumes can be proportionally modified.
This methodology describes the manual procedure to use the kit.
For automated procedure , ask for specific application.

CALCULATION:

$$\text{Albumin g/dl} = \frac{\text{(A) Sample}}{\text{(A) Standard}} \times 4.0$$

Conversion Factor from g/dl × 144.9 = µmol/L

EXPECTED VALUE:

Serum: 3.5 - 5.3g/dL

The above mentioned values are to be considered as a reference. It is strongly recommended that each laboratory establish its own normal range according to its geographic area, according to IFCC protocol.

WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

QUALITY CONTROL:

It is recommended to execute the quality control at every kit utilization to verify that values are With in the reference range indicated by the methodology.

PERFORMANCE:

MEASURE INTERVAL/LINEARITY:	0.11-7.0 g/dl	
DETECTION LIMIT(2DS):	0.11g/dL	
SENSITIVITY:	1g/dL= 0.0922A a 650nm	
INTRA-ASSAY PRECISION: n=20		
LOW LEVEL	M=1.73g/dL	C.V.=1.88%
MEDIUM LEVEL	M=3.77g/dL	C.V.=1.78%
HIGH LEVEL	M=6.62g/dL	C.V.=1.36%
INTER-ASSAY PRECISION: n=20		
LOW LEVEL	M=1.72g/dL	C.V.=0.57%
MEDIUM LEVEL	M=3.80g/dL	C.V.=0.79%
HIGH LEVEL	M=6.52g/dL	C.V.=1.52%
INTER.ANALIZED	2.6-6.1g/dL	
CORRELATION	r = 0.989	n= 60
LIN. REGRESSION	y = 0.9873x + 0.089	n= 60

INTERFERENCE:

Interferences are negligible up to:	
	Bilirubin 30mg/dL
Triglycerides > 300mg/dl Increase the measure reading	Hemoglobin Increase the measure reading

LIMITATIONS :

Avoid excessive hemolysis since every 100mg/dl of hemoglobin corresponds to about 100mg/dL of albumin.

Severely lipemic serum, should have a serum blank with physiologic solution.

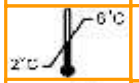
Ampicillin has been found to seriously interfere with BCG methods.

For concentration higher than 7.0 g/dL, repeat the measure on a sample diluted 1:2 with saline solution and multiply the results × 2.

For a thorough evaluation of the interfering substances , consult : Young,D.S.,et al.,Clin.Chem. 21:1D (1975).

REFERENCES:

1. Doumas, B.T., Biggs, H.G., Standard Methods of Clinical Chemistry, Academic Press, N.Y.7(175), 1976.
2. Henry, R.J., Clinical Chemistry, Principles and Technics.Harper and Row Publishers. New York, 1964.
3. Young D.S., et al., Clin. Chem. 21(10),1975.

	Consult Instructions for Use
	Caution, Consult accompanying Documents
IVD	In Vitro Diagnostic Medical Device
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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