

BioMed-Albumin

Colorimetric, Endpoint



REF: ALB100250 (1×150 ml)
ALB100240 (2×120 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 limp and yellow-green.

REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations.

PROCEDURE:

Wavelength: 628nm (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) | 2500 | 2500 | 2500 | μL |
| Distilled water | 10 | | | μL |
| Standard | | 10 | | μL |
| Sample | | | 10 | μL |

Mix, incubate for 3 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:

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

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.

REFERENCES:

1. Dumas, 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.

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 | Hemoglobin | |
| Increase the measure reading | Increase the measure reading | |

LIMITATIONS :






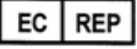

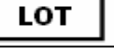

Avoid excessive hemolysis since every 100mg/dl of hemoglobin corresponds to about 100mg/dL of albumin.

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 $\times 2$.

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

| | |
|---|---|
|  | Consult Instructions for Use |
|  | Caution, consult accompanying Documents |
|  | In Vitro Diagnostic Medical Device |
|  | Temperature limitation |
|  | Manufacturer |
|  | Authorized Representative in the European Community |
|  | Catalogue number |
|  | Batch code |
|  | Use by |

| | |
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