# ALBUMIN (BCG)

**INDENDED USE**

Bioline Albumin reagent is intended for the quantitative *in vitro* diagnostic determination of albumin in human serum.

**CLINICAL SIGNIFICANCE**

Albumin, synthetized primarily by the liver, represents 50 to 60% of total serum proteins. Because of its small size and its high plasmatic concentration, albumin is the major protein component of most extra vascular body fluid, including CSF, interstitial fluid, urine and amniotic fluid. Albumin's primary function is the maintenance of colloidal osmotic pressure in both extravascular and vascular spaces, with continuous equilibration. Albumin also binds and transports a large number of compounds (ions, free fatty acids, bilirubin, drugs...). Albumin is a mobile reserve of amino acids.

Increased levels of albumin are present only in acute dehydration, especially critical for new born. Hypo albuminemia is seen in a multitude of diseases bound to different pathological states: acute and chronic inflammation, decreased synthesis: hepatic insufficiency, malnutrition, an albuminemia, increased loss: nephritic syndrome, gastrointestinal loss, sever end large burns, bedsore, increased catabolism: fever, hyperthyroidism etc.

**METHOD AND PRINCIPLE**

Colorimetric Bromocresol Green (BCG)

Colorimetric determination of serum albumin using bromocresol green at acidic pH.

Albumin + BCG acid pH Albumin-BCG complex

**REAGENT COMPOSITION**

| | |
|---|---|
| Succinate buffer | 91 mmol/L |
| Bromocresol green | 0.3 mmol/L |
| Brij 35 | 6.35 ml/L |
| **Standard** | **5gm/dL** |

**WARNINGS AND PRECAUTIONS**

- The standard contains less than 0.1 % sodium azide. Sodium azide can react with copper and lead Plumbing to form explosive metal azides. If discharge in the canalizations, rinse with plenty of water.
- Use clean or single use laboratory equipment only to avoid contaminations.
- The standard should be immediately and tightly capped to prevent contamination and evaporation.

For more information, Material Safety Data Sheet (MSDS) is available on request for professional user

**REAGENT PREPARATION**

The reagent and the standard are ready to use.

**REAGENT STORAGE AND STABILITY**

Store at 2-8 °C and protect from light.

The reagent is stable until the expiry date stated on the label.

**REAGENT DETERIORATION**

The reagent and standard solution should be clear. Cloudiness would indicate deterioration.

Do not use the product if there is visible evidence of biological, chemical or physical deterioration.

**SPECIMEN COLLECTION AND STABILITY**

**Serum:** Lithium heparinized plasma.

Do not use other specimens

Samples are stable for 7 days at 2-8°C and at least 2 months at -20°C. For longer storage, freeze samples at -70°C

- Samples must be free from hemolysis and lipemia.

**INTERFERENCE**

Unconjugated Bilirubin: No significant interference up to 35 mg/dL.

Conjugated Bilirubin : No significant interference up to 24.5 mg/dL.

Hemoglobin: Positive bias from 350 mg/dL (3.5 g/L) on normal human sera and from 50 mg/dL (0.5 g/L) on pathological human sera.

Turbidity: No significant interference up to 600 mg/dL Triglycerides equivalent.

Sodium salicylate: No significant interference up to 250 mg/dL.

**ASSAY PROCEDURE FOR SEMIAUTO ANALYZER.**

Wavelength : 630 nm (600-630) nm

Temperature : RT

| | **Blank** | **Standard** | **Sample** |
|---|---|---|---|
| **Reagent** | 1 mL | 1 mL | 1 mL |
| **Distilled water** | 10 µL | - | - |
| **Standard** | - | 10 µL | - |
| **Sample** | - | - | 10 µL |

Mix and read the optical density of standard and sample against reagent blank (OD) after 1 minutes of incubation at RT. The final color is stable for 20 minutes.

**CALCULATION**

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

Where n = Std Concentration (g/dL)

**CALIBRATION**

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate results. It is recommended to establish a linearity curve up to 6 g/dl with other available commercial standard solutions to verify the performance of the instruments and reagents.

**LIMITATIONS**

The reagent is linear up to 6 g/dl.

1. Samples with values above 6g/dl should be diluted 1:1 with isotonic saline and re-run. Multiply final results by two.
2. Grossly lipemic serums require a "sample blank." Add 0.02ml (20 µl) of sample to 2.0 ml saline, mix and read the absorbance against water. Subtract this value from the patient absorbance to obtain the corrected reading.

**QUALITY CONTROL**

To ensure adequate quality, control normal and abnormal control should be used. These controls must be performed & validated before the patient samples are assayed. The control frequency must be at least once a day, after each calibration and should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take corrective measures. Quality control material should be used in accordance with local guidelines.

**EXPECTED VALUES**

Serum, plasma

Patients at rest

| | |
|---|---|
| Adults | : 3.5-5.2 g/dl |
| 60-90 years | : 3.2-4.6 g/dl |
| 90 years | : 2.9-4.5 g/dl |

**PERFORMANCE CHARECTERSTICS**

**Linearity:** The reagent is linear from up to 6 g/dL (15 to 60 g/L).

**Correlation**

A comparative study has been performed on this reagent on 38 human serum samples. The sample concentrations ranged from 1.25 to 5.95 g/dl.

The parameters of linear regression are as follows:

Correlation coefficient : (r) = 0.9978

Linear regression : (y) = 0.9703 x + 0.13 g/dl

**GENERAL TECHNICAL PARAMETER**

| | |
|---|---|
| Mode | End Point |
| Wavelength (Filter) | 630 nm (600-630) |
| Reaction Direction / Type | Increasing |
| Reagent Blank | Yes |
| Sample Vol. | 10 µL |
| Reagent Vol. | 1000 µL |
| Incubation Time | 1 min at RT |
| Reagent Blank Abs.(Max) | NMT 0.100 Abs |
| Calibration Method | 1- Point |
| Standard (Conc.) | 5.0 g/dL |
| Linearity | 6.0 g/dL |
| Decimal Places | 2 |
| Temp. | RT |
| Unit | g/dL |
| Ref. Low (Male / Female) | 2.9 g/dL |
| Ref. High (Male / Female) | 5.2 g/dL |

**REFERENCES**


1. Tietz, N.W. Clinical Guide to Laboratory Tests, 3rd Ed., Saunders, (1995), 22.
2. Scherwin, J.E, Liver function. Clinical Chemistry: Theory, Analysis, Correlation, 4th Ed., Kaplan, L.A, Pesce, A.J., Kazmierczak, S.C., (Mosby Inc. eds St Louis USA), (2003), 492.
3. Doumas, B., et al., Albumin standards and the measurement of serum albumin with bromocresol green, Clin. Chem. Acta., (1971),31, 87.
4. Doumas, B.T., Biggs, H.G., Determination of serum albumin, Standard Methods of Clinical Chemistry, (Acad. Press N.Y.), (1972), 7, 175.