



TECO DIAGNOSTICS

1268 N. Lakeview Ave.
Anaheim, CA 92807
1-800-222-9880

ALBUMIN REAGENT SET

INTENDED USE

Albumin reagent is used for the quantitative determination of albumin concentration in human serum.

INTRODUCTION

Albumin is the most abundant protein constituent of serum. It is synthesized in the liver and is noted for its ability of configuration changes. This steric affinity allows the albumin molecule to serve as a carrier of many substances such as bilirubin, fatty acids, uric acid, various drugs, and antibiotics. Albumin also functions in the maintenance of proper osmotic pressure.¹

Elevated serum albumin levels are associated with possible dehydration. Low serum albumin levels are indicative of potential malnutrition, liver disease, kidney disorders, and rheumatoid arthritis.²

Earlier salt fractionation methods to determine serum albumin were too laborious to perform and have been replaced by azo dye methods. The use of bromocresol green in the reaction has become the preferred method because of its high specificity for albumin and its negligible interference for hemolysis, bilirubin, and salicylates.^{3,4}

PRINCIPLE

Serum albumin binds selectively to the dye bromocresol green at pH 4.2. The increase in absorbance of the resulting albumin-dye complex, read at 630 nm, is proportional to the albumin concentration.

REAGENT COMPOSITION

1. Bromocresol Green (BCG) 0.25 mM, buffer pH 4.0 ± 0.1, surfactant, non-reactive ingredients and stabilizers.
2. Standard: Bovine Albumin Fraction V with stabilizer (5 g/dl).

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
CAUTION: In vitro diagnostic reagents may be hazardous. Handle in accordance with good laboratory procedures which dictate avoiding ingestion, and eye or skin contact. The reagent is an acid solution. Flush with water when contact occurs.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid contact/ingestion. Reagent is an acid solution. Flush with water when contact occurs.

STORAGE AND STABILITY

1. Store the reagent at room temperature (15 - 30°C).
2. Albumin standard is stored refrigerated (2 - 8°C).

REAGENT DETERIORATION

The reagent should be a clear, yellow-green solution. If turbidity or precipitation has occurred the reagent should be discarded.

SPECIMEN COLLECTION

1. Test specimens should be serum and free from hemolysis.
2. Avoid excessive hemolysis since every 100 mg/dl of hemoglobin corresponds to about 100 mg/dl of albumin.⁵
3. Albumin in serum is stable for one (1) week at room temperature (15 - 30°C) and approximately one (1) month when stored in the refrigerator (2 - 8°C) and protected against evaporation.⁶

INTERFERING SUBSTANCES

Ampicillin and other medications seriously interfere with the dye-binding properties of albumin (Young, et al.).⁷ It is also recommended that only standards and controls containing human albumin be employed with this procedure. The dye-binding properties of albumin from various species have been found to differ widely.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Accurate pipetting devices
2. Test tubes/rack
3. Timer
4. Spectrophotometer

AUTOMATED PROCEDURE

Refer to appropriate application manual available.

MANUAL PROCEDURE

1. Label test tubes Blank, Standard, Control, Patient, etc.
2. Pipette 1.5 ml of reagent into each tube.
3. Transfer 0.01 ml (10 µl) of sample to respective tubes and mix and allow to stand at room temperature for five (5) minutes.
4. Zero spectrophotometer with the blank at 630 nm. (Wavelength range: 580 - 630 nm).
5. Read and record absorbencies of all tubes.

* ALTERNATIVE VOLUMES: 0.02 ml sample to 3.0 ml reagent.

* *TC MULTI-PURPOSE CALIBRATOR MAY BE USED TO REPLACE STANDARD.*

LIMITATIONS

1. The dye-binding properties of albumin, other than human, differ among species.³
2. Samples with values above 8.0 g/dl should be diluted with 0.9% saline 1:1, re-run, and results multiplied by 2. Samples with results below 0.5 g/dl should be done electrophoretically.
3. Severely lipemic serums should have a serum blank.
 - a. Add 0.02 ml (20 µl) sample to 3.0 ml distilled water and read absorbance against distilled water at 630 nm.
 - b. Subtract the serum blank absorbance from the test absorbance and use the corrected absorbance in the calculations.

CALCULATIONS

Abs. = Absorbance

$\frac{\text{Abs. of unknown}}{\text{Abs. of standard}} \times \text{Concentration of Standard} = \text{Albumin g/dl}$

Example: If the absorbance of the unknown = 0.455, the absorbance of the standard is 0.705 and the standard concentration = 5.0 then:

$$\frac{0.455}{0.705} \times 5.0 = 3.23 \text{ g/dl}$$

QUALITY CONTROL

It is recommended that controls be included in each set of assays. Commercially available control material with established albumin values may be routinely used for quality control. The assigned value of the control material must be confirmed by the chosen application. Failure to obtain the proper range of values in the assay of control material may indicate reagent deterioration, instrument malfunction or procedural errors.

EXPECTED VALUES

3.5 - 5.3 g/dl⁹

It is strongly recommended that each laboratory establish its range of expected values, since differences exist between instruments, laboratories, and local populations.

PERFORMANCE CHARACTERISTICS

1. Linearity: 0.5 - 8.0 g/dl
2. Sensitivity: Based on an instrument resolution of $A = 0.001$, the present method has a sensitivity of 0.005 g/dl.
3. Comparison: A comparison study performed between this method and another BCG method resulted in a correlation coefficient of 0.99 with a regression equation of $y = 0.96x + 0.1$.
4. Precision:

Within Run		
<u>Mean (mg/dl)</u>	<u>S.D.</u>	<u>C.V. %</u>
3.3	0.07	2.1
2.7	0.07	2.4

Run-to-Run		
<u>Mean (mg/dl)</u>	<u>S.D.</u>	<u>C.V. %</u>
3.3	0.06	1.8
2.7	0.08	2.9

REFERENCES

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Manufactured by:



TECO DIAGNOSTICS
1268 N. LAKEVIEW AVE.
ANAHEIM, CA 92807
U.S.A.



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands