UDI

المصنع المتحد للكواشف الطبية
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ALBUMIN REAGENT SET (COLORIMETRIC)

BROMOCRESOL GREEN METHOD

REF 003

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

Quantitative determination of albumin in serum using the bromocresol green (BCG) dye binding method.

DIAGNOSTIC SIGNIFICANCE

Elevated serum albumin levels are associated with possible dehydration. Low serum albumin levels are indicative of potential malnutrition, liver disease, kidney disorder and rheumatoid arthritis[1].

RANGE OF EXPECTED VALUES IN SERUM[2]

3.8 - 5.0 g/dl (38 - 50 g/l)
FOR HEALTHY AMBULATORY ADULTS.

METHOD PRINCIPLE

The UDI albumin procedure is based upon the original work of Rodkey[3],as modified by Doumas et al[4, 5],and utilises the dye-binding properties of albumin. When the anionic BCG reacts with
albumin by means of electrostatic forces, tertiary Vander Waal's forces and hydrogen bonding , at a controlled pH, the absorbance of the solution increases in direct proportion to the albumin concentration.
The extent of this increase in absorbance is measured photometrically at 630 nm.
The UDI procedure is a modified bromocresol green method.

REAGENT

1. ***ALBUMIN COLOR REAGENT:*** 150 µmol/L Bromocresol green in succinate buffer at pH 4.0 ± 0.1 with 0.12% w/v surfactant.

Must be kept tightly capped and protected from contamination.

2. ***ALBUMIN STANDARD (5 g/dl)*** : Bovine albumin fraction V solution containing Preservative. Keep tightly capped and protected from contamination.

REAGENT STORAGE & STABILITY

Store the Reagents at 2 ^{0}C to 8 ^{0}C, Stable up to Expiration date indicated on the bottle label.

CHEMICAL PRECAUTIONS

Exercise the normal precautions required for the handling of all laboratory reagents. Pipetting by mouth is not recommended for any laboratory reagent.

INDICATIONS OF REAGENT DETERIORATION

1. Physical appearance
   a) ALBUMIN COLOR REAGENT : Do not use if a precipitate forms or if mold growth is observed
   b) ALBUMIN STANDARD: Do not use if visibly turbid or if mold growth is observed.
2. Control assays
   Failure to obtain accurate results in the assay of control materials may indicate reagent deterioration.

NOTE : UDI cannot guarantee the stability of reagents which have been:
   a) transferred from their original containers.
   b) stored improperly.
   c) contaminated during use.

SPECIMEN

Serum
Collect whole blood by venipuncture and allow to clot. Centrifuge and remove serum.

Albumin in serum is reportedly[5] stable for up to one week at room temperature,(15 °C to 25°C) one month at 2 °C to 8 °C and longer when frozen.(-20 °C)

MATERIALS PROVIDED

ALBUMIN COLOR REAGENT, ALBUMIN STANDARD (5 g/dl)

ADDITIONAL MATERIALS REQUIRED BUT NOT PROVIDED

Sample and reagent pipettes, test vials or cuvettes, timer, test tube rack, control serum, spectrophotometer.

PROCEDURE (MANUAL)

Pipette into clean dry test tubes:

	BLANK	STANDARD	TEST
Albumin Color Reagent	2.5 ml	2.5 ml	2.5 ml
Standard	-	0.01 ml	-
Sample	-	-	0.01 ml
Mix and allow to stand at room temperature for 5 minutes.			
Set wavelength at 630 ± 5 nm and zero instrument with the Blank. Read absorbances of all tubes within 60 minutes.			

CALCULATION OF RESULTS WITH EXAMPLE

Use the absorbance readings of the STANDARD and TEST to calculate albumin values as follows: (A = absorbance)

$$\frac{A\ (TEST)}{A(STANDARD)} \times \text{Conc.of STANDARD(g/dl)} = \text{Albumin in TEST (g/dl)}$$

EXAMPLE: Assume the value of the STANDARD to be 5.0 g/dl and that it gave an absorbance of 0.6, while the TEST gave an absorbance of 0.42 The albumin concentration of the TEST may then be calculated as follows:

$$\frac{0.42}{0.6} \times 5.0\ g/dl = 3.5\ g/dl$$

PROCEDURE LIMITATIONS

Bilirubin, salicylate and moderate lipemia do not interfere in this procedure. However, when serum is markedly lipemic, a serum blank must be run (see PROCEDURE NOTES).

Excessive hemolysis should be avoided since every 100 mg/dl of hemoglobin released into the serum increase the apparent albumin content by an equivalent amount[5].

Albumin Color Reagent has a reduced sensitivity to albumin in the presence of detergents and dioxane[6].

Ampicillin has been found to seriously interfere with bromocresol green methods[7].

At a neutral pH and low albumin concentration, bromocresol green will bind with some of the alpha and beta-globulins present in human serum[8]. However, the buffering capability of the reagent effectively overcomes this potential interference.
For a more comprehensive review of *in vivo* and methodological drug effects, see reference 9.

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PERFORMANCE CHARACTERISTICS

1. **COMPARISON: UDI reagents** tested on MANUAL METHOD (y) was compared with similar UDI reagent for other systems (x) which in turn is matching with CAPS survey results. The systematic difference between the results were within CLIA specified limits,
   N =25
   Correlation Coefficient 0.95
   Regression Equation $y = 0.93x + 0.16$

2. **PRECISION:**

	Mean g/dL	SD	CV%
Within run	3.0	0.09	3.13
Run to run	3.9	0.13	3.39

PROCEDURE NOTES

1. Preparation of SERUM BLANK for markedly lipemic samples:
   a. Add 10 µl of serum to 2.5 ml of distilled water and read absorbance at 630 nm against distilled water.
   b. Subtract this serum blank reading from the initial reading of the TEST obtained from the above procedure and use the corrected absorbance to calculate the albumin concentration.
2. If the albumin concentration exceeds 6.0 g/dl, make a 1:1 dilution of the sample with 0.85% saline, re-run the test and multiply the results by 2.

QUALITY CONTROL

For accuracy and precision check, we recommend the use of normal and abnormal UDI controls based on human serum.

ORDERING INFORMATION:

UDITROL 'N' (Normal Serum Control)REF # 070N-010 2x5 ml
UDITROL 'A' (Abnormal Serum Control) REF # 070A-010 2x5 ml

BIBLIOGRAPHY

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EC REP
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CE

PRODUCT AVAILABILITY

ALBUMIN REAGENT SET (Colorimetric)

REF # 003-192	**4 x 120 ml**
REF # 003-096	**2 x 120 ml**
REF # 003-048	**1 x 120 ml**