Audit Diagnostics

CE

ALBUMIN

Albumin

Bromocresol green. Colorimetric

Quantitative determination of albumin
IVD

Store at 2-8ºC

PRINCIPLE OF THE METHOD

Albumin in the presence of bromocresol green at a slightly acid pH, produces a colour change of the indicator from yellow-green to green-blue. The intensity of the color formed is proportional to the albumin concentration in the sample[1,2,3,4].

CLINICAL SIGNIFICANCE

One of the most important serum proteins produced in the liver is albumin.
This molecule has an extraordinarily wide range of functions, including nutrition, maintenance of oncotic pressure and transport of Ca^{++}, bilirubin, free fatty acid, drugs and steroids.
Variation in albumin levels indicate liver diseases, malnutrition, skin lesions such as dermatitis and burns or dehydration[1,7,8].
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENTS

R	Bromocresol green pH 4,2	0,12 mmol/L
ALBUMIN CAL	Albumin aqueous primary standard 5 g/dL	

PREPARATION

Reagent and standard are ready to use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Signs of reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 630 nm ≥ 0,40.

ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 630 nm.
- Matched cuvettes 1,0 cm light path.
- General laboratory equipment.

SAMPLES

Serum or plasma, free of hemolysis[1]: Stability 1 month at 2-8ºC or 1 week at 15-25ºC.

PROCEDURE

1. Assay conditions:
   Wavelength: . . . . . 630 nm (600-650)
   Cuvette: . . . . . 1 cm light path
   Temperature: 15-25ºC/37ºC
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette (Note 3):

	Blank	Standard	Sample
R (mL)	1,0	1,0	1,0
Standard (Note 1,2) (µL)	--	5	--
Sample (µL)	--	--	5

4. Mix and incubate for 5 min at 37ºC or 10 min at 15-25ºC.
5. Read the absorbance (A) of the samples and Standard, against the Blank. The colour is stable 1 hour at room temperature.

CALCULATIONS

$$\frac{(A)\text{Sample} - (A)\text{Blank}}{(A)\text{ Standard} - (A)\text{Blank}} \times 5 \text{ (Standard conc.)} = \text{g/dL albumin in the sample}$$

Conversion factor: g/dL x 144,9 = µmol/L

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures: CONTROL Normal and Pathologic .
If control values are found outside the defined range , check the instrument, reagents and calibrator for problems.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

3,5 to 5,0 g/dL[1].
These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: From detection limit of 0,0349 g/dL to linearity limit of 6 g/dL.
If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.
Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (g/dL)	4,17	2,84	4,56	3,07
SD	0,02	0,01	0,28	0,18
CV (%)	0,42	0,53	6,20	5,90

Sensitivity: 1 g/dL = 0,2003 A.
Accuracy: Results obtained using Audit Diagnostics reagents (y) did not show systematic differences when compared with other commercial reagents (x).
The results obtained using 50 samples were the following:
Correlation coefficient $(r)^2$: 0,99169.
Regression equation: y= 1,045x – 0,028.
The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Bilirubin up to 110 mg/L, hemoglobin up to 1 g/L and lipemic sera up to 10 g/L no interfere[1,4].
A list of drugs and other interfering substances with albumin determination has been reported[5,6].

NOTES

1. ALBUMIN CAL: Proceed carefully with this product because due its nature it can get contaminated easily.
2. Calibration with the aqueous Standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
3. Use clean disposable pipette tips for its dispensation.
4. **Audit Diagnostics has instruction sheets for several automatic analyzers.**

BIBLIOGRAPHY

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