Reactivos GPL

Barcelona, España

CE

- ALBUMIN -

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Bromocresol green. Colorimetric

Store at: +2+8ºC.

Presentatión:
Cod. SU001 CONT: *R 2 x 125 mL.+ CAL 1 x 5 mL.*

Procedure

Quantitative determination of albumin.

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY
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 colour formed is proportional to the albumin concentration in the sample[1,2,3,4].

REAGENTS COMPOSITION

R.	Bromocresol green pH 4.2 50 mmol/L.
Albumin Cal	Albumin aqueous primary calibrator 5 g/dL.

REAGENT PREPARATION AND STABILITY
Reagent (R) and standard (Albumin Cal) are ready to use.
All the components of the kit are stable until the expiration date on the label when stored at 2-8ºC, protected from light and contamination prevented during their use.
Do not use reagents over the expiration date.
Albumin Cal: Once open is stable up to 1 month when stored tightly closed at 2-8ºC, protected from light and contamination prevented during their use.

Signs of Reagent deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 630 nm. ≥ 0.40

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8ºC. Do not use reagents over the expiration date.

SPECIMEN
Serum or plasma, free of hemolysis[1] . Stable 1 month at 2-8ºC or 1 week at 15-25ºC.
The samples with particles or fibrin should be centrifuged to eliminate them. Do not use haemolized or lipemic samples.

MATERIAL REQUIRED BUT NOT PROVIDED
- Spectrophotometer or colorimeter measuring at 630 nm.
- Matched cuvettes 1.0 cm. light path.

General laboratory equipment.

TEST PROCEDURE
1. Assay Conditions
   Wavelenght : ..... 630 nm.
   Cuvette: ..... 1 cm light path.
   Temperature .....15-25ºC.
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

	Blank	Calibrator	Sample
R.1 (mL.)	1.0	1.0	1.0
Calibrator (note 1-2)(µL.)	--	5	--
Sample (µL.)	--	--	5

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

CALCULATIONS

$$\text{Albumin (g/dL.)} = \frac{(A)\text{Sample}}{(A)\text{Standard}} \times 5 \text{ (Calibrator conc.)}$$

CONVERSION FACTOR. G/DL. X 144,9 = µMOL/L.

QUALITY CONTROL
Control sera are recommended to monitor the performance of the procedure, Control Normal Ref. QC001 and Control Pathological Ref. QC002. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.
Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

REFERENCE VALUES
3.5 to 4 g/dL[1].
(These values are for orientation purpose).

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE
One of the most important serum proteins produced in the liver is albumin. This molecule has an extraordinary wide range rage of functions, including nutrition, maintenance of osmotic 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 dehydratation[1,7,8]. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE
- *Measuring Range*:
  From detection limit 0f 0.04 g/dL. to linearity limit of 6 g/dL., under the described assay conditions.
  If results obtained were greater than linearity limit, dilute the sample ½ with NaCl 9 g/L. and multiply result by 2.
- *Precision*:

	Intra-assay n= 20		Inter-assay n= 20	
Mean (g/dL)	3.34	3.34	3.33	3.34
SD	0.01	0.01	0.06	0.06
CV	0.40	0.38	1.73	1.64

- Sensitivity:
  1 g/dL. = 0.144A
- Accuracy:
  Results obtained GPL reagents did not show systematic differences when compared with other commercial reagents.
  The results obtained using 50 samples were the following:
  Correlation coefficient (r): 0.99
  Regression Equation: y= 0.98x + 0.09
  The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES
- Interference:
  Bilirubin up to 110 mg/L, hemoglobin up to 1 g/L. and lipemic sera up to 10 g/L. no interfere.
  Other substances may interfere. A list of drugs and other substances that could interfere has been reported by Young et. al[5,6].

NOTES
1. Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
2. Use clean disposable pipette tips for its dispensation.

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