Cromatest

LINEAR

ALBUMIN CE

REF 1101000 2 x 50 mL **CONTENTS** R1.Reagent 2 x 50 mL CAL. Standard 1 x 3 mL	REF 1101010 4 x 100 mL **CONTENTS** R1.Reagent 4 x 100 mL CAL. Standard 1 x 3 mL
For *in vitro* diagnostic use only	

ALBUMIN

Colorimetric method

ENDPOINT

PRINCIPLE

The method[1] is based on the specific binding of bromocresol green (BCG), an anionic dye, and the protein at acid pH with the resulting shift in the absorption wavelength of the complex. The intensity of the color formed is proportional to the concentration of albumin in the sample.

$$\text{BCG} + \text{Albumin} \xrightarrow{\text{pH 4.3}} \text{BCG-albumin complex}$$

REAGENT COMPOSITION

R1 **Bromocresol reagent**. Succinate buffer 75 mmol/L pH 4.3, BCG 0.12 mmol/L, tensioactive 2 g/L (w/v).

CAL **Albumin standard**. Bovine serum albumin 5 g/dL (50 g/L) Concentration value is traceable to Standard Reference Material 927c.

STORAGE AND STABILITY

Store at 2-8ºC.
All the kit compounds are stable until the expiry date stated on the label. Do not use reagents over the expiration date.
Store the vials tightly closed, protected from light and prevented contaminations during the use.
Discard If appear signs of deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 630 nm > 0.250 in 1cm cuvette.

REAGENT PREPARATION

The Reagent and Standard are ready-to-use.

SAMPLES

Serum, EDTA plasma unhemolyzed.
Albumin in serum and plasma is stable for 2 weeks at 2-8ºC, and for up to 4 months at –20ºC.

INTERFERENCES

- Lipemia (intralipid >1,25 g/L) may affect the results.
- Bilirubin (40 mg/dL) does not interfere.
- Hemoglobin (1 g/L) may affect the results.
- Other drugs and substances may interfere[5].
- Specimens containing dextran should be avoided.

MATERIALS REQUIRED

- Photometer or colorimeter capable of measuring absorbance at 630 ± 20 nm.
- Pipettes to measure reagent and samples.
- Timer. This is not necessary if the assay is performed in an automated instrument.

PROCEDURE

1. Bring reagents and samples to room temperature.
2. Pipette into labelled tubes:

TUBES	Blank	Sample	CAL. Standard
R1.Reagent	2.0 mL	2.0 mL	2.0 mL
Sample	–	10 µL	–
CAL.Standard	–	–	10 µL

3. Mix and let the tubes stand 1 minute at room temperature.
4. Read the absorbance (A) of the samples and the standard at 630 nm against the reagent blank.

The color is stable for 30 minutes protected from light.

CALCULATIONS

$$\frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times C_{\text{Standard}} = \text{g/dL albumin}$$

Samples with concentrations higher than 6 g/dL should be diluted 1:2 with saline and assayed again. Multiply the results by 2.

If results are to be expressed as SI units apply:
g/dL x 10 = g/L

REFERENCE VALUES[3]

Serum, plasma

Adults	3.81 - 4.65 g/dL (38.1 - 46.5 g/L)

The range of values for hospitalized individuals varies between 1.4 and 4.8 g/dL.

It is recommended that each laboratory establishes its own reference range.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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QUALITY CONTROL

The use of a standard to calculate results allows to obtain an accuracy independent of the system or instrument used.
To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

REF **1980005** HUMAN MULTISERA NORMAL
Borderline level of albumin. Assayed.

REF **1985005** HUMAN MULTISERA ABNORMAL
Elevated level of albumin. Assayed.

If the values are found outside of the defined range, check the instrument, reagents and procedure.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

CLINICAL SIGNIFICANCE[4]

The serum content of the soluble proteins, those circulating in extracellular and intracellular fluids, has been used as a marker to aid in clinical diagnosis. The main diagnostic tests are those measuring serum total protein and serum albumin.
Collectively, serum total protein including albumin is mainly involved in the maintenance of normal water distribution between tissues and the blood and responsible for maintaining the oncotic pressure of plasma and is used to transport many substances including macromolecules.

Hyperproteinemia o hyperalbuminemia, usually occurs during multiple myeloma caused by high levels of the monoclonal immunoglobulins, dehydration, excessive water loss, as in severe vomiting, diarrhea, Addisons´s disease or diabetic acidosis. The *hemoconcentration*, decrease in the volume of plasma water, is reflected as a relative hyperproteinemia since concentration of all the individual plasma proteins are increased to the same degree.

Hypoproteinemia or hypoalbuminemia usually occurs in edema, malnutrition, nephrotic syndrome, malabsortion and severe liver cirrhosis. Since albumin is present in such high concentration low levels of this protein alone may also cause hypoproteinemia.

ANALYTICAL PERFORMANCE

- ***Detection Limit :*** 0.31 g/dL
- ***Linearity :*** Up to 6 g/dL
- ***Precision:***

g/dL	Within-run		Between-run	
Mean	2.77	4.07	2.77	4.07
SD	0.02	0.06	0.08	0.15
CV%	0.61	1.47	2.72	3.76
N	10	10	10	10

- ***Sensitivity :*** 0.176 A / g/dL albumin.
- ***Correlation:*** This assay (y) was compared with a similar commercial method (x). The results were:
  N = 60 r = 0.98 y = 1.06x – 0.15

The analytical performances have been generated using on automatic instrument. Results may vary depending on the instrument.

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES

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