ALBUMIN BCG LS "630" Mono

IVD

Quantitative determination of Albumin in serum or plasma. Colorimetric method (BCG).

REF **CC1000** R1: 4x100 mL + R2:1x3 mL (standard)

METHOD AND PRINCIPLE

Photometric test using bromocresol green. Serum 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 measurable fotometrically at 630 nm.

CLINICAL SIGNIFICANCE

Albumin is the most abundant protein found in plasma and represents, by itself, about half of the circulating proteins. It is produced by the liver and once synthesized by the hepatic cells (hepatocytes), it is poured into the circulatory stream where it carries out important functions such as transporting substances (such as bilirubin, fatty acids and hormones), eliminating waste substances which are expelled in the urine, keeping the oncotic pressure in equilibrium (regulation of the water exchanges between the capillaries and the interstitial fluid that wets the tissues).

The concentration of albumin in the blood reflects the nutritional status of the person. High values of albumin are quite rare, while its decrease may be caused by several factors, which may be transient or result from a real pathology. A reduction in albumin in the blood can be caused by all those conditions in which there are reduced protein deficiencies intake with diet, bad absorption (enteropathy, celiac disease, Crohn's disease, protein intolerance), increased catabolism (severe inflammation, febrile states, cachexia, neoplasms, hyperthyroidism, hypercortisolism or Cushing, overtraining, diseases affecting the liver (decreased ability to synthesize) and the kidney (increased elimination). In particular, the concentration may decrease when cirrhosis of the liver, acute and chronic hepatitis, genetic abnormalities occur (synthesis of defective albumins), nephrotic syndrome and glomerulonephritis. The hypoalbuminemia that is observed during pregnancy is caused both by hormonal modifications (alterations of the vascular permeability), and from the increased use of proteins by the fetus. High values of albumin are mainly found in situations of dehydration.

REAGENT COMPOSITION

Reagent (R1)

Succinate buffer, pH 4.2	75 mmol/L
Bromocresol green	0.26 mmol/L
Tensioactives	2 g/L
Sodium Azide	0.95 g/dL

Reagent (R2)

Standard	see value on label

REAGENT PREPARATION AND STABILITY

Liquid and ready to use reagents, stable until the expiry date shown, if stored as indicated on the label and avoid contamination, evaporation and prolonged exposure to direct light.

Do not freeze the reagents.

Store Reagent 1 at 15° - 25°C, Reagent 2 (standard) at 2-8° C.

Discard the reagent if signs of deterioration appear, such as the presence of particles and turbidity or failure to recover the values of certified control sera.

SPECIMEN

Serum or Plasma. Avoid hemolysate or lipemic samples.

Separate the serum/plasma from the clot quickly.

Stability in serum/plasma:

1 month at 2° - 8 °C, 1 week at 15° - 25 °C, 3 months at -20 °C.

Discard contaminated specimens.

PROCEDURE

Wavelength:	630 nm (600 - 650 nm)
Temperature:	20° – 37° C
Measurement:	against Reagent Blank

Pipette as follow:

Reagent R1	1000 µL
Sample, Std / Cal	10 µL

Mix, incubate for 5 minutes and read the Absorbance against Reagent Blank within 60 minutes.

CALCULATION

$$\text{Albumin} = \frac{\text{Abs Sample}}{\text{Abs Std/Cal}} \times \text{Conc. Std/Cal}$$

Conversion Factor: g/dL x 10 = g/L

CALIBRATION

Results will depend on the accuracy of the instrument calibration, assay settings, the reagent/specimen ratio and the temperature control.

As an alternative to the standard included in the package, it is possible to use

Chemistry Multicalibrator - REF CAL1010 (10 x 3 mL).

QUALITY CONTROL

Normal and abnormal control sera of known concentration should be analysed routinely with each group of unknown samples utilizing **MTD Diagnostics** Quality Control Material:

Chemistry Control N - REF CNN1010 10x5 mL (Level 1)
Chemistry Control P - REF CNP1020 10x5 mL (Level 2)

EXPECTED VALUES

Adults: 3.5 – 5.2 g/dL

Each laboratory should establish a range of expected values based on its patient population and, if necessary, determine its own reference interval. For diagnostic purposes, results should always be assessed together with the patient's medical history, clinical examination and other results.

PERFORMANCE

PRECISION:
Low Level: Samples= 20; Average = 3.52; S.D. = 0.03; CV = 1.91%
High Level: Samples = 20; Average = 6.89; S.D. = 0.12; CV = 1.79%

ACCURACY (CORRELATION): A comparison between this method (x) and a certified method of trade (y) gave the following correlation:

y = 1.00 x – 1.11 r = 0.998

SENSITIVITY: 0.2 g/dL

LINEARITY: 0.2 – 6.0 g/d/L

SPECIFICITY / INTERFERENCES

No interference was observed by ascorbic acid up to 30 mg/dL, bilirubin up to 40 mg/dL, haemoglobin up to 400 mg/dL and triglycerides up to 500 mg/dL.

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 your 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.

PRECAUTIONS

The product does not contain any other hazardous substances or mixtures according to EC Regulation No. 1272/2008 (CLP) or their concentrations are such that they are not considered to be persistent, bioaccumulative or toxic (PBT). Therefore, it is not subject to the special labeling required by the aforementioned regulation. The product is labeled according to the directive for CE marking (98/79 / EC). Sodium Azide less than 0.1%.
However, in compliance with the normal prudential rules that everyone has to keep managing any chemical or laboratory reagent, in case of contact of reagents with the operator, you must apply the following first aid:
S26 (P305 – P351 – P338): In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 (P302 – P352): After contact with skin, wash immediately with plenty of water.
S36/37/39 (P280): Wear suitable protective clothing, gloves and eye/face protection.
S46 (P301 – P310): If swallowed, seek medical advice immediately and show container or label. If victim is conscious and alert, wash out mouth with water.
S56 (P273): Dispose of this material and its container at hazardous or special waste collection point.
S63 (P304 – P340): In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, give oxygen and get medical aid.

All samples, calibrators and controls should be treated as potentially infectious material capable of transmitting HIV and hepatitis.

FOR MORE INFORMATION, REQUEST SAFETY DATA SHEET FOR REAGENT (MSDS) AT THE MANUFACTURER.

SIMBOLOGY

CE	CE Mark (EC Directive 98/79)		
IVD	In Vitro Diagnostic		Temperature Limitation
	Consult instructions for use		Contains sufficient for <n> test
REF	Catalog Number		Use By
LOT	Batch Code		Manufacturer

BIBLIOGRAPHY

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