TOTAL PROTEIN BIURET LS Mono

IVD

Quantitative determination of Total Protein in Serum or Plasma. Colorimetric method (Biuret). Endpoint.

REF CC1280 R1:4x100 mL R2: 1x3 mL (standard)

METHOD AND PRINCIPLE

Photometric test according to biuret method.
Proteins together with copper ions form a violet blue colour complex in alkaline solution. The absorbance of the colour is directly proportional to the concentration.

CLINICAL SIGNIFICANCE

Proteins are important constituents of all cells and tissues; they are necessary for the growth of the organism, development and its health; they are the structural part of most organs, as well as the enzymes and hormones that regulate the body's functions. This test measures the total amount of various types of proteins in the liquid (plasma) part of the blood. There are two classes of proteins in the blood, albumin and globulins. Albumin accounts for about 60% of total proteins. Produced by the liver, carries out a series of functions, including the transport of small molecules and ions, is a source of amino acids for tissue metabolism, and is the main component involved in maintaining the osmotic pressure (preventing the leakage of liquid from the vessels blood). The remaining 40% of plasma proteins are called globulins. Globulins are a heterogeneous group and include enzymes, antibodies, hormones, transport proteins and numerous other types of proteins. The albumin / globulin ratio (A / G ratio) is obtained from the measured albumin and the calculated globulins (total proteins - albumin).
The concentration of total proteins in the blood is usually relatively stable, and reflects a balance in the loss of old molecules and the production of new ones.
Total proteins can decrease in diseases:

- In which the production of albumin or globulins is compromised, as in malnutrition or serious liver disease
- Which accelerate the metabolism or loss of proteins, such as kidney disease (nephrotic syndrome)
- That increase / expand the plasma volume (diluting the blood) as in congestive heart failure

Total proteins may increase as a result of:

- Overproduction of proteins (eg inflammatory conditions, multiple myeloma)
- Dehydration

The A / G ratio can change whenever the proportion between albumin and other proteins changes (increases or decreases).

REAGENT COMPOSITION

Reagent (R1)

Cupric sulfate	6 mmol/L
Sodium-potassium-tartrate	21 mmol/L
Potassium iodide	6 mmol/L
Sodium Hydroxide	0.75 mol/L

Reagent (R2)

Standard (Proteins)	value on label

REAGENT PREPARATION AND STABILITY

Liquid and ready to use Reagents, stable up to the end of expiry, if stored as reported on the labels, protected from light and contamination is avoided. Do not freeze the Reagent.
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 or Blank Absorbance (Abs) at 540 nm > 0.150 in 1 cm cuvette.
After opening the bottles, it is advisable to withdraw the necessary volume, to immediately close the bottles and store them in the fridge in order to avoid contamination, degradation from direct light and evaporation.

SPECIMEN

Serum, heparinized plasma or EDTA plasma.
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:	546 nm (510 - 570)
Temperature:	37° C
Measurement:	against (reagent - blank)

Pipette as follow

Reagent R1	1000 µL
Sample, Std / Cal, H_2O	20 µL

Mix and after 5 minutes read Absorbance of Blank, Calibrator/Standard and Samples within 60 minutes.

CALCULATION

$$\text{Total Protein} = \frac{\text{Abs Sample - Abs Blank Reagent}}{\text{Abs Std/Cal - Abs Blank Reagent}} \times \text{Concentration Std/Cal}$$

Conversion Factor: Proteins (g/dL) x 10 = Proteins (g/L)

CALIBRATION WITH STANDARD OR CALIBRATOR

The results depend on the accuracy of the calibration, on the correct setting of the test on the instrument, on the correct volumetric ratio of reagent / sample and on the correct analysis temperature.
As an alternative to the standard included in the package, it is possible to use **MTD Diagnostics Calibrator:**

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 10 x 5 mL (Level 1)
Chemistry Control P - REF CNP1020 10 x 5 mL (Level 2)

EXPECTED VALUES

Values in g/dL

Adults:		6.6 - 8.8
Children	Female	Male
1 - 30 day(s)	4.2 - 6.2	4.1 - 6.3
1 - 6 month(s)	4.4 - 6.6	4.7 - 6.7
6 months - 1 year	5.6 - 7.9	5.5 - 7.0
1 - 18 year(s)	5.7 - 8.0	5.7 - 8.0

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 = 4.33; S.D. = 0.05; CV = 1.2%

High Level: Samples = 20; Average = 8.99; S.D. = 0.14; CV = 1.59%

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

y = 0.99x - 0,20 r = 0.95

SENSITIVITY: 0.05 g/dL

LINEARITY: 0.05 - 15 g/dL

SPECIFICITY / INTERFERENCES

No interference was observed by Ascorbic Acid up to 30 mg/dL, Bilirubin up to 40 mg/dL, Haemoglobin up to 500 mg/dL and lipemia up to 1000 mg/dL Triglycerides.

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

R1 contains SODIUM HYDROXIDE, 0,75 mol/L - pH 11.5 - CAS N.: 1310-73-2 - C R35 (H314).

COPPER SULPHATE 6 mmol/L - CAS N. 7758-98-7 - Xn N R22 (H302) R36/38 (H319 - H315) R50/53 (H400 - H410).

R22 (H302): Harmful if swallowed

R35 (H314): Causes severe skin burns and eye damage

R36/38 (H319 - H315): Irritating to eyes and skin

R50/53 (H400 - H410): Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

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