PROTEIN (TOTAL)

COD 12500 10 x 50 mL
Only for *in vitro* use in the clinical laboratory

BioSystems

PROTEIN (TOTAL)
BIURET

INTENDED USE

Reagents for the measurement of protein (total) concentration in human serum or plasma. The obtained values are useful as an aid in the evaluation of the states of dehydration and water intoxication and salt retention syndromes, and to control the evolution of multiple myeloma, and to control Wadenström macroglobulinemia.

This reagent is for use in the BioSystems A25 and A15 analyzers.

CLINICAL SIGNIFICANCE

Most of the plasma proteins are synthesized by the liver. The major exception to this is the immunoglobulins which are produced by plasma cells found in the spleen, lymph nodes and bone marrow.

The two general causes of alterations of serum total protein are a change in the volume of plasma water and a change in the concentration of one or more of the serum proteins.

Hyperproteinemia can be caused by dehydration (inadequate water intake, severe vomiting, diarrhea, Addison's disease, diabetic acidosis) or as a result of an increase in the concentration of specific proteins (immunoglobulins in chronic infections, multiple myeloma)[1,2].

Hypoproteinemia may be caused by hemodilution (salt retention syndromes, massive intravenous infusions), by an impaired synthesis (severe malnutrition, chronic liver disease, intestinal malabsorptive disease), or by an excessive protein loss due to a chronic kidney disease or severe burns[1,2].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Protein in the sample reacts with copper (II) ion in alkaline medium forming a coloured complex that can be measured by spectrophotometry[3].

CONTENTS AND COMPOSITION

A. Reagent. 10 x 50 mL. Copper (II) acetate 6 mmol/L, potassium iodide 12 mmol/L, sodium hydroxide 1.15 mol/L, detergent.

DANGER: H314: Causes severe skin burns and eye damage. P280: Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

For further warnings and precautions, see the product safety data sheet (SDS).

STORAGE AND STABILITY

Store at 2-30ºC.

Components are stable once opened until the expiry date marked in the label if they are stored well closed and care is taken to prevent contamination during their use.

On board stability: Reagents open and kept in the refrigerated compartment of the analyzer are stable 2 months.

Indications of deterioration: Absorbance of the blank over the limit indicated in "Test Parameters".

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to BioSystems S.A.

ADDITIONAL MATERIALS REQUIRED (NOT PROVIDED)

Biochemistry Calibrator (BioSystems cod. 18011) or Biochemistry Calibrator Human (BioSystems cod. 18044).

REAGENT PREPARATION

Reagent is provided ready to use.

SAMPLES

Serum or heparinized plasma collected by standard procedures. Stable for 4 weeks at 4-8ºC[4].

Anticoagulants other than heparin should not be used.

CALIBRATION

A reagent blank should be done every day and a calibration at least every 60 days, after reagent lot change or as required by quality control procedures.

QUALITY CONTROL

It is recommended to use the Biochemistry Control Serum level I (cod. 18005, 18009 and 18042) and II (cod. 18007, 18010 and 18043) to verify the accuracy of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if control results are not within the acceptable limits.

REFERENCE VALUES

Serum, adults[1]:

Ambulatory	64-83 g/L
Recumbent	60-78 g/L

Concentrations are lower in child. Plasma total protein concentration is 2 to 4 g/L higher due to the presence of fibrinogen as well as some other trace proteins[1].

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

METROLOGICAL CHARACTERISTICS

The metrological characteristics described below have been obtained using an A25 analyzer. Results are similar with A15.

- Detection limit: 1.6 g/L.
- Linearity limit: 150 g/L. For samples with higher values, dilute manually or refer to the Test Parameterization for Automatic dilution (note that all these samples will be diluted with the same dilution ratio).
- Precision:

Mean concentration	Repeatability (CV)	Within-laboratory (CV)
51.8 g/L	1.0 %	1.1 %
82.1 g/L	1.2 %	1.5 %

- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

LIMITATIONS OF THE PROCEDURE

- Interferences: bilirubin (up to 30 mg/dL), hemolysis (hemoglobin up to 500 mg/dL) and lipemia (triglycerides up to 975 mg/dL) do not interfere. Other drugs and substances may interfere[5].

BIBLIOGRAPHY

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. Burtis CA, Ashwood ER, Bruns DE. WB Saunders Co, 2005.
2. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.
3. Gornall AG, Bardawill CS, David MM. Determination of serum proteins by means of the Biuret reaction. *J Biol Chem* 1949; 177: 751-766.
4. Word Health Organization (WHO). Use of anticoagulants in diagnostic laboratory investigations Document WHO/DIL/LAB/99.1, Rev.2; 2002. http://www.who.int/iris/handle/10665/65957.
5. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

TEST PARAMETERS

R1: use Reagent A.

R2: use Reagent B.

	A25	A15
GENERAL		
Name	**PROTEIN TOTAL**	**PROTEIN TOTAL**
Sample type	SER	SER
Analysis mode	endpoint mon.	endpoint mon.
Units	g/L	g/L
Turbidimetry test	no	no
Decimals	0	0
Type of reaction	increasing	increasing
PROCEDURE		
Reading mode	bichrom.	bichrom.
Main filter	535	535
Reference filter	670	670
Sample	4	4
Vol. R1	300	300
Vol. R2	-	-
Washing	1.2	1.2
Reading 1 (cycle)	21	14
Reading 2 (cycle)	-	-
Reagent 2 (cycle)	-	-
Predilution factor	-	-
Predilution reduced factor	2	2
CALIBRATION AND BLANK		
Calibration type	multiple	multiple
Number of calibrators	-	-
Calibration curve	-	-
OPTIONS		
Blank absorbance limit	0.150	0.150
Kinetic blank limit	-	-
Linearity limit	150	150
Substrate depletion	-	-

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