Total Protein (Biuret Method)

In-vitro Diagnostic reagent/kit for quantitative determination of Total Protein in serum/plasma sample on Photometric System.

Reagent
Reagent: Biuret Reagent
Standard: Total Protein (Conc.5.5 g/dL)

Principle
Proteins together with copper ions form a violet blue color complex in alkaline solution. The absorbance of the color is directly proportional to the concentration.

Summary
Measurement of total protein is a useful test in a variety of disorders. Decreased total protein concentrations can be detected in defective protein synthesis in the liver, protein loss due to impaired kidney function, intestinal malabsorption or nutritional deficiency. Elevated protein levels occur in chronic inflammatory disorders, liver cirrhosis and dehydration.

Reagent Storage instruction and stability
The reagents and standard is stable till the date of expiry, if stored at 2°C - 30°C, protected from light and contamination is avoided.
Do not freeze the reagents

Components and Concentrations
Reagent: Sodium hydroxide 100 mmol/L, Potassium Sodium tartarate 16 mmol/L, Copper Sulphate 0.2 mmol/L.
Standard: Protein (Conc. 5.5 g/dL)

Waste Management
Please refer to local regulatory requirements.

Reagent Preparation
The reagent and the standard are ready to use.

Materials required but not provided
NaCl solution 9 g/L
General laboratory equipment

Specimen
Serum, heparin plasma or EDTA plasma Stability:
1 months at 2° – 8 °C, 3 months at -20 °C
Only freeze once!
Discard contaminated specimens.

Assay Procedure
Wavelength	546 nm
Light path	10 mm
Temperature	37°C

Measurement Against reagent blank

	Blank	Sample/Standard
Sample/Standard	--	10 µL
Reagent	1000 µL	1000 µL
Mix, incubate for 10 min. at 37°C .		

Calculation
$$\text{Total protein (g/dL)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std/Cal}} + \text{conc. std (g/dL)}$$

Quality Control
For internal quality normal and abnormal controls should be assayed with each batch of samples.

Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions
1. The reagent contains sodium Hydroxide. Do not swallow! If the reagents get in contact with skin or mucous membranes rinse immediately with water.
2. Total Protein Standard contains animal material. The standard should be handled as potentially infectious and with the same precautions used for patient specimens.
3. In serum or plasma from patients who have received large intravenous amounts of polydextrans too high values can be measured with the biuret method. In such cases an alternative method (e.g. kjeldahl) has to be used.
4. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings
5. In very rare cases, samples of patients with gammopathy might give falsified results.
6. For professional use only!

Performance Characteristics Measuring Range
Measuring Range of the assay is 0.1 – 15 g/dL. If such value is exceeded the sample should be diluted 1 : 1 with NaCl solution (9 g/L) and results multiplied by 2.

Linearity/ Limit of Maximum Detection
The maximum limit of detection is 15 g/dL.

Sensitivity/Limit of Detection
The lower limit of detection is 0.1 g/dL.

Specificity / Interferences
No Interferences was observed by Ascorbic acid up to 30 mg/dL, Bilirubin up to 40 mg/dL and Triglycerides up to 2000 mg/dL.

Precision
Intra assay n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	5.20	0.04	0.76
Sample 2	7.28	0.06	0.87
Sample 3	9.22	0.04	0.45

Inter assay n = 20	Mean [g/dL]	SD [g/dL]	CV [%]
Sample 1	5.13	0.05	0.89
Sample 2	7.19	0.06	0.80
Sample 3	9.17	0.07	0.75

Method Comparison
A comparison of Precision Biomed Total Protein (y) with a commercially available test (x) using 20 samples gave following results:
$y = 1.033x - 0.184$; $r^2 = 0.954$.

Reference Range
	g/dL	g/L
Adults	6.6 – 8.0	66 - 80
Neonates (1 day - 4 weeks)	4.6 - 6.8	46 - 68
Infants (2-12 months)	4.8 - 7.6	48 -76
Children (over 12 months)	6.0 - 8.0	60 - 80

Note: It is recommended that each laboratory should establish its own reference range based on the patient population.

Quick Reference

Parameter	Total Protein
Mode	End Point
Wavelength	546 nm
Path length	10 mm
Standard conc.	5.5 g/dL
Reagent Vol.	1000 µL
Sample Volume	10 µL
Incubation Time	10 min
Temperature	37^{0}C
Blanking	Reagent Blank
Normal Range	Adults 6.0 - 8.0 g/dL
Linearity	15 g/dL
Sensitivity	0.1 g/dL

Pack Size :

Cat No.	Configuration	Pack
TP000100	Reagent - 2 x 50mL Standard – 1 x 2mL	100mL
TP001000	Reagent - 2 x 500mL Standard – 1 x 4mL	1000mL

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st e.d. Frankfurt: TH- Books Vertagsgesellschaft; 1998.p.644-7.
2. Johnson Am, Rohlfs EM, Silverman LM. Protein. In: Burtis CA, Ashwood ER, editors.
3. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Assocation for Clinical Chemistry Press 2000.
4. Tietz, N.W., Fundamentals of Clinical Chemistry Philadelphia, W.B. Saunders, pp. 299, (1976).

Version No. TP/00

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE

Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :

Precision Biomed Pvt. Ltd.

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