Total Protein (BIURET METHOD)

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

Labgene biotech

ORDER INFORMATION

Cat no.	Kit Information
LG140-100	Reagent - 2 x 50mL Standard – 1 x 2mL
LG140-1000	Reagent - 2 x 500mL Standard – 1 x 4mL

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.

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.

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 legal requirements.

REAGENT PREPARATION & STORAGE

Reagents are ready to use and are stable till the expiry date when stored at recommended temperature and avoid contamination. Do not freeze the reagents!

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution 9 g/L.
General laboratory equipments.

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

CALCULATION

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

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

- The reagent contains sodium Hydroxide. Do not swallow! If th reagents get in contact with skin or mucous membranes rinse immediately with water.
- Total Protein Standard contains animal material. The standard should be handled as potentially infectious and with the same precautions used for patient specimens.
- 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.
- For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings
- In very rare cases, samples of patients with gammopathy might give falsified results.
- 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 RANGE

The maximum limit of detection of the assay is 15.0 g/dL.

SENSITIVITY/LIMIT OF DETECTION

The lower limit of detection of the assay 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; r2 = 0.954.

REFERENCE RANGE

	Total Protein (g/dL)
Neonates (1 day - 4 weeks)	4.6 - 6.8
Infants (2-12 months)	4.8 - 7.6
Children (over 12 months)	6.0 - 8.0
Adult	6.6 – 8.0

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

ASSAY PARAMETERS

Mode	Endpoint
Wavelength	546 nm
Path length	10 µL
Standard conc.	5.5 g/dL
Reagent Vol.	1000 µL
Sample Volume	10 µL
Incubation Time	10 min
Temperature	37°C
Blanking	Reagent Blank
Normal Range	Adults 6.0 - 8.0 g/dL
Linearity	15 g/dL
Sensitivity	0.1 g/dL

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).

INDEX OF SYMBOLS

ISO 13485	International Organization or Standardization		Keep out of Sunlight
	Manufacturer	IVD	For invitro diagnostic use only
	Expiry date		Read product insert before use.
LOT	Lot (batch) number		Do not use if package is damaged
2°C 8°C	Store between 2-8°c		Keep Away From Moisture

ART/IFU/PRC-140-02

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