Pariksha Biotech
A game changer in IVD

Total Protein Estimation Kit

High-Q Total Protein-ML

Biuret Method

HIGH Q
Command on Quality

Intented Use:
Kit for the quantitative determination of Total Protein in human serum and plasma.

Summary and Clinical Significance:

Plasma proteins are synthesized predominantly in the liver, plasma cells, lymph nodes, the spleen and in bone marrow. In the course of disease the total protein concentration and also the percentage represented by individual fractions can significantly deviate from normal values. Hypoproteinemia can be caused by diseases and disorders such as loss of blood, sprue, nephrotic syndrome, severe burns, salt retention syndrome and Kwashiorkor (acuteprotein deficiency). Hyperproteinemia can be observed in cases of severe dehydration and illnesses such asmultiple myeloma. Changes in the relative percentage of plasma proteins can be due to a change in the percentage of one plasma protein fraction. Often in such cases the amount of total protein does not change. The A/G-ratiois commonly used as an index of the distribution of albumin and globulin fractions. Marked changes in this ratio can be observed in cirrhosis of the liver, glomerulonephritis, nephrotic syndrome, acute hepatitis, lupus erythematosus as well as in certain acute and chronic inflammations. Total protein measurements are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow, as well as other metabolic or nutritional disorders.

Test Principle:
Divalent copper reacts in alkaline solution with protein peptide bonds to form the characteristic purple-colored biuret complex. Sodium potassium tartrate prevents the precipitation of copper hydroxide and potassium iodide prevents autoreduction of copper.

protein + Cu^{2+} $\xrightarrow[\text{solution}]{\text{alkaline}}$ Cu-Protein Violet Coloured Complex

The color intensity of the complex is directly proportional to the protein concentration which can be determined photo metrically.

Storage and Stability:
All the reagents are to be stored at 2-8ºC and are stable till the expiry date mentioned on the label.

Specimen:
Serum / Heparinised or EDTA plasma.

Procedure:
Pipette into test tubes labelled Blank (B), Standard (S) and Test (T) as follows:

Reagent	B	S	T
1. Total Protein Reagent	**1.0 ml**	**1.0 ml**	**1.0 ml**
2. Total Protein Standard (Conc. 6 gm/dl)	**-**	**10 µl**	**-**
Specimen	**-**	**-**	**10 µl**

Mix well and incubate at 37ºC for 5 minutes. Read absorbance of Standard (S) and Test (T) against Reagent Blank (B) at 546 nm (540-578 nm)

Calculations:

1.Total Protein(TP) in gm/dl= $\frac{\text{Abs. of T}}{\text{Abs. of S}} \times 6$

3.Globulin (gm/dl)= TP-Ab

4.A/G Ratio= $\frac{\text{Albumin (gm/dl)}}{\text{Globulin (gm/dl)}}$

Note : To calculate Globulin and A/G Ratio user should estimate albumin concentration of the sample also using High-Q Albumin - ML kit.

Normal Range:

Total Protein	:	6.0–8.4 gm/dl
Globulin	:	2.3–3.6 gm/dl
A/G Ratio	:	1.0–2.3 gm/dl

It is recommended that laboratories establish their own normal range.

Analytical sensitivity (Lower Detection Limit):
Detection limit: 0.2 g/dl or 2.0 g/l
The detection limit represents the lowest measurable protein concentration that can be distinguished from zero.

Imprecision:
Reproducibility was determined using controls in an internal protocol. The following results were obtained.

		Within run	
Sample	**Mean(g/dl)**	**SD(g/dl)**	**CV%**
Control serum 1	5.20	0.039	0.73
Control serum 2	5.37	0.039	0.75
Control serum 3	5.70	0.037	0.65

		Between day	
Sample	**Mean(g/dl)**	**SD(g/dl)**	**CV%**
Control serum 1	5.15	0.070	1.36
Control serum 2	5.48	0.086	1.57
Control serum 3	5.95	0.085	1.43

Method comparison:
A comparison of the High-Q Total Protein - ML (y) with a commercial obtainable assay (x) gave following results: y = 0.951 x + 2.75; r=0.999

Quality Control:
To ensure adequate quality control, the use of commercial reference control serum is recommended with each assay batch. Use of Quality Control material checks both, the instrument and the reagent functions.

Notes:
1. If a large volume of reagent is required for absorbance reading, requisite volumes can be taken in multiples keeping the same ratio of reagents to specimen / standard.
2. As with all the diagnostic procedures, the Physician should evaluate data obtained by the use of this kit in light of other clinical information.

System Parameters:

Reaction type	:	End Point
Reaction Slope	:	Increasing
Wave length	:	546 nm (540-578)
Flow cell Temp.	:	37°C
Sample volume	:	10µl
Reagent volume	:	1000µl
Standard concentration	:	6
Units	:	gm/dl
Blanking with	:	Reagent
Low normal	:	6.0
High normal	:	8.4
Linearity	:	10

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Literature:

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2. Brobeck J.R. (ed.). Physiological Basis of Medical Practice, 9th Baltimore, MD: Wilkins and Wilkins, 1973:4-7.
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4. Josephson B, Gyllenswärd C. The Development of the Protein Fractions and of Cholesterol Concentration in the Serum of Normal Infants and Children. Scandinav J Clin Lab Investigation 1957; 9:29.
5. Koller A. Total serum protein. in Kaplan L.A., Pesce A.J. (ed.). Clinical Chemistry, Theory, Analysis, and Correlation. St. Louis: Mosby Company, 1984:1316-1319
6. Passing H. Bablok W. A New Biometrical Procedure for Testing the Equality of Measurements from Two Different Analytical Methods. J Clin Chem Clin Biochem 1983;21:709-720.
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8. Weichselbaum T.E. Amer J Clin Path 1946;16:40.

Order Information:

Ref./Cat. No.	Pack Size	Presentation
P-TPN - 200	4 x 50 ml	Mono Reagent

Product Features

- **Liquid Stable, Ready to use Mono Reagent**
- **5 Minutes End Point Reaction**
- **Lipid Clearing Factor(LCF)**
- **Total Protein standard provided (Standard Conc: 6 gm/dl)**
- **Linearity: 10 gm/dl)**
- **Measuring Wavelength 546 nm (540 – 578 nm)**
- **Serum/ Heparinized or EDTA Plasma the specimens**
- **Available as multipurpose reagents and dedicated system packs**

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Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside
SCAN TO EXPLORE MORE

Manufactured in India by :
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