Total Protein Test Kit

REF	Pack Size	Reagent 1	Reagent 2 (Std)
TTPLMS01	2×50 ml	2×50 ml	1×2 ml
TTPLMS02	4×50 ml	4×50 ml	1×2 ml
TTPLMS03	1x1000 ml	1x1000 ml	1x5 ml

INTENDED USE
Total protein kit is used for the quantitative estimation of protein concentration in human serum or plasma.

CLINICAL SIGNIFICANCE
Proteins are main constituents for the growth of body muscles, Enzymes, Hormones and several other key functional Entities in the body. Increased level of protein is found mainly in dehydration and decreased levels are found mainly in malnutrition. Protein forms a colored complex with cupric ions in alkaline medium. The intensity of the color formed is directly proportional to the amount of protein present in the sample.

METHOD
End point method, Single reagent chemistry & Biuret method.

TEST PRINCIPLE
Protein forms a colored complex with cupric ions in alkaline medium.

Kit Contents/Components
Reagent 1: Biuret Reagent & Reagent 2: Standard Protein (6 gm/dl)

MATERIAL REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi-automated, calibrated micropipettes, glass or high-quality polystyrene cuvettes, test tubes/rack, heating bath, controls, saline.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not pipette by mouth. Avoid contact with skin and eyes. If spilt thoroughly wash affected area with water.
3.Do not use the reagent after the expiration date printed on the kit.

REAGENT PREPARATION AND STABILITY OF REAGENT
Biuret reagent and protein standard are ready to use & are stable up to specified expiry date. Standard vial once open should be stored at 2-8^{o}C.
Stability since first opening of vials: within 60 days at 2-8^{o}C.

REAGENT DETERIORATION
1.Discard the reagent if absorbance exceeds 0.2 at 546 against distilled water.
2.Keep the Standard vial plugged after use, in order to avoid deterioration.

SPECIMEN
Serum/plasma is stable for 7 days at 2-8^{o}C and 1 month at -20^{o}C.

PROGRAM

Reaction mode	End point
Wavelength	546 nm (530 – 570 nm)
Light path	10 mm
Blanking	Reagent blank
Reagent Volume	1000 µl
Standard Volume	10 µl
Sample Volume	10 µl
Incubation time	10 min. at 37°C
Standard concentration	6 gm/dl
Linearity	12 gm/dl

PROCEDURE

Test	Reagent	Standard	Sample
Biuret Reagent	1000 µl	1000 µl	1000 µl
Standard	---	10 µl	---
Sample	---	---	10 µl

Mix & incubate for 10 minutes at 37°C.
Measure the absorbance of sample and standard against the reagent blank.

CALCULATION
Concentration (C) of total protein in the Sample:

$$C = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times 6 \text{ gm/dl (Conc of std.)}$$

C = 19 x Absorbance of Sample (gm/dl)

NORMAL VALUES

Adults:	6.6 – 8.7 gm/dl
Infants (2-12 months)	4.8 – 7.6 gm/dl
Children (over 12 months)	6.0 – 8.0 gm/dl

LIMITATIONS
If the value exceeds 12 gm / dL, dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

QUALITY CONTROL AND CALIBRATION
It is recommended to perform internal quality control with assayed normal and assayed abnormal, to confirm the validity of the test and assure the accuracy of patient result.
Using the recommended calibrator or the Standard included, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

WASTE DISPOSAL
This Product is made to be used in professional laboratories.

HIGHLIGHT
1.Storage condition mentioned on the kit is to be used.
2.Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
3.Before testing bring the reagents to the RT.
4.Avoid reagents contamination.
5.Every time use new pipette-tips for pipetting out the reagents.
6.These Reagent kits meant for laboratory/professional use only, not for Drug use.

REFERENCE
Tietz N.W., ed. Clinical Guide to laboratory Tests, 3rd ed.
Philadelphia, Pa: W.B. Saunders,610 – 611.
Lords Data File.

REF	Catalog No.	Σ	Contain Sufficient for test
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

Lord's Mark Industries Pvt. Ltd., Plot No. A71, Royal Ind. Hub, Poman, Kaman-Bhiwandi Road, Taluka -Vasai, Palghar- 401208, Maharashtra (India). Customer Care No.: 8425982321. Email: ivdcare@lordsmark.com; Website: www.lordsmed.com