Total Protein Test Kit

REF	Pack Size	Reagent 1
TTPLMA01	5 x 20 ml	5 x 20 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

MATERIAL REQUIRED BUT NOT PROVIDED
Fully Auto Biochemistry Analyzer: LM1015-200TPH.
Calibrator
Controls.

REAGENT STORAGE, STABILITY AND HANDLING
Biuret reagent is ready to use & are stable up to specified expiry date.
Stability since first opening of vials: within 60 days at 2-8ºC.

ON - BOARD REAGENT STABILITY-
On board reagent stability is 15 days.

Specimen
Serum/plasma is stable for 7 days at 2-8ºC.

APPLICATION For LM1015-200 TPH

Method	End point
Blank	Reagent blank
Primary filter	546
Secondary filter	No
R1 Volume	300
R1 Position	*
Incubation time (Sec)	560
R2 Volume	-
R2 Position	-
Incubation time (Sec)	-
Sample Volume	3
Read Time	40
Calibrator Concentration	As vial label
Mix speed set	Middle
Unit	gm/dl
Decimal	2

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CALIBRATION
For calibration, it is recommended to use any multi calibrator.

CALCULATION
Calculations Fully automated systems automatically calculate the Total Protirn concentration of
each sample.

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.

SAFETY PRECAUTIONS AND WARNINGS
1.For in-vitro diagnostics use only.
2.Do not use the reagent after the expiration date printed on the kit.
3.Avoid reagents contamination.
4.These Reagent kits meant for laboratory/professional use only, not for Drug use.

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 multi calibrator, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range

PRECISION
Reproducibility was determined using quality control sera as shown below

	Intra run		Inter run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (gm/dl)	6.0	3.75	5.98	3.79
SD	0.21	0.11	0.18	0.06
CV (%)	0.03	0.03	0.03	0.02

WASTE DISPOSAL
Reagents must be disposed off in accordance with local regulations.

REFERENCES
Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa: WB Saunders, 1995:22-24.
Lords Data File.

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

IFU/TTP/02 Rev.: 00; Rev Date.: 22/07/2024

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