LiquiMAX Total Protein-SLR

Biuret Method

ORDER INFORMATION:

Ref. No.	Pack Size	Presentation
AVTPN - 200	4 x 50 ml	Mono Reagent

INTENTED USE:

LiquiMAX Total Protein-SLR is an in-vitro diagnostic kit for the quantitative determination of Total Protein in human serum and plasma.

PRODUCT FEATURES:

1. Liquid Stable, Ready to use Mono Reagent
2. 5 Minutes End Point Reaction
3. Lipid Clearing Factor (LCF)
4. Total Protein standard provided (Standard Conc: 6 gm/dl)
5. Linearity: 10 gm/dl
6. Measuring Wavelength 546 nm (540 – 578 nm)
7. Serum/ Heparinized or EDTA Plasma the specimens
8. Available as multipurpose reagents and dedicated system packs

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+} $\xrightarrow{\text{Alkaline Solution}}$ 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 & STABILITY

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

KIT COMPONENTS

1. Total Protein Reagent
2. Total Protein Standard : Concentration as stated on the label

COMPOSITION

Sodium potassium tartrate	15 mmol/L
Sodium iodide	100 mmol/L
Potassium iodide	5 mmol/L
Copper (II) sulphate	19 mmol/L

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8ºC & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent or blank reagent absorbance exceeds 0.9 at 546 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN

Serum / Heparinised or EDTA plasma.

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

TEST PROCEDURE

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

Reagent	B	S	T
1. Total Protein Reagent	1000µl	1000µl	1000µl
2. Total Protein Standard (Conc. 6 gm/dl)	-	10 µl	-
3. 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 LiquiMAX Albumin - SLR kit.

EXPECTED VALUES

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.

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:

a) When using a new reagent or lot.

b) When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 10 gm/dl

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 0.2 gm/dl

3. Interferences

No significant interference was observed from Bilirubin up to 20 mg/dl (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dl,Lipemia as Triglycerides up to 2000 mg/dl, Ascorbic acid up to 50 mg/dl.

4. Precision:

Intra-Assay

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

Inter-Assay

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

5. Method comparison:

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

LIMITATIONS

Measuring range: 0.2-10 gm/dl. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

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.

RFENENCE

1. Bablok W. et al. A General Regression Procedure for Method Transformation. J Clin Biochem 1988; 26:783-790.
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.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com

Customer Care No. : +91 93065 12576, CIN No.: U24230HR2006PTC118875

Ver. : 05/01-26