TOTAL PROTEIN

METHOD – BIURET
PRODUCT CODE – LT02

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Total Protein in serum / plasma using Biuret method.

SUMMARY AND PRINCIPLE

Increased levels of Total Protein are found in dehydration, multiple myeloma and chronic liver diseases, while decreased levels are found in renal disease and terminal liver failure. Total Protein is a reagent kit for quantitative determination of total protein in human serum and plasma based on Biuret method.

$$\text{Protein} + Cu^{2+} \xrightarrow{\text{Alkaline Medium}} \text{Protein Biuret Complex}$$

KIT COMPONENTS

Reagent 1: Biuret Reagent
Reagent 2: Total Protein Standard (6 gm/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Total Protein is single ready to use reagent. The reagent kit should be stored at room temperature and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDELING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.300 O.D. against D/W at 546 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Total Protein
Reaction Type	End Point
Primary Wavelength	546 nm
Flow Cell Temp.	37 °C
Blank setting	Reagent
Blank abs. limit	< 0.300

Reagent Volume	1000 µl
Sample Volume	10 µl
Incubation Time	5 Min
Incubation Temperature	37 °C
Standard Conc.	6 gm/dL
Linearity	18 gm/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Heparinized or EDTA plasma can be used. Avoid haemolysis since haemoglobin reacts as a protein in the total protein assay. Total protein in serum/plasma is stable for 3 days at 2-8 ^{0}C and 6 months at -20 ^{0}C.

COMPONENTS OF REAGENT

Component	Concentration
Cupric Sulphate	7 mmol/l
Potassium Iodide	6 mmol/l
Na^+ / K^+ Tartarate	40 mmol/l
Sodium Hydroxide	700 mmol/l
Stabilizers, inactive ingredients and surface-active agents.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	10 µl	NA
Sample	NA	NA	10 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 5 mins at 37.			
Aspirate reaction mixture into flow cell and measure the absorbance.			
The final colour is stable for 8 hours if not directly exposed to light.			

CALCULATION

$$\text{Total Protein (gm/dL)} = \frac{\text{Abs. of sample} \times 6}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

Adults - 6.2 – 8.5 gm/dL

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 0.35 - 18 g/dL. If the Total Protein value exceeds linearity limit (above 18 g/dL), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Total Protein value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL and Haemoglobin upto 500 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (g/dL)	SD (g/dL)	CV %	Mean (g/dL)	SD (g/dL)	CV %
Low Value Serum	4.18	0.08	1.8	3.90	0.08	2.1
High Value Serum	6.65	0.03	0.5	6.28	0.06	0.9

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Total Protein. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

BIBLIOGRAPHY

1. Tietz NW, ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia Pa : W.B. Saunders, 1995 : 518 - 522.

2. Koller A. Total serum protein. In Kaplan LA, Pesce AJ, eds. Clinical Chemistry Theory, Analysis and Correlation. St. Louis : Mosby Company, 1984 : 1316 - 1319.

3. Henri R.J., et.al. "Clinical Chemistry - Principles and Techniques" - Harper & Row II ed (1974).

4. Flack C.P. and Woolen J.W. Clin. Chem. 30, 559 (1984).

Symbol	Explanation	Symbol	Explanation
	Manufactured By	IVD	In Vitro Diagnostic Use
LOT	Lot Number		Read Instructions Before Use
REF	Catalogue Number		Storage Temperature
	Manufacturing Date	Σ	Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485 : 2016
GMP
CE