QUANTON BIOLIFE SCIENCES

YOUR PARTNER IN PRECISION MEDICINE

Total Protein Test Kit

Colorimetric test - Biuret Method

QBL/PDS/TP_022

Quantitative determination of Total Protein in serum/plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
TP 100	2 X 50 mL
TP 200	2 X 100 mL

CLINICAL SIGNIFICANCE

The proteins are macromolecular organic compounds, widely distributed in the organism. They act like structural and transport elements. The proteins of the serum are divide in two fractions, albumin and globulins the determination of total proteins is useful in the detection of: - High protein levels caused by hemoconcentration like in the dehydrations or increase in the concentration of specific proteins. - Low protein level caused by hemodilution by an impaired synthesis or loss (as by hemorrhage) or excessive protein catabolism4,5. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method
Photometric test according to biuret method.

PRINCIPLE

Proteins give an intensive violet-blue complex with copper salts in an alkaline medium. Iodide is included as an antioxidant. The intensity of the color formed is proportional to the total protein concentration in the sample.

REAGENT

Reagent I : Biuret reagent
Protein Standard : 6 g/dl (store at 2-8 °C)

REAGENT PREPARATION

The Reagent is ready to use.

REAGENT STORAGE AND STABILITY

The Reagent is stable till expiry when stored at 2 - 8°C.
Store protected from light.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum, heparin plasma or EDTA plasma
Stability: 7 days at 4 – 8°C
1 Year at –20°C
Discard contaminated specimens! Freeze only once!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	540 nm
Reaction Temperature	Room Temperature
Reaction Type	End point
Cuvette	1 cm light path
Measurement	Against Reagent
Sample Volume	20 µl
Reagent Volume	1000 µl
Incubation	10 minutes
Low Normal	6.6 g/dl
High Normal	8.3 g/dl
Linearity	10 g/dl

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	Blank	Standard	Test
Reagent 1	1000µL	1000µL	1000µL
Standard	--	20µL	--
Sample	--	--	20µL

- Mix well, Incubate for 10 min at 20-25°C. Measure absorbance of the sample (Ac) and standard (As) against reagent blank.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 10 g/dL.
- Dilute samples above this concentration 1:1 with 0.9% saline
- Repeat assay. Multiply the result by 2.

CALCULATION

$$\text{Total Protein g/dL} = \frac{\text{Abs.of Sample (AT)}}{\text{Abs.of Standard (AS)}} \times \text{Standard Value (6g/dL)}$$

CLIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of **Total Protein standard** have been made traceable to the NIST Standard Reference Material® SRM 927d[2].

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox 2	5.23	0.11	2.01
Randox 3	4.09	0.06	1.47

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	5.24	0.08	1.44
Randox 3	4.08	0.03	0.85

LINEARITY

The method is linear upto a concentration of 10 g/dL. Dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Total Protein is 0.1 g/dL.

METHOD COMPARISON

A comparison of Accucare Total Protein with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9300$

REFERENCE VALUES

Serum / Plasma	6.6-8.3 g/dl

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 20 mg/dl.
- Hemoglobin: No interference found upto 350 mg/dL.
- Lipemia: No interference found upto 200 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Gournall A et al Journal of Biol.Chem 177 (1949), 751.
Tietz, N.W., Fundamentals of Clinical Chemistry. W.B. Saunders Co., Philadelphia, PA (1970), 302.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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