ROBONIK®

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prietest™ ...Clinical Chemistry Reagents

TOTAL PROTEIN

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of Total Protein in serum or plasma on photometric systems.

ORDERING INFORMATION	**Pack Size**	**Cat No.**
	2 X 50 ml	TP 02 50
	4 X 50 ml	TP 04 50
	2 X 500 ml	TP 02 500

CLINICAL SIGNIFICANCE :
Measurement of Total Protein is a useful test in a variety of disorders. Decreased Total Protein concentrations can be detected in defective protein synthesis in the liver, protein loss due to impaired kidney function, intestinal malabsorption or nutritional deficiency. Elevated protein levels occur in chronic inflammatory disorders, liver cirrhosis and dehydration.

METHOD :
Photometric test according to Biuret method, End Point.

PRINCIPLE :
Proteins together with copper ions form a violet blue color complex in alkaline solution. The absorbance of the color is directly proportional to the concentration.

Proteins + Cu^{2+} ⟶ Colored complex

REAGENTS :
COMPONENTS AND CONCENTRATIONS:
N. B: Concentrations are those in the final test mixture.

Sodium Hydroxide	:	0.1 N
Potassium Sodium Tartrate	:	16 mmol/l
Copper Sulphate	:	6 mmol/l
Preservative & Stabilizer		
Standard	:	6.0 g/dl (60 g/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :
The reagents are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 30°C and contamination is avoided. Do not freeze the reagents!
The standard is stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C

WARNINGS AND PRECAUTIONS :
1. In serum or plasma from patients who have received large intravenous amounts of polydextrans too high values can be measured with the biuret method. In such cases an alternative method (e.g. Kjeldahl) has to be used.
2. The reagents contain sodium hydroxide. Do not swallow! If the reagents come in contact with skin or mucous membranes rinse immediately with water!
3. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :
Please refer to local regulation requirements.

REAGENT PREPARATION :
The reagent and standard are ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED :
NaCl solution 9g/l, General laboratory equipment, Analyser/Photometer, Pipettes etc.

SPECIMEN :
Serum or plasma.
Stability: 6 days at 20 to 25°C, 4 weeks at 4 to 8°C, at least one year at –20°C
Discard contaminated specimens.

ASSAY PROCEDURE :
Application sheets for automated systems are available on request.

Wavelength	:	Hg 546 nm, 540 nm
Optical Path	:	1 cm
Temperature	:	37°C
Mode	:	End Point

Bring all the contents of the kit to Room Temperature prior to use.
Read absorbance of sample against reagent blank
Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

	Blank	**Standard**	**Sample / Control**
Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	20 µl	—	—
Standard	—	20 µl	—
Sample / Control	—	—	20 µl

Mix and read the absorbance (A) after 10 minutes of incubation but within 60 minutes.

CALCULATION :
With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. Standard} - \text{Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

CONVERSION FACTOR : Total Protein (g/dl) X 10 = Total Protein (g/L)

CALIBRATION :
For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :
To ensure adequate quality, use of the commercially available control sera is recommended.

ADDITIONAL CALCULATIONS :
following formulas are used to calculate Globulin & A to G Ratio

Globulin (g/dl)	=	Total Proteins – Albumin
A to G Ratio	=	Albumin / Globulin

PERFORMANCE CHARACTERISTICS :
MEASURING RANGE :
The test has been developed to determine Total Protein concentrations within a measuring range from 0.1 to 15 g/dl (1 to 150 g/L). When values exceed higher limit of the range samples should be diluted 1+1 with NaCl solution (9 g/l) and the result multiplied by 2.

SPECIFICITY / INTERFERENCES :
No interference was observed by Ascorbic Acid up to 30 mg/dl (1703.4 µmol/L), Bilirubin up to 40 mg/dl (684 µmol/L), Hemoglobin up to 500 mg/dl (5 g/L) and lipemia up to 1000 mg/dl (11.4 mmol/L) Triglycerides. A list of drugs and other interfering substances with Total Protein determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :
The lower limit of detection is 0.1 g/dl (1g/L).

PRECISION :

Intra-assay precision n = 20	Mean [g/dl]	SD [g/dl]	CV [%]
Sample 1	7.95	0.06	0.78
Sample 2	6.88	0.03	0.49
Sample 3	5.49	0.04	0.73

Inter-assay precision n = 20	Mean [g/dl]	SD [g/dl]	CV [%]
Sample 1	5.37	0.08	1.49
Sample 2	6.70	0.09	1.34
Sample 3	7.87	0.13	1.65

METHOD COMPARISON :
A comparison between Robonik Prietest Total protein (y) and a commercially available test (x) using 20 samples gave following results:

Linear Regression	:	y = 0.9551 x + 0.9705 g/dl
Correlation Coefficient	:	r = 0.9246

REFERENCE RANGE :

Adults	6.6 to 8.8 g/dl (66 to 88 g/L)			
Children	**Female** g/dl		**Male** g/dl	
1 to 30 day(s)	4.2 to 6.2	(42 to 62 g/L)	4.1 to 6.3	(41 to 63 g/L)
1 to 6 month(s)	4.4 to 6.6	(44 to 66 g/L)	4.7 to 6.7	(47 to 67 g/L)
6 months to 1 year	5.6 to 7.9	(56 to 79 g/L)	5.5 to 7.0	(55 to 70 g/L)
1 to 18 year(s)	5.7 to 8.0	(57 to 80 g/L)	5.7 to 8.0	(57 to 80 g/L)

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Christensen, S. E., *Proteins*. Clinical Chemistry : Concepts and Application, Anderson, S. C., Cockayne, S. (W. B Saunders eds. Philadelphia USA), (1983), 188
2. Tiez, N. W., Clinical guide to laboratory tests. 3rd Ed, (W. B. Saunders eds. Philadelphia USA), (1995), 518.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995

INSTRUMENT APPLICATION ***prietest TOUCH***
Name : TOTPROT, Mod : END-P Pri.: 546 , Sec.: 0 Temp: 37C , KF : 1.000 Vol : 500ul , Unit : g/dl Lag : 5 , Read : NA Blk : Y, QC : Y, Norm : Y Std : 1 , Concen : Std.: 1 = 6.0 Normal HI = 8.8 Normal LO = 6.6 QCNH : * QCNL : * QCABH = * QCABL = * Rgnt. Linearity : 15 NOTE : * Indicates user definable parameter. NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	TOTAL PROTEIN
Reaction	End Point
Reaction Slope	Increasing
Wavelength 1	546 nm
Temperature	37°C
Zero Setting	Reagent Blank
Standard Conc.	6
Units	g/dl
Sample Volume	20 µl
Reagent Volume	1000 µl
Incubation Time	10 minutes
Reference Range	6.6 to 8.8
Reagent Linearity	15

ROBONIK®

An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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