

BioMed-Total Protein



Colorimetric, Endpoint

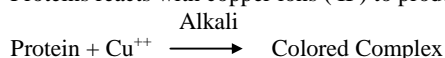
REF: TP116250 (1x250 ml)
TP116240 (2x120 ml)
TP1161000 (2x500 ml)

INTENDED FOR USE

For the quantitative determination of Total Proteins in serum .

PRINCIPLE:

Proteins reacts with copper ions (II) to produce a blue violet color compound in alkaline medium .



The color intensity is proportional to the concentration of total proteins present in the sample

SPECIMEN COLLECTION:

Non hemolyzed fresh serum , plasma with heparin .

Do not use lipemic or hemolyzed samples .

Total protein in serum or plasma is reported stable for one week at room temperature (+ 15-25°C.) , and approximately one month when stored in the refrigerator at - 20°C . and protected against evaporation .

Shake and bring the samples at room temperature (+ 15-25°C) before using.

REAGENT COMPOSITION:

R1 Standard	Total protein standard	6 g/dl
R2 Corrosive	Sodium hydroxide	1-5%
	Copper sulphate	< 1%
	Potassium iodide	6 mmol/l
	Potassium Sodium tartrate	12 mmol/l

PACKAGE : Collection & storage .

Store at temperature indicated upon the label .

Stable until the expiration date reported upon the package .

After the unsealing and the taking of the reagent, it is advised to close up the bottle immediately in order to avoid evaporation , direct light exposure and bacterial contamination .

PRECAUTIONS & WARNING:

Avoid pipetting with mouth.

The Reagent (R2) , according to current regulation , is classified as : **C-Corrosive**

R34-Causes burns .

R52/53-Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S26-in case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S45-in case of accident or if you feel unwell , seek medical advice immediately (show the label where possible)

S60-This material and its container must be disposed of as hazardous waste.

S61-Avoid release to the environment Refer to special instructions/Safety data sheets.

S36/37/39-Water suitable protective clothing, gloves and eye/face protection .

Contents : sodium hydroxide ; potassium iodide : may produce an allergic reaction .

The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation .

Anyway handle with care , avoid ingestion , avoid contact with eyes , skin and mucous membranes

The samples must be handle as potentially infected from GIV or Hepatitis .

REAGENT PREPARATION & STABILITY :

Ready to use liquid reagent . Stability indicated upon the label .

REQUIRED MATERIALS NOT PROVIDED :

General Laboratory Equipment and Instrumentations .

PROCEDURE :

Wave length : 546 nm (530-550)
Optical path: 1 cm light path
Temperature : + 25/30/37° C .
Reading : Against blank reagent
Assay Type End Point

Pipetting in tubes :

	BLANK	STANDARD	SAMPLE
Reagent (R2)	1000 µL	1000 µL	1000 µL
Distilled water	20 µL		
Standard		20 µL	
Sample			20 µL

Mix , incubate for 10 min at room temperature (+15-25°C) and read sample and calibrator extinction .

Color is stable at least 60 min at room temperature.

Volumes can be proportionally modified .

This methodology describes the manual procedure to use the kit . for automated procedure, ask for specific application .

CALCULATON :

$$\text{Total Protein g/dl} = \frac{(\text{A}) \text{ Sample}}{(\text{A}) \text{ calibrator}} \times 6$$

EXPECTED VALUE :

SERUM : 6.6 – 8.3 g/dl

The above mentioned values are to be considered as a reference .

It is strongly recommended that each laboratory establish its own normal range

WASTE DISPOSAL :

The disposal of the product must be in accordance with local regulation concerning waste disposal .

QUALITY CONTROL:

It is recommended to execute the quality control at every kit utilization to verify that values are within the reference range indicated by the methodology.

PERFORMANCE :

MEASURE INTERVAL / LINEARITY:	0. 27 – 15 g/ dL
LOWEST MEASURABLE LIMIT (2DS):	0.27 g/dL
SENSITIVITY :	1g/dL = 0.0274A a 546nm

INTRA-ASSAY PRECISION : n=20

LOW LEVEL	M = 2.71 g/dL	C.V = 2.90%
MEDIUM LEVEL	M = 5.14 g/dL	C.V = 2.39%
HIGH LEVEL	M = 12.56 g/dL	C.V = 1.94%

INTER-ASSAY PRECISION : n=20

LOW LEVEL	M = 2.70 g/dL	C.V = 0.36%
MEDIUM LEVEL	M = 5.21 g/dL	C.V = 1.35%
HIGH LEVEL	M = 12.32 g/dL	C.V = 1.92%
INTER ANALYZED	3.6-9.1 g/dL	
CORRELATION	r = 0.9879	n = 60
LIN. REGRESSION	y = 0.9968x + 0.182	n = 60

INTERFERENCE :

Interference are negligible up to:			
Glucose	500mg/dL	Bilirubin	30 mg/dL
Triglycerides	> 300mg/dL	Hemoglobin	> 0.3 mg/dL
Increase the reading		Increase the reading	

LIMITATIONS :

Lipemic and hemolyzed serum , should have a serum blank .

For concentration higher than 15 g/dl , repeat the measure on a sample diluted 1:2 with saline solution and multiply the results $\times 2$










For a thorough evaluation of the interfering substances , consult : Young , D,S,et al , Clin , Chem , 21:1D (1975) .

REFERENCES :

Kingsley , G, R : Bio , chem , 131, 197-200 (1939) .

Yatzidis , H , L : J , Clin , Chem , 23/908 (1987) .

Vassault , A et al , Ann , Biol Clin , 44, 686 , (1986)

	Consult Instructions for Use
	Caution, Consult accompanying
	In Vitro Diagnostic Medical
	Temperature Limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue Number
	Batch Code
	Use by

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