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 .

$$\text{Protein} + Cu^{++} \xrightarrow{\text{Alkali}} \text{Colored Complex}$$

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^{o}C.) , and approximately one month when stored in the refrigerator at - 20^{o}C . and protected against evaporation .
Shake and bring the samples at room temperature (+ 15-25^{o}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^{o} C .
Reading :	Against blank reagent
Assay Type	End Point

Pipeting 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^{o}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 :

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

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 .

QUAITYCONTROL:

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 MEASURABLELIMIT (2DS):	0.27 g/dL
SENSITIVITY :	1g/dL = 0.0274A a 546nm

INTRA-ASSAY PRECISION : n=20

LOWLEVEL	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 PRECISSION : n=20

LOWLEVEL	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 ANALGYZED	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 Increase the reading	> 300mg/dL	Hemoglobin Increase the reading	> 0.3 mg/dL

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 × 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
IVD	In Vitro Diagnostic Medical
	Temperature Limitation
	Manufacturer
EC REP	Authorized Representative in the European Community
REF	Catalogue Number
LOT	Batch Code
	Use by

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