Total Protein M

Total Protein Mono Reagent test Kit

Intended Use
Diagnostic reagent for in vitro quantitative determination of total protein in human serum or plasma on photometric analyzers.

Order Information

Item Code	Packsize
700029934840	R: 4 x 60 mL

Summary
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

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

Reagents
Components and Concentrations

R:	Sodium Hydroxide	0.1N
	Copper Sulphate	6mmol/L

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8℃ and contamination is avoided. Do not freeze the reagents and protect them from light!
Unopened, the standard is stable up to the end of the indicated month of expiry, if stored at 2 – 8℃.

Warnings and Precautions
1. Reagent 1: May be corrosive to metals. Keep only in original container. Absorb spillage to prevent material damage.
2. Reagent 2: Warning. May be corrosive to metals. Causes skin irritation. Causes serious eye irritation. Harmful to aquatic life with long lasting effects. Keep only in original container. Wash hands and face thoroughly after handling. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
3. The reagents contain sodium hydroxide. Do not swallow! If the reagents get in contact with skin or mucous membranes rinse immediately with water!
4. In serum or plasma of 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.
5. In very rare cases, samples of patients with gammopathy might give falsified results [5].
6. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
7. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use.

Traceability
The assigned values of the calibrator or standard are traceable to the biuret method.

Specimen
Serum or plasma

Stability [3]:	6 days	at	20 – 25℃
	4 weeks	at	4 – 8℃
	at least one year	at	– 20℃

Freeze only once!
Discard contaminated specimens!

Assay Procedure

Wavelength	546 nm
Optical path	1 cm
Temperature	20 – 25°C/37°C
Measurement	Against reagent blank

	Blank	Sample or Calibrator
Sample or Calibrator	-	4 µL
Dist. water	4 µL	-
Reagent	200 µL	200 µL

Mix, incubate for 10 min. at 20 – 25℃/37℃ and read absorbance within 60 min.

ΔA = (A2 – A1) sample or standard

Calibrators and Controls
For the calibration of automated photometric systems, DiaSys TruCal U calibrator is recommended. For Semi Auto, given standard is recommended. The assigned values of the calibrator are traceable to the biuret method. DiaSys TruLab N and P controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics
Measuring range
The test has been developed to determine total protein concentrations within a measuring range from 0.2 – 12 g/dL. When values exceed this 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, bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL, dextran up to 2000 mg/dL and lipemia up to 1000 mg/dL triglycerides. For further information on interfering substances refer to Young DS [4].

Sensitivity/Limit of Detection
The lower limit of detection is 0.2 g/dL.

Linearity
The linearity is 12 g/dL.

Precision (at 37°C)

Intra-assay precision n = 20	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	5.24	0.06	1.0
Sample 2	7.07	0.1	1.55
Sample 3	10.4	0.11	1.3

Intra-assay precision n = 20	Mean [µg/dL]	SD [µg/dL]	CV [%]
Sample 1	5.27	0.05	0.9
Sample 2	7.05	0.0	1.0
Sample 3	10.4	0.0	0.8

Method Comparison
A comparison of DiaSys Total protein Test Kit (y) with a commercially available test (x) using 68 samples gave following results:

y = 1.00 x - 0.07 g/dL; r = 0.997

Reference Range [1]

	[g/dL]	
Adults:	6.6 – 8.8	
Children	Female	Male
1 - 30 day(s)	4.2 – 6.2	4.1 – 6.3
1 – 6 month(s)	4.4 – 6.6	4.7 – 6.7
6 months – 1 year	5.6 – 7.9	5.5 – 7.0
1 – 18 year(s)	5.7 – 8.0	5.7 – 8.0

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Clinical Interpretation
The low concentration of Total protein level indicates liver or kidney problem, or it may be that protein isn't being digested or absorbed properly. The high concentration of total protein level could indicate dehydration or a certain type of cancer, such as multiple myeloma, that causes protein to accumulate abnormally.
Results should be correlated clinically.

Limitations
Result interreference can be observed in patient samples exceeding triglyceride concentration above 1000 mg/dL

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 644-7.
2. Johnson Am, Rohlfs EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 477-540.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 42-3.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Assocation for Clinical Chemistry Press 2000.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Notes on Symbols and Marks

	Consult instructions for use
	Use-by date
LOT	Batch code
REF	Catalouge number
	Caution
	Manufacturer
IVD	*In vitro diagnostic* medical device
	Temperature limit
	Do not re-use
CONT.	The pack contains
	Recycle
	Date of manufactures

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

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