Total protein FS*

Order Information

Cat. No.	Kit size				
1 2311 99 10 021	R1	5 x 20 mL	+	R2	1 x 25 mL
1 2311 99 10 026	R1	5 x 80 mL	+	R2	1 x 100 mL
1 2311 99 10 023	R1	1 x 800 mL	+	R2	1 x 200 mL
1 2311 99 10 704	R1	8 x 50 mL	+	R2	8 x 12.5 mL
1 2311 99 10 917	R1	8 x 60 mL	+	R2	8 x 15 mL

Intended Use

Diagnostic reagent for quantitative in vitro determination of total protein in human serum or heparin plasma on automated photometric systems.

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. [1,2]

Method

Photometric test according to biuret method

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

R1:	Sodium hydroxide	100 mmol/L
	Potassium sodium tartrate	17 mmol/L
R2:	Sodium hydroxide	500 mmol/L
	Potassium sodium tartrate	80 mmol/L
	Potassium iodide	75 mmol/L
	Copper sulphate	30 mmol/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 - 25°C and contamination is avoided. Protect from light.

The in-use stability of the reagent is 18 months.

Warnings and Precautions

1. Components contained in Total protein FS are classified according to EC regulation 1272//2008 (CLP) as follows:

⚠ Reagent 1: Warning. H290 May be corrosive to metals. P234 Keep only in original packaging. P390 Absorb spillage to prevent material damage.

⚠ Reagent 2: Warning. Contains Potassium iodide. H290 May be corrosive to metals. H315 Causes skin irritation. H319 Causes serious eye irritation. H373 May cause damage to organs through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects. P234 Keep only in original packaging. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contactlenses, if present and easy to do. Continue rinsing. P314 Get medical advice/attention if you feel unwell.

2. 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.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) 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

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [4]:

6 days	at	20 – 25°C
4 weeks	at	4 – 8°C
At least one year	at	–20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	545 nm
Temperature	37°C
Measurement	Endpoint
Sample/calibrator	2.0 µL
Reagent 1	80 µL
Reagent 2	20 µL
Addition Reagent 2	Cycle 19 (286 s)
Absorbance 1	Cycle 17/18 (231 s/244 s)
Absorbance 2	Cycle 41/42 (586 s/600 s)
Calibration	Linear

Calculation

With calibrator

$$\text{Total protein [g/dL]} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Cal.}} \times \text{Conc. Cal. [g/dL]}$$

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the biuret method. Total protein Standard FS may be used alternatively for calibration. Use DiaSys TruLab N and P for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
Total protein Standard FS	1 2300 99 10 030	6 x 3 mL

Performance Characteristics

Data evaluated on BioMajesty® JCA-BM6010/C

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 14 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.	
Limit of detection**	0.05 g/dL

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin (conjugated and unconjugated)	60 mg/dL
Hemoglobin	500 mg/dL
Lipemia (triglycerides)	1000 mg/dL
For further information on interfering substances refer to Young DS [5,6].	

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	4.78	6.17	7.40
CV [%]	0.57	0.52	0.35
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	5.97	6.63	7.13
CV [%]	1.00	1.00	1.15

Method comparison (n=100)	
Test x	Competitor Total protein
Test y	DiaSys Total protein FS
Slope	1.00
Intercept	0.040 g/dL
Coefficient of correlation	0.998

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

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.

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 644-7.
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4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 42-3.
5. 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.
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* Fluid Stable