

Total protein FS*

Order Information

Cat. No.

1 2311 99 10 962

Kit size



1890 (R1: 6 x 315, R2: 6 x 315)

Intended Use

Diagnostic reagent for quantitative in vitro determination of total protein in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

Measurements of total protein in human serum or plasma are essential for diagnosing and monitoring various diseases, including those affecting the liver, kidneys, and bone marrow, as well as other metabolic and nutritional disorders [1]. Plasma proteins are primarily synthesized in the liver, plasma cells, lymph nodes, spleen, and bone marrow. Disease conditions can cause deviations in total protein concentration and the distribution of individual protein fractions from normal values [1-3]. Hypoproteinemia, or low protein levels, can result from conditions such as blood loss, intestinal malabsorption (sprue), nephrotic syndrome, severe burns, salt retention syndrome, and kwashiorkor (acute protein deficiency) [4]. Hyperproteinemia, or high protein levels, may be observed in severe dehydration and diseases like multiple myeloma. Changes in the percentage of plasma proteins can occur due to shifts in one protein fraction, often without altering the total protein amount. The albumin/globulin (A/G) ratio serves as a common index for assessing the distribution of these protein fractions. Notable changes in this ratio can indicate liver cirrhosis, glomerulonephritis, nephrotic syndrome, acute hepatitis, systemic lupus erythematosus, and various acute and chronic inflammations [4,5].

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. Do not freeze and protect from light.

The open-vial stability of the reagent is 18 months until expiry date.

Warnings and Precautions

- 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 contact lenses, if present and easy to do. Continue rinsing. P314 Get medical advice/attention if you feel unwell.

- 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.
- In very rare cases, samples of patients with gammopathy might give falsified results [6].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- 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.
- 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.
- 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. The bottles are placed directly into the reagent rotor.

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 [7]:

6 days	at	20 – 25°C
4 weeks	at	4 – 8°C
1 year	at	-20°C

Only freeze once. Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the biuret method. Use DiaSys TruLab N and P for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. 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

Performance Characteristics

Measuring range from 0.35 g/dL up to 16 g/dL. Linearity ≤ 1.6 g/dL is given within ± 10%, at > 1.6 g/dL within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.3 g/dL
Limit of quantitation**	0.3 g/dL
Onboard stability	14 days
Calibration stability	7 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/dL]
Ascorbic acid	30 mg/dL	6.27
	60 mg/dL	8.87
Bilirubin (conjugated)	60 mg/dL	7.17
	60 mg/dL	9.13
Bilirubin (unconjugated)	60 mg/dL	6.79
	60 mg/dL	8.46
Dextran	30 mg/dL	6.99
	30 mg/dL	8.96
Hemolysis	500 mg/dL	6.31
	600 mg/dL	9.25
Lipemia (triglycerides)	1000 mg/dL	6.34
	1800 mg/dL	9.20

For further information on interfering substances, refer to the literature [8-10].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/dL]	4.50	6.67	8.18
CV [%]	0.347	0.347	0.338
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [g/dL]	4.48	6.63	8.17
CV [%]	1.08	1.23	1.04

Method comparison (n=154)	
Test x	Competitor Total protein (cobas c 501)
Test y	DiaSys Total protein FS (BioMajesty® JCA-BM6010/C)
Slope	0.987
Intercept	-0.016 g/dL
Coefficient of correlation	0.999

** according to CLSI document EP17-A2, Vol. 32, No. 8

Reference Range [3]

Adults [g/dL]
6.6 – 8.3

Children	Female	Male
1 – 30 day(s)	4.2 – 6.2	4.1 – 6.3
31 – 182 days	4.4 – 6.6	4.7 – 6.7
183 – 365 days	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

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Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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* Fluid Stable

Total protein FS

Chemistry code 10 231

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	20
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	2
Sample vol (U)	2
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	TP
Digits	2
M-wave L.	545
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	Serum	Urine
Reac. sample vol.	2	2
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.l	0
M-DET.P.m	41
M-DET.P.n	42
S-DET.P.p	17
S-DET.P.r	18
Check D.P.l.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999