


Total protein FS*

Order Information

Cat. No.

1 2311 99 10 920

Kit size

 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of total protein in human serum or heparin plasma on automated respons[®]910.

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. 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 0.06 g/dL up to 14 g/dL, linearity is given 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**	0.06 g/dL
Limit of quantitation**	0.06 g/dL
Onboard stability	10 days
Calibration stability	7 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [g/dL]
Ascorbic acid	30 mg/dL	4.84
Bilirubin (conjugated)	60 mg/dL	6.28
	60 mg/dL	7.85
Bilirubin (unconjugated)	70 mg/dL	6.33
	70 mg/dL	7.80
Dextran	2000 mg/dL	5.05
	2000 mg/dL	6.10
Hemolysis	550 mg/dL	6.43
	550 mg/dL	7.94
Lipemia (triglycerides)	1000 mg/dL	6.03
	2000 mg/dL	8.18
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]	5.27	6.57	11.8
CV [%]	1.22	0.939	0.834
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [g/dL]	4.37	7.52	10.5
CV [%]	1.39	1.13	0.926

Method comparison (n=130)	
Test x	DiaSys Total protein FS (Hitachi 917)
Test y	DiaSys Total protein FS (respons [®] 910)
Slope	0.997
Intercept	0.208 g/dL
Coefficient of correlation	0.999

** according to CLSI document EP17-A, Vol. 24, No. 34

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.



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable

Total protein FS

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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	TP
Shortcut:	
Reagent barcode reference:	050
Host reference:	050

Technic	
Type:	End point
First reagent:[μ L]	180
Blank reagent	Yes
Sensitive to light	
Second reagent:[μ L]	45
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	546
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics	
Substrate depletion: Absorbance li	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics	
Substrate depletion: Absorbance limit	
Endpoint	
Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [μ L]	0 (no hemolysis)
Cleaner	
Sample [μ L]	0
Technical limits	
Concentration technical limits-Lower	0.0600
Concentration technical limits-Upper	14.0000
SERUM	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6
URIN	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [μ L]	5.0
Normal dilution (factor)	1
Below normal volume [μ L]	
Below normal dilution (factor)	
Above normal volume [μ L]	5.0
Above normal dilution (factor)	6

Results	
Decimals	2
Units	g/dL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	#
URINE	
PLASMA	#
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants	
Please refer to r910 Carryover Pair Table	

Calibrators details	
Calibrator list	Concentration
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
	Max delta abs.
Cal. 1	0.002
Cal. 2	0.020
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value

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