respons®920

Total protein FS*

Order Information

Cat. No.	Kit size
1 2311 99 10 920	Σ 800 (4 x 200)

Intended Use

Diagnostic reagent for quantitative in vitro determination of total protein in human serum or heparin plasma on automated DiaSys respons®920.

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 case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
3. 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.
4. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
5. 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.
6. 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 [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.

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. 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

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

Measuring range up to 15 g/dL. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	0.05 g/dL
Onboard stability	7 days
Calibration stability	1 day

Interfering substance	**Interferences ≤ 10% up to**
Ascorbic acid	30 mg/dL
Bilirubin	60 mg/dL
Dextran	2000 mg/dL
Hemoglobin	500 mg/dL
Lipemia (triglycerides)	2000 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]	5.09	6.20	10.9
CV [%]	1.02	0.93	0.90
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	4.91	5.96	11.0
CV [%]	2.11	1.62	2.25

Method comparison (n=110)	
Test x	DiaSys Total protein FS (Hitachi 917)
Test y	DiaSys Total protein FS (respons®920)
Slope	1.02
Intercept	0.017 g/dL
Coefficient of correlation	0.955

** 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.
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. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in April 2021. Published by AACC Press and John Wiley and Sons, Inc.

Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.

IVD CE

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* Fluid Stable

respons®920

Total protein FS

Application for serum and plasma

Test Details

Test	:	TP				Auto Rerun	☐
Report Name	:	Total protein				Online Calibration	☐
Unit	:	g/dL	Decimal Places	:	2	Cuvette Wash	☐
Wavelength-Primary	:	546	Secondary	:	0	Total Reagents	: 2
Assay Type	:	2-Point	Curve Type	:	Linear	Reagent R1	: TP R1
M1 Start	:	15	M1 End	:	15	Reagent R2	: TP R2
M2 Start	:	33	M2 End	:	33		
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:	
Control Replicates	:	1	Control Interval	:	0	Blank/Level 0	: 0
Reaction Direction	:	Increasing	React. Abs. Limit	:	0.00	Calibrator 1	: *
Prozone Limit %	:	0	Prozone Check	:	Lower		
Linearity Limit %	:	0	Delta Abs./Min.	:	0.00		
Technical Minimum	:	0.05	Technical Maximum	:	15.00		
Y = aX + b a=	:	1.00	b=	:	0.00		

* Enter calibrator value.

Test Details

Test	:	TP
Sample Type	:	Serum

Sample Volumes

Normal	:	5.00 µL	Dilution Ratio	:	1 X
Increase	:	9.00 µL	Dilution Ratio	:	1 X
Decrease	:	2.00 µL	Dilution Ratio	:	1 X
Standard Volume	:	5.00 µL			

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180 µL	R1 Stirrer Speed	:	Medium
RGT-2 Volume	:	45 µL	R2 Stirrer Speed	:	High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details

Test	:	TP
Sample Type	:	Serum
Reference Range	:	DEFAULT
Category	:	Male

Reference Range

		Lower Limit (g/dL)	Upper Limit (g/dL)
Normal	:	6.60	8.80
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other