respons®910

Total protein FS*

Diagnostic reagent for quantitative in vitro determination of total protein in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 2311 99 10 920
4 twin containers for 200 tests each

Method

Photometric test according to biuret method

Principle

Together with copper ions, proteins form a violet blue color complex in alkaline solution. The absorbance of the color is directly proportional to the protein 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 Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 - 25 °C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions

1. Reagents: S24/25: Avoid contact with skin and eyes.
2. Reagent 2 is irritating. R36/38: Irritating to eyes and skin. R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S2: Keep out of the reach of children. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37/39: Wear suitable gloves and eye/face protection. S61: Avoid release to the environment. Refer to special instructions/safety data sheets.
3. In serum or plasma from patients who received large intravenous amounts of polydextran, too high values can be measured with the biuret method. In such cases an alternative method (e.g. Kjeldahl) has to be used.
4. In very rare cases, samples of patients with gammopathy might give falsified results.
5. 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.

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen

Serum or plasma

Stability [1]:

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

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, DiaSys TruCal U calibrator is recommended. The assigned values of the calibrator are traceable to the biuret method. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective actions 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 up to 14.8 g/dL protein (in case of higher concentrations re-measure samples after manual dilution or use rerun function)	
Limit of detection**	0.06 g/dL protein
On-board stability	10 days
Calibration stability	7 days

Interfering substance	Interferences < 10%	Protein [g/dL]
Ascorbate	up to 30 mg/dL	4.84
Dextran	up to 2000 mg/dL	5.05
	up to 2000 mg/dL	6.10
Hemoglobin	up to 550 mg/dL	6.43
	up to 550 mg/dL	7.94
Bilirubin, conjugated	up to 60 mg/dL	6.28
	up to 60 mg/dL	7.85
Bilirubin, unconjugated	up to 70 mg/dL	6.33
	up to 70 mg/dL	7.80
Lipemia (triglycerides)	up to 1000 mg/dL	6.03
	up to 2000 mg/dL	8.18
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	5.27	6.57	11.8
Coefficient of variation [%]	1.22	0.94	0.83
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [g/dL]	4.37	7.52	10.5
Coefficient of variation [%]	1.39	1.13	0.93

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 NCCLS document EP17-A, vol. 24, no. 34

Conversion factor:

Total protein [g/dL] x 10 = Total protein [g/L]

Reference Range [3]

		[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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 42-3.
2. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th. ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press, 2000.
3. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 644-7.
4. 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.

Manufacturer

IVD CE

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respons®910

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
Name:	TP
Shortcut:	
Reagent barcode reference:	050
Host reference:	

Technic	
Type:	Endpoint
First reagent:[µL]	180
Blanc correction	Yes
Second reagent:[µL]	45
Blanc correction	Yes
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 deplation: absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate deplation: absorbance limit	
Endpoint Stability: largest remaining slope	-
Prozone Limit [%]	-

Sample	
Diluent	NaCl
Concentration technical limits-Lower	0.06
Concentration technical limits-Upper	14.8
SERUM	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume [µL]	9
Below normal dilution (factor)	1
Above normal volume [µL]	5
Above normal dilution (factor)	6
URIN	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume [µL]	9
Below normal dilution (factor)	1
Above normal volume [µL]	5
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume [µL]	9
Below normal dilution (factor)	1
Above normal volume [µL]	5
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	5
Normal dilution (factor)	1
Below normal volume[µL]	9
Below normal dilution (factor)	1
Above normal volume [µL]	5
Above normal dilution (factor)	6

Results	
Decimals	2
Units	g/dL
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	>=6.6 <=8.8
URINE	
PLASMA	>=6.6 <=8.8
CSF	
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*

	Max delta abs.
Cal. 1	0.015
Cal. 2	0.020
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X degree
Degree	1

* Enter calibrator value