respons®910

Total protein UC FS*

Diagnostic reagent for quantitative in vitro determination of total protein in urine or cerebrospinal fluid on DiaSys respons®910

Order Information

Cat. No. 1 0210 99 10 921
4 containers for 120 tests each

Method

Photometric test using pyrogallol red

Principle

Proteins form a red complex with pyrogallol red/ molybdate. The absorbance is directly proportional to the protein concentration.

Reagents

Components and Concentrations

Reagent:

Pyrogallol red	60 µmol/L
Sodium molybdate	40 µmol/L

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

Note: A slight blue precipitate may occur in the reagent which does not affect the performance of the test.

Warnings and Precautions

1. In very rare cases, samples of patients with gammopathy might give falsified results [8].
2. To avoid contamination and carryover, special care should be taken in combination with Ethanol FS reagent.
3. 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.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

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

Specimen

Urine or cerebrospinal fluid

Stability [1]:

in urine:	1 day	at	20 – 25°C
	7 days	at	4 – 8°C
	1 month	at	–20°C
in cerebrospinal fluid:	1 day	at	20 – 25°C
	6 days	at	4 – 8°C
	1 year	at	–20°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

DiaSys Total Protein UC Standard FS is recommended for calibration. The assigned value of the standard has been made traceable to SRM 927 reference material. DiaSys TruLab Urine controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
Total Protein UC Standard FS	1 0260 99 10 030	6 x 3 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range from 35 to 2900 mg/L total protein (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).	
Limit of detection**	9 mg/L total protein
On-board stability	2 weeks
Calibration stability	2 weeks

Interfering substance	Interferences < 10%	Total protein [mg/L]
Hemoglobin interferes even at low concentrations		
Bilirubin, conjugated	interferes even at low concentrations	91.6
	up to 13.5 mg/dL	420
Bilirubin, unconjugated	interferes even at low concentrations	82.7
	up to 25 mg/dL	469
Lipemia (triglycerides)	up to 600 mg/dL	73.4
	up to 800 mg/dL	409
Urea	up to 45 g/L	80.6
	up to 45 g/L	453
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	86.0	645	1529
Coefficient of variance [%]	1.54	1.13	1.11
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	78.4	618	1399
Coefficient of variance [%]	3.25	1.66	1.28

Method comparison (n= 178)	
Test x	Acid protein precipitation GP Dosatec
Test y	DiaSys Total protein UC FS respons®910
Slope	1.01
Intercept	32.5 mg/L
Coefficient of correlation	0.996

** according to NCCLS document EP17-A, vol. 24, no. 34

Reference Range [3,4]

Urine	24 – 141 mg/24 h
Cerebrospinal fluid	< 500 mg/L ***

****The value is an approximate guideline only.*

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. 52-3; 54-5.
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. Felgenhauer K. Laboratory diagnosis of neurological diseases. In: Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1308-26.
4. Boege F. Urinary proteins. In: Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 382-400.
5. Orsonneau JL, Douet P, Massoubre C, Lustenberger P, Bernard S. An improved pyrogallol red-molybdate method for determining total urinary protein. Clin Chem 1989; 35: 2233-6.
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7. 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.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

IVD CE

respons®910

Total protein UC FS

Application for urine 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:	TPU
Shortcut:	
Reagent barcode reference:	051
Host reference:	051

Technic	
Type:	End point
First reagent:[µL]	200
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	
Blank reagent	
Sensitive to light	
Main wavelength:[nm]	600
Secondary wavelength:[nm]	700
Polychromatic factor:	1.0000
1 st reading time [min:sec]	(-00:12)
Last reading time [min:sec]	10:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
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 [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	35.0000
Concentration technical limits-Upper	2900.0000
SERUM	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6
URINE	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6
PLASMA	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6
CSF	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6
Whole blood	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	6.0
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mg/L
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	
URINE	>=24.0 <=141.0 mg/24h
PLASMA	
CSF	< 500.0 mg/L
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	0.01
Cal. 2	0.02
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.80

Calculations	
Model	X
Degree	1

* Enter calibrator value