

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
Standard: 1300 mg/L (1.3 g/L)

Storage Instructions and Reagent Stability

Reagent and standard are 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!

Warnings and Precautions

- Each individual blood donation used for production of Total protein UC Standard FS was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the standards with the same precautions used for patient specimens.
- The Total Protein UC Standard FS contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- In very rare cases, samples of patients with gammopathy might give falsified results.
- 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

Reagent and standard are 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
in cerebrospinal fluid:	1 month	at	-20 °C
	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

For calibration the DiaSys Total Protein UC Standard FS is recommended. The assigned value of the standard has been made traceable to SRM 927 reference material. For internal quality control DiaSys TruLab Urine controls should be assayed. 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 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 up to 13.5 mg/dL	91.6 420
Bilirubin, unconjugated	interferes even at low concentrations up to 25 mg/dL	82.7 469
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

- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 52-3; 54-5.
- 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.
- Felgenhauer K. Laboratory diagnosis of neurological diseases. In: Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1308-26.
- Boege F. Urinary proteins. In: Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 382-400.
- 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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- Johnson AM, Rohlf 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



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Total protein UC 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:	TPU
Shortcut:	
Reagent barcode reference:	051
Host reference:	

Technic	
Type:	Endpoint
First reagent:[μ L]	200
Blanc correction	Yes
Second reagent:[μ L]	
Blanc correction	
Main wavelength:[nm]	600
Secondary wavelength:[nm]	700
Polychromatic factor:	1.000
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 [%]	

Sample	
Diluent	NaCl
Concentration technical limits-Lower	35
Concentration technical limits-Upper	2900
SERUM	
Normal volume [μ L]	6
Normal dilution (factor)	1
Below normal volume [μ L]	10
Below normal dilution (factor)	1
Above normal volume [μ L]	6
Above normal dilution (factor)	6
URIN	
Normal volume [μ L]	6
Normal dilution (factor)	1
Below normal volume [μ L]	10
Below normal dilution (factor)	1
Above normal volume [μ L]	6
Above normal dilution (factor)	6
PLASMA	
Normal volume [μ L]	6
Normal dilution (factor)	1
Below normal volume [μ L]	10
Below normal dilution (factor)	1
Above normal volume [μ L]	6
Above normal dilution (factor)	6
CSF	
Normal volume [μ L]	6
Normal dilution (factor)	1
Below normal volume [μ L]	10
Below normal dilution (factor)	1
Above normal volume [μ L]	6
Above normal dilution (factor)	6

Results	
Decimals	1
Units	mg/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Genre	All
Age	
SERUM	
URINE	$\geq 24 \leq 141$ mg/24h
PLASMA	
CSF	< 500 mg/L
Genre	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	Lactate
Wash with	CLN A
Cycle	1
Volume [μ L]	250
Contaminant 2	
Wash with	
Cycle	
Volume [μ L]	

Calibrators details	
Calibrator list	Concentration
Cal. 1	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 [%]	0.8
Calculations	
Model	X degree
Degree	1

* Enter calibrator value