Total protein UC FS*

Diagnostic reagent for quantitative in vitro determination of total protein in urine or cerebrospinal fluid on photometric systems

Order Information

Cat. No.	Kit size				
1 0210 99 10 021	R 5 x	25 mL	+	1 x	3 mL Standard
1 0210 99 10 026	R 6 x	100 mL			
1 0210 99 10 930	R 6 x	20 mL			
1 0260 99 10 030	6 x	3 mL	Standard		

Summary [1,2]

Elevated concentration of total protein in urine (proteinuria) can be detected in the majority of kidney diseases. Primary and secondary nephropathies may cause increased glomerular permeability or decreased tubular reabsorption. Post-renal causes of proteinuria are infections, bleedings or malignant diseases of the urinary tract. Elevated urine protein levels can also be related to other acute disorders like fever, as well as to physical or psychological stress.
In cerebrospinal fluid (CSF), elevated protein levels can be measured in case of increased intracranial pressure (due to brain tumors, intracerebral hemorrhage or traumatic injury), in inflammation, (especially in bacterial meningitis) as well as in multiple sclerosis. Increased permeability of the blood-CSF barrier is reflected in an elevated CSF/serum ratio of total protein.

Method

Photometric test using pyrogallol red. The assigned values of Total protein UC Standard FS are traceable to standard reference material NIST SRM®-927.

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

The Reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8℃, protected from light and contamination is avoided. Do not freeze the reagents!
Unopened, the standard is stable up to the end of the indicated month of expiry, if stored at 2 – 8℃.

Warnings and Precautions

1. 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.
2. 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.
3. In very rare cases, samples of patients with gammopathy might give falsified results [7].
4. 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.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

Reagent and standard are ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Urine or cerebrospinal fluid
Stability [3]:

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

Discard contaminated specimens. Freeze only once.

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	600 nm
Optical path	1 cm
Temperature	37℃
Measurement	Against reagent blank

	Blank	Sample/standard
Sample or standard	-	20 µL
Dist. water	20 µL	-
Reagent	1000 µL	1000 µL

Mix and read absorbance against reagent blank exactly after 10 min.

Calculation

With standard or calibrator

$$\text{Total protein [mg/L]} = \frac{\text{A Sample}}{\text{A Std/Cal}} \times \text{Conc. Std/Cal [mg/L]}$$

Calibrators and Controls

For internal quality control DiaSys TruLab Urine controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

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

The test has been developed to determine total protein concentrations within a measuring range from 20 – 3000 mg/L. When values exceed this range samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2. Samples with lower concentrations should be used with higher volumes (e.g. 50 µL sample + 1000 µL reagent).

Specificity/Interferences

Errors due to interfering components in urine are < 2%. For further information on interfering substances refer to Young DS [8].

Sensitivity/Limit of Detection

The lower limit of detection is 20 mg/L.

* fluid stable

Precision (at 37°C)

Intra-assay precision n = 20	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	178	5.23	2.94
Sample 2	450	5.10	1.14
Sample 3	1564	27.6	1.77

Inter-assay precision n = 20	Mean [mg/L]	SD [mg/L]	CV [%]
Sample 1	170	3.94	2.32
Sample 2	449	9.68	2.16
Sample 3	1484	42.5	2.86

Method Comparison

A comparison of DiaSys Total protein UC FS (y) with a commercially available test (x) using 69 samples gave following results: y = 1.02 x + 2.20 mg/L; r = 0.990

Reference Range [2,4]

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

**The value is an approximate guideline only.*

Literature

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8. 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.

Manufacturer

IVD CE

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