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

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.

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. Do not freeze the reagents!

Warnings and Precautions
1. In very rare cases, samples of patients with gammapathy might give falsified results [7].
2. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.
3. 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°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.

Assay Procedure
Application sheets for automated systems are available on request.

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

Sample or standard
Dist. water 20 µL
Reagent 1000 µL
Mix and read absorbance against reagent blank exactly after 10 min.

Calculation
With standard or calibrator
Total protein [mg/L] = \( \frac{A \text{ Sample}}{A \text{ Std/Cal}} \times \text{Conc. Std} / \text{Cal [mg/L]} \)

Calibrators and Controls
For calibration of automated photometric systems, DiaSys Total protein UC Standard FS is recommended. The assigned values of Total protein UC Standard FS are traceable to standard reference material NIST SRM®-927. For internal quality control DiaSys TruLab Urine controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

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.
Precision (at 37°C)

<table>
<thead>
<tr>
<th></th>
<th>Intra-assay precision</th>
<th>Inter-assay precision</th>
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<tbody>
<tr>
<td></td>
<td>n = 20</td>
<td>n = 20</td>
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<tr>
<td></td>
<td>Mean [mg/L]</td>
<td>Mean [mg/L]</td>
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<tr>
<td></td>
<td>SD [mg/L]</td>
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<td></td>
<td>CV [%]</td>
<td>CV [%]</td>
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<tr>
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<td>170</td>
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<td>5.23</td>
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<td>1484</td>
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<td>27.6</td>
<td>42.5</td>
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<tr>
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<td>1.77</td>
<td>2.86</td>
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Method Comparison
A comparison of DiaSys Total protein UC FS (y) with a commercially available test (x) using 69 samples gave following results: 

\[ y = 1.02 x + 2.20 \text{ mg/L} \]

\[ r = 0.990 \]

Reference Range [2,4]

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

*The value is an approximate guideline only.

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9  65558 Holzheim  Germany