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 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

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
6 days at 20 – 25°C
1 year 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.

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Protein UC Standard FS</td>
<td>1 0260 99 10 030 6 x 3 mL</td>
</tr>
<tr>
<td>TruLab Urine Level 1</td>
<td>5 9170 99 10 062 20 x 5 mL</td>
</tr>
<tr>
<td>TruLab Urine Level 2</td>
<td>5 9170 99 10 061 6 x 5 mL</td>
</tr>
<tr>
<td>TruLab Urine Level 2</td>
<td>5 9180 99 10 062 20 x 5 mL</td>
</tr>
<tr>
<td>TruLab Urine Level 2</td>
<td>5 9180 99 10 061 6 x 5 mL</td>
</tr>
</tbody>
</table>

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 (8 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 Total protein

<table>
<thead>
<tr>
<th>Interfering substance</th>
<th>Interferences</th>
<th>Total protein [mg/L]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>interferes even at low concentrations</td>
<td>91.6</td>
</tr>
<tr>
<td>Bilirubin, conjugated</td>
<td>interferes even at low concentrations</td>
<td>420</td>
</tr>
<tr>
<td>Bilirubin, unconjugated</td>
<td>interferes even at low concentrations</td>
<td>82.7</td>
</tr>
<tr>
<td>Lipemia (triglycerides)</td>
<td>up to 600 mg/dL</td>
<td>469</td>
</tr>
<tr>
<td>Urea</td>
<td>up to 800 mg/dL</td>
<td>73.4</td>
</tr>
<tr>
<td></td>
<td>up to 45 g/L</td>
<td>409</td>
</tr>
<tr>
<td></td>
<td>up to 45 g/L</td>
<td>409</td>
</tr>
</tbody>
</table>

For further information on interfering substances refer to Young DS [2].

Precision

<table>
<thead>
<tr>
<th>Within run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/L]</td>
<td>86.0</td>
<td>645</td>
<td>1529</td>
</tr>
<tr>
<td>Coefficient of variance [%]</td>
<td>1.54</td>
<td>1.13</td>
<td>1.11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Between run (n=20)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/L]</td>
<td>78.4</td>
<td>618</td>
<td>1399</td>
</tr>
<tr>
<td>Coefficient of variance [%]</td>
<td>3.25</td>
<td>1.66</td>
<td>1.28</td>
</tr>
</tbody>
</table>

Method comparison (n=178)

<table>
<thead>
<tr>
<th>Test x</th>
<th>Acid protein precipitation GP Dosatex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test y</td>
<td>DiaSys Total protein UC FS respons®910</td>
</tr>
<tr>
<td>Slope</td>
<td>1.01</td>
</tr>
<tr>
<td>Intercept</td>
<td>32.5 mg/L</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.996</td>
</tr>
</tbody>
</table>

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

Reference Range [3,4]

Urine
- 24 – 141 mg/24 h
- Cerebrospinal fluid < 600 mg/dL

***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
3. For further information on interfering substances refer to Young DS [2].

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany
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:

**Technic**
- Type: End point
- First reagent [µL]: 200
- Blank correction
- Second reagent [µL]:
- Blank correction
- Main wavelength [nm]: 600
- Secondary wavelength [nm]: 700
- Polychromatic factor: 1.000
- 1st 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: DIL A (NaCl)
- Hemolysis:
- Agent [µL]: 0 (no hemolysis)
- Sample [µL]:
- Concentration technical limits-Lower: 35
- Concentration technical limits-Upper: 2900
- SERUM
  - Normal volume [µL]: 6
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 10
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 6
  - Above normal dilution (factor): 6
- URIN
  - Normal volume [µL]: 6
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 10
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 6
  - Above normal dilution (factor): 6
- PLASMA
  - Normal volume [µL]: 6
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 10
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 6
  - Above normal dilution (factor): 6
- CSF
  - Normal volume [µL]: 6
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 10
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 6
  - Above normal dilution (factor): 6

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

**Range**
- Gender: All
- Age: 
- SERUM
  - URINE: >=24 <=141 mg/24h
  - PLASMA
  - CSF: < 500 mg/L

**Contaminants**
- Contaminant 1 Please refer to r910 Carryover Pair Table
  - Wash with Cycle
    - Volume [µL]:
    - Contaminant 2
      - Wash with Cycle
        - Volume [µL]:
        - Contaminant 3
          - Wash with Cycle
            - Volume [µL]:
            - Contaminant 4
              - Wash with Cycle
                - Volume [µL]:

**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 [%]: 0.8

**Calculations**
- Model: X
- Degree: 1

* Enter calibrator value