Total protein UC FS*

Order Information

Cat. No.	Kit size	
1 0210 99 10 021	6 x	25 mL
1 0210 99 10 026	6 x	100 mL
1 0210 99 10 930	6 x	20 mL

Kits for use in conjunction with DiaSys CE applications.

Intended Use

Diagnostic reagent for quantitative in vitro determination of total protein in human urine or cerebrospinal fluid (CSF) on automated photometric systems.

Summary

Elevated concentrations of total protein in urine are related to kidney diseases whereas measuring total protein concentration in cerebrospinal fluid (CSF) serves to detect increased permeability of the blood-brain barrier. Healthy kidneys normally filter blood by removing waste and excess water while retaining essential proteins. In case of damaged kidneys, proteins can leak into urine, causing a state of elevated protein concentration known as proteinuria, which can be detected in the majority of kidney diseases [1]. The underlying cause is to be found in the glomerular filtration barrier, specifically in the podocytes located there. The amount of plasma proteins passing through is directly linked to the permeability of the podocytes [2]. Multiple acquired diseases, such as diabetic nephropathy and primary and secondary nephropathies, cause dysfunction of podocytes, leading to proteinuria [3]. In addition, determination of total protein to creatinine ratio is a valuable tool for assessing the severity of proteinuria, monitoring chronic kidney disease (CKD) progression, for aiding the prediction of renal outcomes and guiding treatment decisions [4]. Elevated urine protein levels can also be related to other acute disorders like fever, as well as to physical or psychological stress [3]. Total protein determination in CSF is used to identify an elevated CSF/serum ratio, which may indicate an increased permeability of the blood-brain barrier. An increased ratio can reflect various neurological conditions, such as infections, multiple sclerosis, and other inflammatory or autoimmune diseases [5].

Method

Photometric test using pyrogallol red

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

Reagent

Components and Concentrations

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

Storage and Stability

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 - 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 21 months until expiry date.

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

Warnings and Precautions

1. The reagent contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
2. In very rare cases, samples of patients with gammopathy might give falsified results [6].
3. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
4. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
5. Please refer to the safety data sheets (SDS) 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.
6. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagent is ready to use.

Materials Required

General laboratory equipment

Specimen

Human urine or CSF

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability in Urine [7]:

1 day	at	20 – 25°C
7 days	at	4 – 8°C
1 month	at	-20°C

Stability in CSF [7]:

1 day	at	20 – 25°C
6 days	at	4 – 8°C
1 year	at	-20°C

Only freeze once. Discard contaminated specimens.

Assay Procedure

Basic settings for respons®910

Wavelength	600/700 nm
Temperature	37°C
Measurement	Endpoint
Sample/Calibrator	6.0 µL
Reagent	200 µL
Absorbance	10:00 min
Calibration	Linear

Calculation

With Standard

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

Calibrators and Controls

DiaSys Total protein UC Standard FS is recommended for calibration. Standard values have been made traceable to the standard reference material NIST SRM-927. Use DiaSys TruLab Urine Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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

Data evaluated on respons®910

Urine

Measuring range from 35 mg/L up to 2900 mg/L. Linearity at lower limit is given within ± 20%, at the decision point within ± 10%, at upper limit within ± 5%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.	
Limit of detection**	8.56 mg/L
Limit of quantitation**	8.56 mg/L

Interference by	**Interferences ≤ 10% up to**	**Analyte concentration [mg/L]**
Bilirubin (conjugated)	13.5 mg/dL	420
Bilirubin (unconjugated)	25 mg/dL	469
Lipemia (triglycerides)	600 mg/dL	73.4
	800 mg/dL	409
Urea	45 g/L	80.6
	45 g/L	453
Hemolysis interferes. **Bilirubin (conjugated/unconjugated)** interferes at low concentrations.		
For further information on interfering substances, refer to the literature [8,9].		

Precision			
Repeatability (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	86.0	645	1529
CV [%]	1.54	1.13	1.11
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/L]	78.4	618	1399
CV [%]	3.25	1.66	1.28

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

** according to CLSI document EP17-A, Vol. 24, No. 34

Reference Range [5,10]

Urine: 24 – 141 mg/24 h
CSF: < 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

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* Fluid Stable