

Liquid Reagents – ready to use

PROTEIN TOT. IN URINE/CSF

Pyrogallol red
Single Reagent

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

REF

Cont.

D03200 5 x 25 ml Single Reagent

Additionally offered:

D03600 1 x 3 ml Protein total Standard (for Urine/CSF)
D08581 12 x 5 ml Diacon Urine Level 1
D08582 12 x 5 ml Diacon Urine Level 2

TEST PARAMETERS

Method: Colorimetric, Endpoint,
Increasing Reaction, Pyrogallol red
Wavelength: 600 nm, Hg 578 nm (580-600nm)
Temperature: 20 - 25°C, 37°C
Sample: Urine or cerebrospinal fluid (CSF)
Linearity: 20 up to 3000 mg/L
Sensitivity: The lower limit of detection is 20 mg/L

REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION
Reagent 1	
Pyrogallol red	60 µmol/L
Sodium molybdate	40 µmol/L
Detergents	

REAGENT PREPARATION

The Reagent is ready for use.

REAGENT STABILITY AND STORAGE

Conditions: protect from light
close immediately after use
do not freeze the reagent!

Storage: at 2 – 8°C
Stability: up to the expiration date

SAMPLE STABILITY [3] AND STORAGE

urine: at 20–25°C 1 day
at 4–8 °C 7 days
at -20°C 1 month
cerebrospinal fluid: at 20–25°C 1 day
at 4–8°C 6 days
at -20°C 1 year

Discard contaminated specimens.

STANDARD

(has to be ordered separately)
Concentration 1300 mg/L (1.3 g/L)
Storage: 2 – 8°C
Stability: up to the expiration date
CLOSE IMMEDIATELY AFTER USE!

INTERFERING SUBSTANCES

Errors due to interfering components in urine are < 2%.

MANUAL TEST PROCEDURE

Bring reagents and samples to room temperature.

Pipette into test tubes	Blank	Std.	Sample
Sample, Std.	-	20 µl	20 µl
Dist. water	20 µl	-	-
Reagent	1000 µl	1000 µl	1000 µl
Mix incubate for 5 min. at 20-25°C/37°C			
Read absorb. against Reagent blank within 30 min.			

CALCULATION (light path 1 cm)

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

UNIT CONVERSION

g/dl x 10 = g/L
g/L x 1000 = mg/L

REFERENCE RANGE [2,4] * (mg/L)

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

*It is recommended that each laboratory establishes its own normal range.
** The value is an approximate guideline only



[Handwritten signature]

TEST PRINCIPLE

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

Proteins + pyrogallol red / molybdate → red complex

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 are reflected in an elevated CSF/serum ratio of total protein.

PERFORMANCE CHARACTERISTICS

LINEARITY

The test is linear from 20 – 3000 mg/l. If values exceed this range samples should be diluted 1 + 1 with NaCl (9 g/L sodium chloride in dist. water) and the result multiplied by 2. Samples with lower concentrations should be used with higher volumes.

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 between Dialab Total protein (y) and a commercially available test (x) using 69 samples gave following results: $y = 1.02 x + 2.20$ mg/l; $r = 0.990$.

QUALITY CONTROL

All control solutions with protein total values determined by this method can be used.

We recommend:

REF	Cont.
D08581	12 x 5 ml Diacon Urine Level 1 Urine Control Normal
D08582	12 x 5 ml Diacon Urine Level 2 Urine Control Abnormal

CALIBRATION

The assay requires the use of a Protein total Standard
We recommend:

REF	Cont.
D03600	1 x 3 ml PROTEIN TOTAL STANDARD (for Urine/CSF)

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

WARNINGS AND PRECAUTIONS

- Each individual blood donation used for production of the Protein Total in Urine/CSF Standard 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 in Urine/CSF Standard contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Take the necessary precautions for the use of laboratory reagents.

REFERENCES

- Johnson AM, Rohlfis 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.
- Feigenhauer K. Laboratory diagnosis of neurological diseases. In: Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1308-26.
- Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p.52-3; 54-5.
- 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.
- Watanabe N, Kamei S, Ohkubo A, Yamanaka M, Ohsawa S, Makino K et al. Urinary protein as measured with a pyrogallol red-molybdate complex. Manually and in a Hitachi 726 automated analyzer. Clin Chem 1986;32:1551-4.

8 °C



DIALAB Produktions- und Vertriebs von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A – 7351 Wiener Neudorf – Austria
IX-NO-Süd, Hondastrasse, Objekt M55
Postfach 7743 (0) 2236 660910-0
Telefon 7743 (0) 2236 660910-30 e-mail office@dialab.at