



Presentation:

Cod. SU031 CONT: R 2 x 125 mL . + Cal 1 x 5 mL

Store at: +2+8°C.

Procedure

Quantitative determination of total urinary and CSF protein.

Only for *in vitro* use in clinical laboratory (IVD)

TEST SUMMARY

Protein react in acid solution with pirogallol red and molybdate to form a colored complex.

The intensity of the color formed is proportional to the protein concentration in the sample^{1,2}.

REAGENTS COMPOSITION

R	Pyrogallol red Sodium molybdate	50 mmol/L 0.04 mmol/L
μPROTEIN CAL	Albumin/Globulin aqueous primary standard 1000 mg/L	

REAGENT PREPARATION AND STABILITY

Reagent and standard are ready to use.

All the components of the kit are stable until the expiration date on the label when stored at 2-8°C, protected from light and contamination prevented during their use.

Do not use reagents over the expiration date.

μPROTEIN CAL: Once open is stable up to 1 month when stored tightly closed at 2-8°C, protected from light and contamination prevented during their use.

Signs of Reagent deterioration:

- Presence of particles and turbidity.
- Blank absorbance (A) at 598 nm. ≥ 0.30

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Stored at tightly closed at 2-8°C. Do not use reagents over the expiration date.

SPECIMEN

Urine 24 h: Stability 8 days at 2-8°C.

Cerebrospinal fluid (CSF): Stable 4 days at 2-8°C.

MATERIAL REQUIRED BUT NOT PROVIDED

- Spectrophotometer or colorimeter measuring at 598 nm.
- Matched cuvettes 1.0 cm. light path.

General laboratory equipment.

TEST PROCEDURE

- Assay conditions:
Wavelength: 598 nm
Cuvette: 1 cm light path
Temperature 37°C / 15-25°C
- Adjust the instrument to zero with distilled water.
- Pipette into a cuvette:

	Blank	Standard	Sample
R (mL)	1.0	1.0	1.0
Calibrator ^(Note 1-2) (μL)	--	20	--
Sample (μL)	--	--	20

- Mix and incubate for 5 min at 37°C or 10 min at room temperature (15-25°C).
- Read the absorbance (A) of the samples and Standard, against the Blank. The color is stable for at least 30 minutes.

CALCULATIONS

Urine 24 h

$$\text{mg protein/24 h} = \frac{(A)\text{Sample}}{(A)\text{Standard}} \times 1000 \text{ (Standard conc.)} \times \text{vol. (L)urine 24 h}$$

CSF

$$\text{mg/L protein in the sample} = \frac{(A)\text{Sample}}{(A)\text{Standard}} \times 1000 \text{ (Standard conc.)}$$

QUALITY CONTROL

Control sera are recommended to monitor the performance of the procedure, Control Normal Ref. QC001 and Control Pathological Ref.

QC002. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Serum controls are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

REFERENCE VALUES

Urine:	< 100 mg/24 h (< 150 mg/24 h in pregnancy)
CSF:	Children 300 -1000 mg/L
	Adults 150 - 450 mg/L

(These values are for orientation purpose).

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE

In healthy persons, the urine contains no protein or only a trace amount of protein; normally the glomeruli prevent passage of protein from the blood to the glomerular filtrate. Glomerular injury causes increased permeability to plasma proteins, resulting in proteinuria, which refers to the presence of protein in the urine.

A persistent finding of proteinuria is the single most important indication of renal disease.

Elevated concentration of protein in cerebro-spinal fluid (CSF) can be cause by infections and intracranial pressure^{1,5,6}.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE

- Measuring Range:
Up to *linearity limit* of 4000 mg/L..
If results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L. and multiply result by 2.
- Accuracy:
Results obtained GPL reagents did not show systematic differences when compared with other commercial reagents.
The results of the performance characteristics depend on the analyzer used.

INTERFERING SUBSTANCES

Hemolysis^{1,2}.

A list of drugs and other interfering substances with protein determination has been reported by Young et. al^{3,4}.

NOTES

- Calibration with the aqueous standard may cause a systematic error in automatic procedures. In these cases, it is recommended to use a serum Calibrator.
- Use clean disposable pipette tips for its dispensation.

BIBLIOGRAPHY

- Orsonneau JL et al. An improved Pyrogallol Red-Molybdate Method for Determining Total Urinary Protein. Clin Chem 1989 (35):2233-2236.
- Koller A. Total serum protein. Kaplan A et al. Clin Chem The C.V. Mosby Co. St Louis. Toronto. Princeton 1984; 1316-1324 and 418.
- Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
- Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
- Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
- Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

