



URINARY PROTEINS LR liquid reagent

REF E4550650 6x50 ml

CE 4550630 6X30 ml

IVD For in vitro medical device

Use

Kit for measurement of Total Protein in urine and CSF, Pyrogallol red colorimetric method.

Summary

Urinary proteins measurements are used for nephrologic screening and tracking of nephropathy.

Principle

Proteins react in acid solution with Pyrogallol red and molybdate to form a coloured complex. Increase in absorbance, read at 600 nm, is proportional to the protein concentration in the sample.

Reagents

R1	Pyrogallol Red	50.0 mmol/l
	Sodium Molybdate	0.04 mmol/l

Reagent Preparation

Reagents are liquid and ready to use. After opening it is stable up to the expiry date if recapped immediately.

Storage and stability

- Store the kit at 2 – 8 °C.

Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with care, according to good laboratory practice.

Waste Management

Please refer to the local legal requirements.

Specimen Collection and Preparation

- 24 hour Urine
- Cerebrospinal Fluid (CSF)
- Urine samples are stable 8 days at 2 – 8° C
- CSF samples are stable 4 days at 2 – 8° C

Note

- The kit, according to this method, must be used in manual procedures. About automatic using follow specific applications.
- Avoid direct light, contamination and evaporation.
- The volumes in the procedure can be changed proportionally.
- In case of complaint or quality control request, refer to the lot number on the package or the lot number on the single vials.

Procedure

Wavelength	λ: 600 nm
Working Temperature	37°C
Optical path	1 cm
Reaction	"End point"

-- Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	--	--
Sample	--	--	10 µl
Standard	--	10 µl	--

Mix, then incubate for 5' at 37°C. Measure the absorbance of the sample (EC) and standard (ESTD) against blank reagent.

Calculation

$$\text{Total Urinary Protein (g/dl)} = \text{EC} / \text{ES} \times \text{Conc. STD}$$

The reagent performances are related to 37°C, 1 cm and 600 nm.

Reference Values

Urine	0.028 – 0.141 g/24h
C.S.F.	0.150 – 0.450 g/l

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

ANALYTICAL PERFORMANCES

Linearity

Reaction is linear up to a concentration of 4000 mg/dl. Samples with values exceeding 4000 mg/dl must be diluted with saline solution. Then multiply the result for diluting factor.

"Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (g/dl)	N = 12.18	H = 43.90
D.S.	N = 0.25	H = 1.14
C.V.%	N = 2.04	H = 2.59

"Inter-Assay" precision (between-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (g/dl)	N = 13.00	H = 44.46
S.D.	N = 0.19	H = 0.36
C.V.%	N = 1.45	H = 0.81

Analytical sensitivity

The test sensitivity in terms of detection limit is: 1.5 g/dl.

Correlation

A study based comparing this method with a similar method on 20 samples has given a correlating factor: **r = 0.99**

$$y = 1.1137x + 0.728$$

Interferences

No interference was observed by the presence of:
Ascorbate Acid ≤ 25 mg/dl
Hemoglobin ≤ 50 mg/dl
Tryglicerides ≤ 500 mg/dl
For a comprehensive review of interfering substances, refer to the publication by Young.

Quality controls

It's necessary, every time the kit is used, to make the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Bibliography

- Orsonneau JL et Al. An improved Pyrogallol RedMolybdate 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.
Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.

Symbols

CE CE Mark (requirement of 98/79 regulation)

IVD in vitro medical device

LOT Batch Code

Use by

Storage temperature limits

Read instruction for use

Gesana Production srl

Gesana Production s.r.l.

Urinary Proteins LR
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