ROBONIK®

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prietest™*...Clinical Chemistry Reagents*

MICRO PROTEIN

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of activity of Micro Protein in Urine and CSF on photometric systems.

ORDERING INFORMATION	**Pack Size**	**Cat No.**
	1 X 25 ml	MP 01 25
	1 X 50 ml	MP 01 50

CLINICAL SIGNIFICANCE : An increase of urinary protein (normally very low) most often indicates a renal disorder due to an increased glomerular permeability (nephrotic syndrome, progressive renal failure, hypertension) or to a decreased tubular reabsorption (Fanconi syndrome, chronic pyelonephritis, heavy metal poisoning). There are also pathological proteinurias due to protein overload or to disorders of the lower urinary tract. Under some conditions (intense exercise, strong fever, prolonged upright posture...), the urinary protein rate can be increased in an intermittent way. The protein concentration in the cerebrospinal fluid (CSF) can increase in some CNS diseases (cerebral tumours, multiple sclerosis), and particularly those of an inflammatory nature (meningitis for example).

METHOD :
Colorimetric. Pyrogallol Red, End point.

PRINCIPLE :
Proteins bound to the pyrogallol red-molybdate complex form in an acidic medium a blue/purple complex whose absorbance is pro- portional to the protein concentration in the sample.

$$\text{Proteins} + \text{Pyrogallol Red} + \text{Molybdate} \xrightarrow{\text{Acidic Medium}} \text{Blue Purple Colored Complex}$$

REAGENTS :
COMPONENTS AND CONCENTRATIONS:
Pyrogallol Red : 60 µmol/l
Sodium Molybdate : 40 µmol/l
Preservative & Stabilizer

Standard : 50 mg/dl (0.5 g/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :
The reagents are stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C, protected from light and contamination is avoided. Do not freeze the reagent!
The standard is stable up to the end of the indicated date of expiry on the vial label, if stored at 2 to 8°C.

WARNINGS AND PRECAUTIONS :
Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :
Please refer to local regulation requirements.

REAGENT PREPARATION :
The reagent and the standard are ready-to-use.

MATERIALS REQUIRED BUT NOT PROVIDED :
NaCl solution 9 g/l, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :
Urine, 24h collection recommended. Cerebral Spinal Fluid (CSF).
Stability: **urine** should be stored at 2 to 8°C.
CSF may be analyzed fresh or stored 3 days at 2 to 8°C
Discard contaminated specimens.

ASSAY PROCEDURE :
Application sheets for automated systems are available on request.
Wavelength : Hg 630 nm, 600 nm
Optical Path : 1 cm
Temperature : 37°C
Mode : End Point
Bring all the contents of the kit to Room Temperature prior to use.
Read absorbance of sample against reagent blank
Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

	Blank	Standard	Sample / Control
Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	—	—
Standard	—	10 µl	—
Sample / Control	—	—	10 µl

Mix and read the absorbance (A) after a 5 minutes incubation but within 30 minutes.

CALCULATION :
With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. of Standard - Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

CONVERSION FACTOR : Micro Protein [mg/dl] X 0.01 [g/L]

CALIBRATION :
For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :
To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :
MEASURING RANGE :
The test has been developed to determine Micro Protein concentrations within a measuring range from 10 to 200 mg/dl (0.1 to 2 g/L) . When values exceed higher limit of the range, such samples should be diluted 1+4 with NaCl solution (9 g/l) and the result multiplied by 5.

SPECIFICITY / INTERFERENCES :
No interference was observed by ascorbic acid up to 5 mg/dl (283.9 µmol/L), bilirubin up to 20 mg/dl (342.08 µmol/L), Glucose 500 mg/dl (27.75 mmol/L), Hemoglobin up to 200 mg/dl (2 g/L) and triglycerides up to 600 mg/dl (6.84 mmol/L). A list of drugs and other interfering substances with Micro Protein determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :
The lower limit of detection is 10 mg/dl (0.1 g/L).

PRECISION :

Intra-assay precision n = 20	Mean [mg/dl]	SD [mg/dl]	CV [%]
Sample 1	72.3	0.85	1.18
Sample 2	50.6	0.18	0.35

METHOD COMPARISON :
A comparison between Robonik Prietest Micro Protein (y) and a commercially available test (x) using 20 samples gave following results :
Linear Regression : y = 0.9551 x + 0.9705 mg/dl
Correlation Coefficient : r = 0.9246

REFERENCE RANGE :
Urine (Random) : 1 to 14 mg/dl (0.01 to 0.14 g/L)
Urine (24 Hrs) : 28 to 140 mg/24 hrs.
CSF : 10 to 40 mg/dl (0.1 to 0.4 g/L)
It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Johnson, A.M., *et al., Proteins*, Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burtis, C. A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 325.
2. Privitera, M.D., *et al., Nervous System*. Clinical Chemistry, Theory, Analysis and Correlation (Mosby ed.), (2003), 4th Ed., 787 and appendix.
3. Tietz, N.W., Clinical guide to laboratory tests, 3rd Ed, (W.B. Saunders eds. Philadelphia USA), (1995), 520.
4. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995

INSTRUMENT APPLICATION ***prietest TOUCH***
Name : MICTP Mod : END-P Pri.: 630 , Sec.: 0 Temp: 37C , KF : 1.000 Vol : 500ul , Unit : mg/dl Lag : 5 , Read : NA Blk : Y, QC : Y, Norm : Y Std : 1 , Concen : Std.: 1 = 50 Normal HI = 14 Normal LO = 1 QCNH : * QCNL : * QCABH = * QCABL = * Rgnt. Linearity : 200 NOTE : * Indicates user definable parameter. NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	MICRO PROTEIN
Reaction	End Point
Reaction Slope	Increasing
Wavelength 1	630 nm
Temperature	37°C
Zero Setting	Reagent Blank
Standard Conc.	50
Units	mg/dl
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation Time	5 minutes
Reference Range	1 to 14
Reagent Linearity	200

ROBONIK®
An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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