OBio...
Supporting Care to Cure
A Division of Orchard Medical

Micro Protein

Order Information

Cat. No.	Kit Configuration
OMR1139	Reagent: 1 x 20 mL
	Standard: 1 x 2 mL

Summary

The presence of protein in urine is a very sensitive indicator of renal disorders. There are four ways by which increased amounts of protein can occur: increased glomerular permeability; defective tubular re-absorption; increased plasma concentration of an abnormal, low molecular weight protein; and abnormal secretion of protein into the urinary tract Albuminuria, increased amounts of albumin in urine, has been recognized as an early indicator of renal damage in diabetes that can be reversed if detected and treated early.

Method

Colorimetric Pyrogallol Red method.

Principle

Pyrogallol Red is combined with molybdenum acid at a low pH. When the complex is combined with protein, a blue-purple color is formed. The increase in absorbance at 620 nm is directly proportional to the protein concentration in the sample

Proteins + Pyrogallol Red + Molybdate —(Acidic Medium)→ Blue Purple Colored Complex

Reagents

Storage Instructions and Reagent Stability
Reagent are stable up to the end of the indicated month of expiry, if stored at 2° – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!
Reagent: Pyrogallol Red
Solution Standard: Micro
Protein (50 mg/dL)

Composition:

Sodium Molybdate 80 mg/L, Succinic Acid 5 g/L, Pyrogallol red 2.5 mg/dL, preservatives and stabilizers.

Warnings and Precautions

1. Do not swallow! Avoid contact with skin and mucous membranes.
2. In very rare cases, samples of patients with gammopathy might give falsified results.
3. Please refer to the safety data sheets 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.
4. For professional use only!

Waste Management

Please refer to local legal 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

Specimen

Urine & CSF. Proteins are reported to be stable in the samples for 3 days at 2°–8 °C.
Discard contaminated specimens.

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	620nm (610-640)
Optical path	10 mm
Temperature	37 °C
Measurement	against reagent Blank

	Blank	Sample/Standard
Sample/Standard	--	20 µl
Reagent	1000 µl	1000 µl
Mix, Incubate for 15 min. at room temperature and read absorbance.		

Calculation

With Standard or Calibrator

$$\text{Micro Protein (mg/dL)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Std. /Cal}} \times \text{Conc. of Std. /Cal (mg/dL)}$$

To determine the 24-Hour Urinary Protein, measure the 24-hour urine total volume (T V) in mL and assay the urine protein content (mg/dL). Calculate the 24-Hour Urinary Protein using the following formula:

$$\text{Protein (mg/day)} = \text{Protein (mg/dL)} \times \frac{\text{T V}}{100}$$

Where: T V = 24-hr. urine total volume in mL 100 = converts mL/day to dL/day

Calculation factor

To convert the results into S.I. units, multiply the micro protein concentration (mg/dL) by 0.0100. For example, micro protein concentration = 21.8 mg/dL x 0.0100 = 0.218 g/L.

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics

Measuring range
The test has been developed to determine Micro Protein activities within a measuring range from 1-180 mg/dL. When values exceed this range 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 30 mg/dL and Triglycerides up to 1000 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 1 mg/dL.

Linearity

Linearity of detection is 180 mg/dL.

Precision

Intra-assay N = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	16.58	1.02	6.15
Sample 2	44.83	1.55	3.46

Inter-assay N = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	21.82	1.11	5.09
Sample 2	34.28	1.32	3.84

Method Comparison

A comparison of Nucleus Diagnosys Micro Protein (y) with a commercially available test (x) using 15 samples gave following results:
$y = 0.981x + 0.447$; $r^2 = 0.990$.

Reference Range

[mg/L]

Urine: 20 – 140 mg/24 hrs
CSF : 100 – 450 mg/L
Each laboratory should check if the references range are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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DIAMOND ARCADE, 68 JESSORE ROAD,

1st FLOOR, UNIT No. 110 & 112, KOLKATA – 700 055

CUSTOMER CARE No: 84200 69980

CUSTOMER CARE E-MAIL: sales.orchardmedical@gmail.com