Spectrum For Diagnostic Industries

Micro Total Protein (MT-P)
Pyrogallol - Red

IVD

REF.	Pack size
140 02 030	(2 x 30 ml) 60 tests
140 02 050	(2 x 50 ml) 100 tests

Intended Use

Micro total protein reagent is intended for the in-vitro quantitative and diagnostic determination of total protein in human cerebrospinal fluid (CSF) and urine .

Introduction

Protein level in spinal fluid may be increased in a variety of diseases including tumors, meningitis,and polyneuritis. Most of the proteins found in CSF originate from plasma; only 20% originate from intrathecal synthesis. The two main proteins found in human urine are albumin and uromucoid. Increased urinary proteins may be associated with a number of diseases, among them are destructive lesions of the kidney, primary and secondary nephropathies and also during pregnancy.

Method

Colorimetric method (Pyrogallol–red molybdate complex).

Principle

In acidic medium, protein in the specimen reacts with pyrogallol red in the presence of molybdate ions to form a purple colored complex. This colored complex absorbs maximally at 600 nm and the optical density is directly proportional to protein concentration of the test sample.

Reagents

Reagent

Succinate buffer	100 mmol/L
Sodium oxalate	4.0 mmol/L
Sodium molybdate	60 µmol/L
Pyrogallol red	80 µmol/L

Harmful (Xn): R20/22: Harmful by inhalation and if swallowed.
S24/25: Avoid contact with skin and eyes.

For further information, refer to the Micrototal protein MT-P reagent material safety data sheet.

Standard protein 150 mg/dL

Reagents preparation, storage and stability

Microprotein reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles,when stored at 2 – 8 °C.Once opened, the reagent vial is stable for 6 months and the standard vial is stable for 3 months at the specified temperature.

Deterioration

Do not use the Spectrum Micrototal protein reagents if turbid. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water.
In case of severe injuries; seek medical advice immediately.

Specimen collection and preservation

Use urine and CSF free from blood contamination.
Urine: 24 hour urine is the specimen of choice. Centrifuge urine specimen if turbidity is obvious. No special additives are required but keep the specimen cool during collection. To avoid enhanced albumin excretion, samples should not be collected after exertion or following acute ingestion of a fluid load.

CSF: Avoid blood contamination since protein.concentration in whole blood is 1000 times higher than normal CSF.
Centrifuge CSF specimen if turbidity is obvious.

Stability (urine): 1 day at 15 – 25 °C; 8 weeks at 4 – 8 °C; 1 year at -20 °C **Stability (CSF):** 1 day at 15 – 25 °C; 4 weeks at 4 – 8 °C; 6 months at -20 °C

Procedure

Wavelength	600 nm (578 is an optional)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 50
Temperature	15 – 25 °C
Zero adjustment	Reagent blank
Incubation time	10 minutes (15– 25 °C)
Sensitivity	6 mg/dL
Linearity	500 mg/dL
Reagent Blank Limits	Low 0.1 AU High 0.26 AU

	Blank	Standard	Specimen
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard	------	20 µl	------
Specimen	------	------	20 µl

Mix and incubate for exactly 10 minutes at 15 - 25 °C. Measure absorbance of specimen ($A_{specimen}$) and standard($A_{standard}$) against reagent blank within 10 minutes.

Calculation

$$\text{CSF or Urine protein conc. (mg/dL)} = \frac{A_{specimen}}{A_{standard}} \times 150$$

Concentration / 24hr urine:

Measure the urine volume and calculate the concentration of M-TP in 24hr urine as following:

$$\text{Concentration of MTP /24hr urine} = \text{Concentration /dL} \times \frac{\text{ml of urine}}{100}$$

Quality control

Normal and abnormal control serum of known concentration should be analyzed with each run.

Interference

Avoid erythrocyte contamination. There is no significant interference from the following substances present in urine up to the following concentrations:

Uric Acid: 85 mg/dL (5 mmol/ L)

Oxalate: 90 mg/dL (10 mmol/L)

Phosphate: 1.2 g /L (39 mmol/L)

Calcium: 130 mg/dL (32 mmol/L)

Creatinine: 6 g/L (53 mmol/L)

Ascorbic acid: 10 mg/dL (568 µmol/L)

Bilirubin: 60 mg/dL (1.0 mmol/L)

Expected values

Urine (24 hrs) : 20 – 145 mg/day

Urine (random) : < 10 mg/dL

CSF : 15 – 45 mg/dL

Performance characteristics

Methods Comparison

A comparison between Micrototal Protein reagent and a commercial reagent of the same methodology was performed on 20 human Urine samples. A correlation of 0.975 was obtained.

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	37	105
SD	0.74	1.27
CV%	2.0	1.3

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	39	109
SD	0.79	1.36
CV%	2.7	1.9

Sensitivity

When run as recommended, the minimum detection limit of the assay is 6 mg/dL.

Linearity

The reaction is linear up to microprotein concentration of 500 mg/dL. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result × 2).

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Watanabe N., Kamei, S., Oh Kubo A., and Tok uda K., Clin, Chem., 1986.
2. Henry R.J., Cannon, D.C., Winkelman J.W., "Clinical Chemistry, Principles and Techniques." Harper & Row, 2nd Ed.1974.

SYMBOLS IN PRODUCT LABELLING

IVD For in-vitro diagnostic use
LOT Batch Code/Lot number
REF Catalogue Number
Consult instructions for use
Temperature Limitation
Use by/Expiration Date
CAUTION. Consult instructions for use
Manufactured by

Spectrum For Diagnostics Industries - Free Zone
Ismailia Free Zone , Block 5 .
Cairo- Port said Avenue.
Ismailia,Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com
E-mail:info@sdi-fz.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

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