SPECTRUM

The Creative Approach to Bioscience

Micrototal Protein (MT-P)
Pyrogallol - Red

REF:282 001 (2 x 50 ml) 100 test
REF:282 002 (4 x100ml) 400 test
REF:282 003 (2 x100ml) 200 test

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum Diagnostics Micrototal protein reagent is intended for the in-vitro quantitative, diagnostic determination of total protein in human cerebrospinal fluid (CSF) and urine on both automated and manual systems.

Background

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 lesion of the kidney, primary and secondary nephropathies and also during pregnancy.

Method

Colorimetric method (Pyrogallol–red molybdate complex).

Assay Principle

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

Reagents

Standard protein (ST)
150 mg/dL

Reagent (R)

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.

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.

Reagent Preparation, Storage and Stability

Spectrum Micrototal protein reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles,when stored at 2 – 8 ^{o}C.Once opened, the reagent vial is stable for 6 months and for standard is stable for 3 months at the specified temperature if contamination is avoided.

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.

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 ^{o}C; 8 weeks at 4 – 8 ^{o}C;
1 year at -20 ^{o}C

Stability (CSF): 1 day at 15 – 25 ^{o}C; 4 weeks at 4 – 8 ^{o}C;
6 months at -20 ^{o}C

System Parameters

Wavelength	600 nm (578 is an optional)
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 50
e.g.: Reagent volume	1 ml
Sample volume	20 µl
Temperature	15 – 25 ^{o}C
Zero adjustment	Reagent blank
Incubation time	10 minutes (15– 25 ^{o}C)
Reagent Blank Limits	Low 0.1 AU
	High 0.26 AU
Sensitivity	6 mg/dL
Linearity	500 mg/dL

Procedure

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

Mix and incubate for exactly 10 minutes at 15 - 25 ^{o}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 MTP 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 urine control of known concentrations should be analyzed with each run.

Performance Characteristics
Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	37	105
SD	0.74	1.27
CV%	2.0	1.21

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	39	109
SD	0.79	1.36
CV%	2.03	1.25

Methods Comparison

A comparison between Spectrum Diagnostics 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.

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).

Interfering Substances

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

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretition of the results is considered the responsibality of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

6 – 500 mg/dL.

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. Henry R.J., Cannon, D.C., Winkelman J.W., “Clinical Chemistry, Principles and Techniques.” Harper & Row, 2nd Ed.1974.
2. Watanabe N., Kamei, S., Oh Kubo A., and Tok uda K., Clin, Chem., 1986., 32/8:1551.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
282 001	2 x 50 ml
282 002	4 x 100 ml
282 003	2 x 100 ml

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