TECO DIAGNOSTICS
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MICROPROTEIN
DYE BINDING METHOD
TC MATRIX

INTENDED USE
For the quantitative determination of total protein in urine and cerebrospinal fluid (CSF) on TC Matrix analyzers.

SUMMARY AND EXPLANATION OF THE TEST
Measurement of total protein in urine and in cerebrospinal fluid (CSF) is important in the detection of renal pathology. Proteinuria can occur in increased glomerular permeability, defective tubular reabsorption and glomerular permeability, and abnormal secretion of protein into the urinary tract. Albumin-urea has been recognized as an early indicator of renal damage in diabetes, that can be reversed if detected and treated sufficiently early.
The measurement of CSF total protein is used to detect increased permeability of the blood/brain barrier to plasma proteins or to detect increased intrathecal secretion of immunoglobulins.
This test is based on the procedure developed by Watanabe et. al. which is a dye-binding method utilizing pyrogallol red-molybdate complex, modified to equalize the reactivity of albumin and γ-globulin, and provide good precision and linearity.
The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 600 nanometers. This change in absorbance is directly proportional to the concentration of protein in the sample and is used by the TC Matrix System to calculate and express the protein concentration.

Pyrogallol red (PR) + Molybdate (Mo) + Protein $\longrightarrow$ PR-Mo-Protein complex.

REAGENT CONTENTS:
Each kit contains: Six Microprotein Reagent (6×40 ml)
One Microprotein Standard (1x20 ml)
Instruction Insert.

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Pyrogallol red: 0.058 mmol/L
Molybdate: 0.12mmol/L
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Microprotein Reagent stored unopened at 2ºC to 8ºC stable until the expiration date shown on the bottle label. Once opened, Microprotein Reagent is stable for 30 days, or until the expiration date on the label.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. It is recommended that urine assays be performed within 2 hours of collection. For timed specimens, the collection container should be kept in the refrigerator or on ice during the timed period. Preservatives are not recommended.
2. CSF specimens should be centrifuged and analyzed immediately. Specimens may be refrigerated or frozen for 7-10 days for repeat determinations.

CALIBRATION
1. Calibrator required: Microprotein Standard (1 x 20 ml)
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

Note: Refer to the TC Matrix manual for further instructions on calibrating the instrument

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

At least two levels of control material.

INTERFERENCE
1. It is recommended not to use urine specimens with added preservatives since some preservatives such as HCl or Benzoic acid have shown to interfere in the protein assay, yielding false low results.
2. On this method, refer to the work of Young for a review of drug and comprehensive list of substances which affect the Microprotein level.

EXPECTED VALUE
CSF: 15-45 mg/dL or 0.15-0.45g/L
Urine (random): <10 mg/dL or < 0.1g/L
Urine (24 hours):50-100mg/dL or 0.05 to 0.1g/24 hours
Urine (average): 1 to 14 mg/dL or 0.01 to 0.14 g/L

PRECAUTIONS:
1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH Biosafety in Microbiological and Biomedical Laboratories, manual and in accordance with national or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to ensure the results are reliable before testing the specimens.

PROCEDURES

TEST NAME:	MTP	R1:	300
TEST NO.		R2:	0
FULL NAME:	Microprotein	SAMPLE VOLUME:	5
REFERENCE NO.:		R1 BLANK:	/
ANALY.TYPE:	Endpoint	MIX REAG. BLANK:	0.1 - 1.5
PRI. WAVE :	630 nm	CONCENTRATION:	/
SECON. WAVE:	/	LINEARITY LIMIT:	/
TREND:	Increase	SUBSTRATE LIMIT:	/
REACT. TIME:	0 - 18	FACTOR:	/
INCUBATE TIME:	/	PROZONE CHECK:	/
UNIT:	mg/dl	Q1: / Q2: / Q3: / Q4: /	
PRECISION:	Integer	PC: / ABS.: /	
Calibration Type: Calibrate+ Reag.Blank		Calibration Rule: Two-point linear	

PERFORMANCE CHARACTERISTICS

Analytical Range: CSF 6.0- 300 mg/dL
Urine 6-150mg/dL

Accuracy: Comparison study was performed on TC Matrix System for 40 samples. Beckman Coulter Microprotein Reagent was used to compare with Microprotein Reagent. The results of this study yielded a correlation coefficient of 0.99 with a regression equation of y=0.99X +0.8.

Precision: Within Run precision for Microprotein Reagent Set was determined following a modification of NCCLS EP5-A.Two commercial human urine samples were assayed on the TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	9	21
Standard Deviation (mg/dl)	9.4	2.5
Coefficient of Variation (%)	4.1	9.0

Run-Day precision for Microprotein Reagent was determined following a modification of NCCLS EP5-A. Two commercial human urine samples were assayed on the TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	9	21
Standard Deviation (mg/dl)	8.7	1.6
Coefficient of Variation (%)	4.5	8.2

REFERENCES:

1. MeElderry LA, Tarbit IF. Cassells-Amith AJ. Six methods for urinary protein compared. Clin Chem 1982; 28:356-60.
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3. Watanabe N, Kamei S, Ohkubo A, et al. Urinary protein as measured with a pyrogallol red-molybdate complex, manually and in a Hitachi 726 automated analyzer. Clin Chem 1986l 32:1551-4.
4. Fujita y, Mori I, Kitano S. COLOR Reaction Bertween Pyrogallol red-molybdenum (VI) Complex and Protein. Benseki Kagaku 1983; 32:379-86

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Manufactured by:

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