TECO DIAGNOSTICS
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CSF/URINE PROTEIN
TC MATRIX-160

INTENDED USE
The test is applied for the quantitative determination of Protein HS-Microprotein concentration in urine and cerebrospinal fluid (CSF).

TEST SUMMARY AND PROCEDURE [1, 2, 3, 4, 5]
Proteins combine with pyrogallol red to form a color complex, the absorbance of which is measured at 600 nm.Sodium dodecylsulphate is added to increase accuracy inmeasuring proteins other than albumin (Watanabe).

TEST PARAMETERS
Method : Colorimetric, Endpoint, Increasing Reaction, Biuret
Wavelength : Hg 600 nm (580- 620)
Linearity : 350 mg/dL

REAGENT COMPONENTS
Succinate buffer	≤ 0.08 M pH 2.50,
Pyrogallol red	≤ 0.06 mM,
Sodium molybdate	≤ 0.15 mM,
Sodium oxalate	≤ 1.2 mM,
Sodium benzoate	≤ 0.37 mM,
SDS	≤ 0.12 mM.

Material required but not provided
This assay requires the use of a MicroProtein Control Level I-II / MicroProtein Calibrator

REAGENT PREPARATION
Reagents are ready for use.

REAGENT STABILITY AND STORAGE[6]
Reagents are stable at 2-8°C until the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at 2-8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.
Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE
It can be used for both urine and cerebrospinal fluid.
A rapid sample collection is not required but a decrease in lipemia is necessary. Hemolysis should be avoided.

Samples that have been frozen and thawed should be thoroughly mixed before assay.
For sample collection and preparation, only use suitable tubes or collection containers. Only the samples listed below were tested and found acceptable:

Urine: Use random or 24-hour urine specimens. Use no preservatives. Refrigerate the sample during collection.

Cerebrospinal Fluid (CSF): No special additives are required. Blood in a CSF specimen invalidates the protein value. Samples for urinary/CSF protein should be collected before fluorescein is given or at least 24 hours later.
When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer. Centrifuge samples containing precipitates before performing the assay. Non centrifuged samples may produce elevated results.

Stability:

Urine	1 day at 20 - 25°C	7 days at 2 - 8°C	1 month at -20°C
CSF	1 day at 20 - 25°C	6 days at 2 - 8°C	1 year at -20°C

Unit Conversion:
mg/dL x 10 = mg/L

REFERENCE INTERVAL (NORMAL VALUES) [1, 2, 3, 7]
Expected Values:
Urine :24 hour : < 140 mg/24 h
Random : < 150 mg/dL

Values Obtained from Centrifuged Samples:
CSF: Reference Interval According to Tietz: 150-450 mg/L
It is recommended that each laboratory establish its own normal range. Reference interval has been verified by using CLSI EP28- A3c protocol.

CALIBRATION AND QUALITY CONTROL
Commercially available control material with established values determined by this method may be used.

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyzer and capacity of cooling. Calibration stability is 15 days.

If controls are not within acceptable limits, calibration is required, and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

Daily quality control testing is recommended. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

PROCEDURE
Test Name:	CSF/Urine Protein	R1:	150
Full Name:	CSF/Urine Protein	R2:	0
Pri. Wave:	578 nm	Sample volume:	8
Sec. Wave:	700 nm	Calibration Type:	Spline
Assay/ Point:	1 Point End	K Value:	/
Start - End:	1 - 15	Point:	5
Decimal place:	2	Blank Type:	Reagent
Unit:	mg/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	1.00 - 350.00	Point 1 (STD) Con:	Standard/Calibrator
Correlation Factor:	1.0000 - 0.0000	Point 2 (STD) Con:	Standard/Calibrator
		Point 3 (STD) Con:	Standard/Calibrator
		Point 4 (STD) Con:	Standard/Calibrator

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of the test detection is1 mg/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ≤ 20%][8] **:** 7 mg/dL.

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 350 mg/dL

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.
Linearity may vary considerably depending on the instrument used.

Precision Studies : [9]

Repeatability (Within Run) (Intra-Assay)

Mean Concentration	SD	CV%	n
37.1 mg/dL	0.74	2.00	40
103.7 mg/dL	1.27	1.20	40

Repeatability (Day to Day) (Inter-Assay)

Mean Concentration	SD	CV%	n
38.01 mg/dL	0.79	2.00	40
100.09 mg/dL	2.46	2.00	40

**SD: Standard Deviation*

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:[10, 11]

Correlation with a comparative method is: r= 0.978
According to Passing-Bablok Fit:
Slope: 0.97,
Intercept: -0.54

Interference:[3, 4, 12]

No significant interactions were observed for ascorbic acid up to the interferent concentration given.
Ascorbic Acid : ≤ 200 mg/dL

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery ofthe target.
Interferences may affect the results due to medication orendogenous substances.
These performance characteristics have been obtained byusing an analyzer. Results may vary if a different instrument or a manual procedure is used.

WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only. Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

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