DXC (M-TP) MICROPROTEIN

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PURPOSE

To provide instructions for the quantitative determination of Microprotein on the DXC 600/800.

PRINCIPLE

M-TP reagent, when used in conjunction UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Microprotein Calibrator, is intended for the quantitative determination of total Microprotein in human urine and cerebrospinal fluid (CSF).

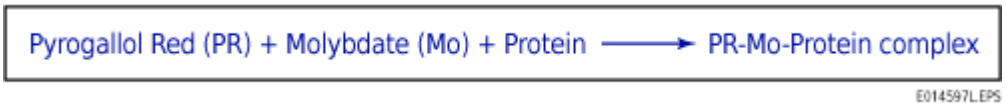
BACKGROUND

Clinical Significance

An increase in spinal fluid protein is seen in a variety of disease states. Among them are meningitis, polyneuritis, and some tumors. Increases in urinary proteins are associated with a number of conditions among them are nephrosis hypergammaglobulinemia, pregnancy, and destructive lesions of the kidney.

Methodology

M-TP reagent is used to measure the protein concentration by a timed endpoint method. Protein in the sample reacts with the pyrogallol red (PR) and molybdate (Mo) to form a purple color complex that has a maximum absorbance at 600 nanometers.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample and 60 parts reagent for cerebrospinal fluid and one part sample and 30 parts reagent for urine. 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 System to calculate and express the protein concentration.



RELATED DOCUMENTS

R-PO-CH-0810	Quality Control Program General Laboratory
R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
M-F-CJ-0820	Chemistry Controls
J-F-CH-0826	DXC 800 Calibrators
M-F-CH-0826	Chemistry Calibrators
M-F-CH-1940	DXC 600 (AMR) Analytical Measurement Range
J-F-CH-1940	DXC 800 (AMR) Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly collected spinal fluid or urine are the preferred specimens. Whole blood, serum or plasma is not recommended for use as a sample.

Specimen Storage and Stability

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 without delay. Specimens may be refrigerated or frozen for 7 to 10 days for repeat determinations.

Sample Type	Volume	Sample Stability
CSF	0.5mL	• Analyze immediately • Room Temp 2 hours • Refrigerated 72 hours • Frozen 7-10 days
Urine		• Recommend testing within 2 hours or kept refrigerated or on ice • No preservative required

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two Microprotein Reagent Cartridges (2 x 50 tests) (Ref# 445860)

Volume per Test	
Sample Volume Urine CSF	 10 µL 5 µL
Total Reagent Volume	300 µL
Cartridge Volumes	A – – B 300 µL C – –

Reactive Ingredients	
Pyrogallol Red	0.058 mmol/L
Sodium Molybdate	0.12 mmol/L

Also non-reactive chemicals necessary for optimal system performance.

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility`s acceptance criteria.

Reagent Storage and Stability

M-TP reagent, when stored unopened at +2°C to +8°C, will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent cartridge is stable for 30 days. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

CALIBRATION

Calibrator Required

SYNCHRON® Systems Microprotein Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems Microprotein Calibrator when stored unopened at -15°C to -20°C will remain stable until the expiration date printed on the label. Once opened, resealed calibrators are stable for 60 days at +2°C to +8°C unless the expiration date is exceeded.

Calibration Information

1. The system must have a valid calibration curve in memory before control or patient samples can be run.

2. Under typical operating conditions the M-TP reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH-0820 DXC 800 Controls & M-F-CH-0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration may be required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. .For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Age	Conventional Units
CSF	Full Term <1 day	40 – 120 mg/dL
	1 – 30 days	20 – 80 mg/dL
	>1 month	15 – 45 mg/dL

Sample Type	Type	Conventional Units
Urine	Random	No Range Established
	12 hr collection	No Range Established
	24 hr collection (average)	0 – 14 mg/dL
	24 hr collection (g/24h)	0.000 – 0.165 g/24h

Analytic Range

The SYNCHRON® System(s) method for the determination of M-TP in CSF or urine provides the following analytical range:

Sample Type	Conventional Units
CSF	6 – 300 mg/dL
Urine	6 – 150 mg/dL

CSF and urine samples with concentrations exceeding the high end of the analytical range should be diluted with normal saline and reanalyzed.

Reporting results outside of analytical range

Lower limit of detection: CSF and Urine	6 mg/dL	Results below 6; Report as <6 mg/dL
Upper limit of detection: CSF	300 mg/dL	Result >300 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >600 are reported as >600 mg/dL. See limitations below regarding serum protein carryover.
Upper limit of detection: Urine	150 mg/dL	Result >150 should be diluted with 0.9% saline starting at X3, reanalyzed and dilution factor applied. Dilute to final result.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for M-TP determination is 6 mg/dL.

LIMITATIONS

1. Do not use hemolyzed samples.

2. If serum protein carryover is suspected, a saline cup should be assayed prior to analysis of microprotein samples.

3. Samples containing light chains may produce falsely low results.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Level Tested	Observed Effect
Hemoglobin	N/A	Avoid Hemolysis
Ascorbic Acid	500 mg/dL	≤-2.0 mg/dL
Calcium	130 mg/dL	≤-3.2 mg/dL
Citrate	50 mg/dL	≤-2.0 mg/dL
Creatinine	160 mg/dL	≤+3.2 mg/dL
Glucose	200 mg/dL	≤-1.0 mg/dL
Magnesium	400 mg/dL	≤+1.0 mg/dL
Oxalate	30 mg/dL	≤-2.0 mg/dL
Urea	140 mg/dL	≤-2.0 mg/dL

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
Updated formatting, added maximum dilution, added sample stability for CSF, updated related documents			
Committee Approval Date	☒ Date: 8/13/15 ☐ NA – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 7/30/15