DXC 800 (TPm) TOTAL PROTEIN

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PURPOSE

To provide instructions for the quantitative determination of total protein on the DXC 800

PRINCIPLE

TPm reagent, when used in conjunction with UniCel® DxC 800 System and SYNCHRON® Systems Protein Calibrator, is intended for the quantitative determination of Total Protein in human serum, plasma or cerebrospinal fluid (CSF).

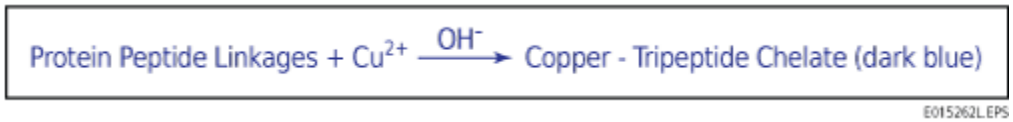
BACKGROUND

Clinical Significance

Total protein measurements are used in the diagnosis and treatment of diseases involving the liver, kidney or bone marrow, as well as other metabolic or nutritional disorders.

Methodology

SYNCHRON® System(s) determine total protein concentration by means of a rate biuret method.
A precise volume of sample (8.0 microliters serum or 60 microliters CSF) is injected into the reaction cup containing alkaline copper reagent. The ratio used is one part sample to 79 parts reagent for serum or one part sample to 11 parts reagent for CSF. Proteins in the sample combine with the reagent producing alkaline copper-protein chelate. The rate change in absorbance is monitored by a detector at 545 nanometers. The observed rate of chelate formation is directly proportional to the total protein concentration in the sample.



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
J-F-CH-0826	DXC 800 Calibrators
J-F-CH-1940	DXC 800 Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum, plasma, or CSF are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine is not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

3. CSF specimens should be centrifuged and analyzed without delay.

4. Refer to References for additional information on the effects of preanalytical variables on sample storage and stability. Each laboratory should determine if the recommended requirements are appropriate.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• Separate serum from cells within 2 hours • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months CSF specimens are not run by this method. Refer to M-TP procedure R-W-CH1925

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 Total Protein Reagent Bottles (2 x 2 L)

Volume per Test	
Sample Serum/Plasma Volume	8.0 µL
CSF	60 µL
Total Reagent Volume	630 µL

Reactive Ingredients	
Copper Sulfate	8.8 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

TPm reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. TPm reagent is stable on instrument for 60 days, unless the expiration date is exceeded.
If the reagent is frozen in transit, thaw completely, warm to room temperature and mix thoroughly by gently inverting the bottle at least 10 times. Excessive exposure to heat may cause irreversible deterioration of the reagent, as indicated by the appearance of dark brown precipitates. If such precipitation occurs, discard reagent.

CALIBRATION

Calibrator Required

SYNCHRON® Systems Protein Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems Protein Calibrator Levels 1 and 2 is stable until the expiration date printed on the calibrator bottle if stored unopened at -15°C to -20°C. Once opened, resealed calibrators stored at +2°C to +8°C are stable for 60 days unless the expiration date is exceeded.

Calibration Information

1. The system must have valid calibration factors in memory before controls or patient samples can be run.

2. Under typical operating conditions the TPm assay must be calibrated every 14 days or with each new bottle of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 Systems *Instructions for Use* (IFU) manual.

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

Do not use controls containing diethylamine HCl.

STEPS

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

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

3. Program samples and controls for analysis.

4. After loading samples and 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.

ANTICOAGULANT TEST RESULTS

If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Anticoagulant	Level Tested for In Vitro Interference
Ammonium Heparin	14 Units/mL
Lithium Heparin	14 Units/mL
Sodium Heparin	14 Units/mL

The following anticoagulants were found to be incompatible with this method:

Anticoagulant	Level Tested for In Vitro Interference	Plasma-Serum Bias (mg/dL)
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	- 1.2

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Male and Female	
	Age (yrs)	Range
Serum/ Plasma	0-1	4.3-6.9 g/dL
Serum/ Plasma	1-4	5.2-7.4 g/dL
Serum/Plasma	4-7	5.6-7.7 g/dL
Serum/Plasma	7-11	6.5-8.3 g/dL
Serum/Plasma	11-18	6.1-8.0 g/dL
Serum/Plasma	>18	6.1-8.4 g/dL

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample Type	Conventional Units
Serum or Plasma	1.0 – 12.0 g/dL
CSF	10 – 1500 mg/dL

Samples with activitiess exceeding the high end of the analytical range should be diluted with saline and reanalyzed. The appropriate dilution factor should be applied to the reported result.

Reporting results outside of analytical range

Lower limit of range: serum / plasma	1.0 g/dL	Results below 1.0, report as <1.0
Upper limit of range: serum / plasma	12.0 g/dL	Results >12.0 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >24.0 are reported as >24.0 g/dL.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for TPm determination is 1.0 g/dL (10 g/L) for serum or plasma, and 10.0 mg/dL (100 mg/L) for CSF.

LIMITATIONS

1. Plasma samples generally yield values slightly higher than serum samples due to the presence of fibrinogen in the plasma. Experimental data showed an average increase of 0.3 g/dL with a range 0.1 to 0.5 g/dL.

2. Samples at a Lipemia Index Level of 4 and above should be ultracentrifuged and the analysis performed on the infranate.

3. Samples with high immunoprotein levels may falsely decrease total protein results. These samples should be diluted one part sample plus one part saline and reanalyzed. The result should be multiplied by two.

4. CSF samples showing evidence of hemolysis should not be used. Hemolysis may cause falsely elevated results.

Interferences

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

Substance	Source	Level Tested	Observed Effect
Bilirubin (unconjugated)	Bovine	30 mg/dL INDEX of 20	No significant interference (within ±0.4 g/dL or 4%)
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	No significant interference (within ±0.4 g/dL or 4%)
Lipemia	Human	Lipemia INDEX of 4	-0.4 g/dL
Carbenicillin	Carbenicillin Disodium Salt	2500 µg/mL	+0.2 g/dL
Methylbenzethonium Chloride	NA	0.5 mg/dL	-0.2 g/dL

2. Refer to References for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

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

REFERENCES

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