# DXC 600 (TP) TOTAL PROTEIN

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## PURPOSE

To provide instruction for the quantitative determination of total protein on the DXC 600.

## PRINCIPLE

TP reagent, when used in conjunction with UniCel® DxC 600 System(s) and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Total Protein concentration in human serum or plasma.

## 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

TP reagent is used to measure the total protein concentration by a timed-endpoint biuret method. In the reaction, the peptide bonds in the protein sample bind to cupric ions in an alkaline medium to form colored peptide/copper complexes.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 50 parts reagent. The System monitors the change in absorbance at 560 nanometers. This change in absorbance is directly proportional to the concentration of TP in the sample and is used by the System to calculate and express the TP concentration.

## RELATED DOCUMENTS

| | |
|---|---|
| R-PO-CH0810 | Quality Control Program General Laboratory |
| R-PO-CH0809 | Quality Control Westgard Rules Statistics |
| R-PR-AD0540 | Specimen Rejection/Cancellation Protocol |
| M-F-CH0820 | Chemistry Controls |
| M-F-CH0826 | Chemistry Calibrators |
| M-F-CH1940 | DXC 600 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 or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood, urine or cerebrospinal fluid are 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.

| Sample Type | Volume | Sample Stability |
|---|---|---|
| Plasma/Serum | 0.5ml | • 8 hours at 18-26° **C**<br>• 48 hours at 2-8° **C**<br>• After 48 hours, freeze at -15 to -20° C<br>CSF specimens are not run using this method. Refer to M-TP procedure R-W-CH-1925 |

## 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 TP Reagent Cartridges, Kit number 442740 (2 x 300 tests)

| Volume per Test | |
|---|---|
| Sample Volume | 6 µL |
| Total Reagent Volume | 300 µL |
| Cartridge Volumes | A 300 µL<br>B – –<br>C – – |

| Reactive Ingredients | |
|---|---|
| Cupric Sulfate | 12 mmol/L |
| pH | >12.5 |

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

TP reagent when stored unopened at room temperature will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent cartridge is stable for 20 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

## CALIBRATION

### Calibrator Required

SYNCHRON® Systems Multi Calibrator

### Calibrator Preparation

No preparation is required.

### Calibrator Storage and Stability

If unopened, the SYNCHRON® Systems Multi Calibrator may be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days. Do not use beyond the manufacturer's expiration date printed on the bottle.

### 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 TP reagent cartridge must be calibrated every 7 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 Systems *Instructions For Use* (IFU) manual.

3. This assay has within-lot calibration available. For detailed calibration instructions, refer to the UniCel DxC 600/800 Systems *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 print out with error codes and the system will alert the operator of the failure. An explanation of these error codes can be found in the UniCel DxC 600/800 Systems *Instructions For Use* (IFU) manual.

### Traceability

For Traceability information refer to the Calibrator instructions for use.

## QUALITY CONTROL

See Related Documents M-F-CH0820 Chemistry Controls

## STEPS

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

2. After reagent load is completed, calibration is 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.

**NOTICE: The system must be operating at +37°C.**

## CALCULATIONS

The system performs 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

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

## PERFORMANCE CHARACTERISTICS

### Reference Range

| Age | Range |
|---|---|
| 0 – 12 mo | 4.3 – 6.9 g/dL |
| 13 mo – 3 yrs | 5.2 – 7.4 g/dL |
| 4 – 6 yrs | 5.6 – 7.7 g/dL |
| 7 – 10 yrs | 6.5 – 8.3 g/dL |
| 11 – 18 yrs | 6.1 - 8.0 g/dL |
| >18 yrs | 6.1 – 8.4 g/dL |

### Analytic Range

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

| Sample Type | Conventional Units |
|---|---|
| Serum or Plasma | 3.0 – 12.0 g/dL |

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

### Reporting results outside of analytical range

| | | |
|---|---|---|
| Lower limit of range: serum / plasma | 3.0 g/dL | Results below 3.0, report as <3.0 |
| Upper limit of range: serum / plasma | 12.0 g/dL | Results >12.0, should be diluted with saline, reanalyzed and dilution factor applied.<br>The maximum allowable dilution is X2.<br>Results >24.0 should be reported as >24.0. |

## LIMITATIONS

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.

### Interferences

The following substances were tested for interference with this methodology:

| Substance | Source | Level Tested | Observed Effect |
|---|---|---|---|
| Bilirubin | Porcine | 30 mg/dL INDEX of 20 | NSI |
| Lipemia | Human | 500 mg/dL INDEX of 10 | NSI |
| Hemoglobin | Human | 500 mg/dL INDEXof 10 | NSI |
| Dextran | Dextran 40 | 7,500 mg/dL | NSI |
| Fluorescein | NA[c] | 25 mg/dL | -1.8 g/dL |
| Methyl dopa | Methyl Dopa HCI | 5.0 mg/dL | NSI |
| Sulfasalazine (Azulfidine) | NA | 7.5 mg/dL | -2.4 g/dL |

NSI = No Significant Interference. Refer to References (9, 10,11) for other interferences caused by drugs, disease and preanalytical variables.

## ADDITIONAL INFORMATION

For more detailed information on UniCel DxC System(s), refer to the appropriate system manual.

## REFERENCES


1. Hiller, A., Plazin, J., Van Slyke, D. D., *J. Biol Chem.*, 176:1401 (1976).
2. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation", *Textbook of Clinical Chemistry*, 2nd Edition, W. B. Saunders, Philadelphia, PA (1994).
3. National Committee for Clinical Laboratory Standards, *Procedures for the Handling and Processing of Blood Specimens*, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
4. CDC-NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, U.S. Government Printing Office, Washington, D.C. (1984).
5. Tietz, N. W., *Clinical Guide to Laboratory Tests*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1995).
6. National Committee for Clinical Laboratory Standards, *How to Define, Determine, and Utilize Reference Intervals in the Clinical Laboratory*, Approved Guideline, NCCLS publication C28-A, Villanova, PA (1994).
7. Tietz, N. W., ed., *Fundamentals of Clinical Chemistry*, 3rd Edition, W. B. Saunders, Philadelphia, PA (1987).
8. Henry, J. B., *Clinical Diagnosis and Management by Laboratory Methods*, 18th Edition, W. B. Saunders Company, Philadelphia, PA (1991).
9. Young, D. S., *Effects of Drugs on Clinical Laboratory Tests*, 3rd Edition, AACC Press, Washington, D.C. (1990).
10. Friedman, R. B., Young, D. S., *Effects of Disease on Clinical Laboratory Tests*, 2nd Edition, AACC Press, Washington, D.C. (1989).
11. Young, D. S., *Effects of Preanalytical Variables on Clinical Laboratory Tests*, AACC Press, Washington, D.C. (1993).
12. National Committee for Clinical Laboratory Standards, *Method Comparison and Bias Estimation Using Patient Samples*, Tentative Guideline, NCCLS publication EP9-T, Villanova, PA (1993).
13. National Committee for Clinical Laboratory Standards, *Precision Performance of Clinical Chemistry Devices*, 2nd Edition, Approved Guideline, Vol. 19, No. 2, NCCLS publication EP5-A, Villanova, PA (1999).

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