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WORK INSTRUCTION

J-W-CH-4361-01

DXC 800 (TRFN) TRANSFERRIN

☒ St. Joseph Medical Center, Tacoma, WA	☐ St. Anthony Hospital Gig Harbor, WA	☐ Harrison Medical Center, Bremerton, WA
☐ St. Francis Hospital, Federal Way, WA	☐ St. Elizabeth Hospital Enumclaw, WA	☐ Harrison Medical Center, Silverdale, WA
☐ St. Clare Hospital Lakewood, WA	☐ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide instructions for the quantitative determination of transferrin on the DXC 800.

PRINCIPLE

TRFN reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems CAL 1, is intended for quantitative determination of transferrin concentration in human serum or plasma.

BACKGROUND

Clinical Significance

The measurement of transferrin aids in the diagnosis of malnutrition, acute inflammation, infection, assessment of renal function and red blood cell disorders, such as iron deficiency anemia.

Methodology

TRFN reagent is used to measure the TRFN concentration by a turbidimetric method.[1,2] In the reaction, TRFN combines with specific antibody to form insoluble antigen-antibody complexes.
The SYNCHRON® System(s) automatically dilutes sample and dispenses the appropriate sample and reagent volumes into a cuvette. The ratio used is one part diluted sample to 37.5 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is proportional to the concentration of transferrin in the sample and is used by the system to calculate and express the transferrin concentration based upon a single-point calibration.

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.3 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 or urine 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	0.5mL	• Separate serum from cells within 2 hours. • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months.

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 TRFN Reagent Cartridges (2 x 150 tests)
One lot-specific Parameter Card

Volume per Test	
Sample Volume	15 µL
Diluent Volume	6 µL
Diluted Sample Volume (1:20 dilution)	6 µL
Total Reagent Volume	225 µL
Cartridge Volumes	A 200 µL B 25 µL C – –

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Reactive Ingredients	
Reaction Buffer	43.0 mL
Antibody Monospecific for human Transferrin (Goat)	6.2 mL

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 acceptance criteria.

Reagent Storage and Stability

- TRFN reagent when stored unopened at +2°C to +8°C, will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 60 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.
- DIL 1 stored unopened at room temperature is stable until the expiration date indicated on each cartridge. Once opened, DIL 1 is stable for 60 days on instrument or until the expiration date, if sooner.

CALIBRATION

Calibrator Required

SYNCHRON® Systems CAL 1

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems CAL 1 is stable until the expiration date printed on the calibrator bottle if stored capped in the original container at +2°C to +8°C. DO NOT FREEZE.

Calibration Information

1. The system must have a lot-specific parameter card and a valid calibration adjustment in memory before controls or patient samples can be run.

2. Under typical operating conditions the TRFN 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.

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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

STEPS

1. If necessary, load the reagent onto the system. A lot-specific parameter card must be loaded one time for each lot.

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

3. Program samples and controls for analysis.

4. After loading samples and controls onto the system, follow the protocols for system operations.

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

CALCULATIONS

The SYNCHRON® System(s) 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

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)
EDTA	1.5 mg/mL	-33.3
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	-63.5

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PERFORMANCE CHARACTERISTICS

Reference Range

214 – 365 mg/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	70 – 850 mg/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 detection	70 mg/dL	Results below 70, report <70 mg/dL
Upper limit of detection	850 mg/dL	Results >850 mg/dL should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >1700 are reported as >1700 mg/dL.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for TRFN determination is 70 mg/dL (0.7 g/L).

LIMITATIONS

None identified.

Interferences

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 ± 10.0 mg/dL or 10%)
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	No significant interference (within ± 10.0 mg/dL or 10%)
Lipemia	Intralipid[d]	400 mg/dL INDEX of 10	No significant interference (within ± 10.0 mg/dL or 10%)

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ADDITIONAL INFORMATION

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

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