DXC 800 (FE) IRON

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PURPOSE

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

PRINCIPLE

FE reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems FE/IBCT Calibrator Kit, is intended for the quantitative determination of Iron in human serum or heparinized plasma.

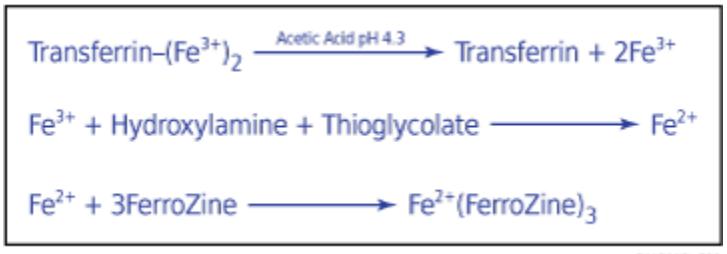
BACKGROUND

Clinical Significance

Alterations in iron and total iron binding capacity levels result from changes in iron intake, absorption, storage, and release mechanisms. Such changes are indicative of a wide range of dysfunctions including anemias, nephrosis, cirrhosis and hepatitis. Both iron and total iron binding capacity measurements are important for definitive diagnosis because they are interrelated. Tietz has presented a summary of these relationships and the patterns of iron/total iron-binding capacity associated with various disease states.

Methodology

FE reagent is used to measure the iron concentration by a timed-endpoint method. In the reaction, iron is released from transferrin by acetic acid and is reduced to the ferrous state by hydroxylamine and thioglycolate. The ferrous ion is immediately complexed with the FerroZine Iron Reagent.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 8 parts reagent. The system monitors the change in absorbance at 560 nanometers. This change in absorbance is directly proportional to the concentration of FE in the sample and is used by the System to calculate and express the FE 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
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 or heparinized-plasma is the preferred specimen. Whole blood, urine, and non-heparinized plasma 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, the separated sample should be stored at +2°C to +8°C. If assays are not completed within 24 hours, plasma samples should be recentrifuged and separated from precipitate before testing. 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	• 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 FE Reagent Cartridges (2 x 200 tests)

Volume per Test	
Sample Volume	25 µL
Total Reagent Volume	210 µL
Cartridge Volumes	A 200 µL

	B - - C 10 µL

Reactive Ingredients	
FerroZine[b]	0.4 mmol/L
Acetic acid	0.5 mol/L
Hydroxylamine hydrochloride	0.3 mol/L
Thioglycolic acid	22.3 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

FE 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 is stable for 60 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE.

CALIBRATION

Calibrator Required

SYNCHRON® Systems FE/IBCT Calibrator Kit

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems FE/IBCT Calibrator Kit is stable until the expiration date printed on the calibrator bottles if stored capped in the original container at room temperature. DO NOT FREEZE.

Calibrator 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 FE 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.

3. This assay has within-lot calibration available. 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.

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 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 25 healthy volunteers:

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

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Male	Female
Serum / Plasma	45 – 190 µg/dL	30 -180 µg/dL

Analytic Range

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

Sample Type	Conventional Units
Serum or Plasma	5 – 500 µg/dL

Reporting results outside of analytical range

Lower limit of detection	5 µg/dL	Results below 5, report as <5 µg/dL
Upper limit of detection	500 µg/dL	**DO NOT DILUTE**

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for FE determination is 5 µg/dL (0.9 µmol/L).

LIMITATIONS

1. EDTA, sodium citrate, and potassium oxalate are known to interfere with this method.
2. Samples showing evidence of hemolysis should not be used. Hemolysis may cause falsely elevated results.
3. Use disposable labware whenever possible. Rinse glassware with 0.1N HCl before use.
4. Ingestion of oral contraceptives will elevate iron and/or total iron binding capacity values.
5. Iron-dextran administration can cause elevations in total serum iron with this methodology.
6. Use of this assay is not recommended for patients undergoing treatment with deferoxamine (e.g., Desferal®) or other iron-chelating compounds.
7. Ingestion of iron (including iron-fortified vitamins or supplements) may cause transient elevated iron levels.
8. Some gadolinium magnetic resonance contrast agents such as Omniscan®, Optimark®, and Magnevist® may interfere with this method.

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 ±7 µg/dL or 5%)
Hemoglobin	RBC hemolysate	50 mg/dL INDEX of 1	+7 µg/dL AVOID HEMOLYSIS
Lipemia	Intralipid[h]	200 mg/dL INDEX of 6	No Significant Interference (within ±7 µg/dL or 5%)
Copper	NA[i]	250 mg/dL	No Significant Interference (within ±7 µg/dL or 5%)
Magnesium	NA	5.0 mg/mL	No Significant Interference (within ±7 µg/dL or 5%)

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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