Iron, Serum or Plasma

Purpose

This procedure provides instructions for IRON on Abbott Instrumentation. The Alinity c IRON2 assay is used for the quantification of Iron in human serum or plasma on the Alinity c analyzer.

The Iron2 assay is to be used as an aid in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.[1]

Policy Statements

This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children's Minnesota Laboratory.

Principle

Methodology: Ferene

The Iron2 assay is an automated clinical chemistry assay. At an acidic pH, iron is released from transferrin to which it is bound, and then quantitatively reduced to a ferrous state. The iron forms with ferene-S (3-(2-pyridyl)-5,6-bis-[2-(5-furylsulfonic acid)]-1,2,4- triazine), a stable colored complex of which the color intensity is proportional to the amount of iron in the sample. Particular reaction conditions and a specific masking agent almost entirely eliminate the interference from copper.[1]

Clinical Significance

Iron exists in biological fluids as a component of hemoglobin and myoglobin and is bound in serum and plasma to transferrin, which acts as a carrier protein. Increased iron concentrations are seen in hemolytic anemias, hemochromatosis, and acute liver disease. Decreased iron concentrations are seen in iron deficiency and anemia of chronic disease, such as in chronic renal disease. Major causes of iron deficiency include gastrointestinal and menstrual bleeding. For the assessment of the body's iron status, the measurement of transferrin and ferritin can provide more accurate information.[1]

Materials

Product Description	*Product Code*	*Stability*
Iron2 Reagent (900tests per box; each box contains 4 reagent sets of 225tests). Each reagent set consists of an R1 and R2 component. Alinity c **R1:** Active ingredient: guanidine hydrochloride (382.120 g/L). Preservative: ProClin 300. **R2:**	**MFR#** 04T9820 **CHC#** 33996	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 30 days onboard the analyzer. Stable until expiration if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.

Active ingredients: ferene-S (4.944 g/L) and L-ascorbic acid (96.866 g/L). Preservative: ProClin 300. Abbott Diagnostics		
Consolidated Chemistry Calibrator (ConCC) Each calibrator set consists of 6 lyophilized calibrator vials, and 6 empty barcode labeled vials. Abbott Diagnostics	**Alinity** **MFR#** 04V6201 **CHC#** 37653	**Store at:** 2-8 °C **Unopened:** Until Expiration **Reconstituted:** Stable 7 days if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.
Biorad MultiQual Controls Levels 1 and 3 Each box contains 12 5mL vials of control material. Biorad Laboratories	**Level 1 MFR#** 697 **Level 1 CHC#** 34574 **Level 3 MFR#** 699 **Level 3 CHC#** 34575	**Store at:** -20°C or colder **Unopened:** Until Expiration **Opened:** Stable 7 days at 2-8 °C storage with caps tightly secured.

Special Safety Precautions

The following warnings and precautions apply to: R1 **WARNING** Contains guanidine hydrochloride, acetic acid, thiourea and methylisothiazolones. H302 Harmful if swallowed. H332 Harmful if inhaled. H315 Causes skin irritation. H319 Causes serious eye irritation. H317 May cause an allergic skin reaction. H351 Suspected of causing cancer. H361 Suspected of damaging fertility or the unborn child. H402* Harmful to aquatic life. H412 Harmful to aquatic life with long lasting effects. **Prevention** P202 Do not handle until all safety precautions have been read and understood. P261 Avoid breathing mist / vapors / spray. P264 Wash hands thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves / protective clothing / eye protection. **Response** P301+P330+P312 IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor / physician if you feel unwell. P302+P352 IF ON SKIN: Wash with plenty of water. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P308+P313 IF exposed or concerned: Get medical advice / attention. P333+P313 If skin irritation or rash occurs: Get medical advice / attention. P337+P313 If eye irritation persists: Get medical advice / attention. P362+P364 Take off contaminated clothing and wash it before reuse. **Disposal** P501 Dispose of contents / container in accordance with local regulations.[1]

The following warnings and precautions apply to: R2 **WARNING** Contains methylisothiazolones. H317 May cause an allergic skin reaction. H402* Harmful to aquatic life. H412 Harmful to aquatic life with long lasting effects. Prevention P261 Avoid breathing mist / vapors / spray. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves / protective clothing / eye protection. P273 Avoid release to the environment. Response P302+P352 IF ON SKIN: Wash with plenty

of water. P333+P313 If skin irritation or rash occurs: Get medical advice / attention. P362+P364 Take off contaminated clothing and wash it before reuse. Disposal P501 Dispose of contents / container in accordance with local regulations.[1]

Calibration material contains human-sourced and/or potentially infectious components.[3]

Sample

Sample: Plasma collected with lithium heparin with or without gel barrier is preferred. Alternatively, serum collected with or without gel barrier is also accepted.

Stability: 10 hours at room temperature, 7 days at 2-8 C, or up to 12 months frozen at –20 C or colder.

Test Code

LIS Test code: FE for Iron in Serum or Plasma.

Analyzer

Primary Analyzer or Method: MACC (Minneapolis), SALIC (St. Paul).

Backup: Each analyzer may act as a backup for the other.

Calibration

Calibration Information[3]

Reference Material	ConCC; 04V6201
Calibration Frequency	Calibration is due every 15 days and with each new reagent lot.
Calibration Scheme	3-Point Calibration; 2 replicates per level. The IRON2 assay utilizes the Linear data reduction method to generate a calibration and results.

Quality Control

Material: Biorad Multiqual, Levels 1 and 3.
Frequency: Run 2 levels, once per day.
Acceptable Ranges: Acceptable ranges are set in Unity Real Time software.

Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, section 4 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report.
- To minimize the effect of evaporation, verify that adequate sample cup volume is present prior to running the test.
- Maximum number of replicates sampled from the same sample cup: 10
    - Sample volume for the first test: 20 uL + 50 uL for over-aspiration and dead volume

- Sample volume for each additional test from the same sample cup: 20 uL

Dilutions

Available Auto Dilutions:	None
Maximum Auto Dilution:	None
Maximum Manual Dilution:	None
Diluent:	Not Applicable
Manual Dilution Instruction:	Not Applicable

Calculations

Not applicable.

Interpretation and Resulting

Results will be reported to the whole number (xx).
Results between 7 and 1143 ug/dL without error messages are released.
Results below 7 ug/dL without error messages are reported as <7 ug/dL.
Results greater than 1143 ug/dL without error messages are reported as >1143 ug/dL.

Reference Intervals

Critical Values: None defined
Reference Ranges[2]

Age	*Reference Interval (ug/dL)*
0 to <14 years	Male 16-128 Female 16-128
15 to 18 years	Male 31-168 Female 20-162
Adult	Male 65-175 Female 50-170

Method Performance Specifications

Analytical Measuring Range: 7-1143 ug/dL

AMR/Calibration Verification Frequency: Not Required, 3 point calibration every 30 days or less

AMR recommended verification product: Maine Standards GC1
AMR proximity budget: 50% (low) or 20% (high)
AMR systematic error budget: 50%

Allowable Error: 15% (CAP)

Precision: 2 ug/dL SD or 4.0% CV, whichever is greater

Limitations

HIL Indices Cutoff Values[1,4]				At HIL levels at or above the specified cutoff value, append the appropriate comment AFTER visually confirming presence of interferent: -HP for "Hemolysis present, may affect results." -BIN for "Bilirubin Interference" -LINT for "Lipid Interference"
Interpretation	H	I	L	
Quant (Index)	500	30	250	
Semi Quant	4+	4+	4+	

Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.

Falsely elevated iron results may be observed at the low end of the analytical measuring interval in samples with triglyceride concentrations above 200 mg/dL.[1]

Falsely elevated iron results may be observed at the low end of the analytical measuring interval in samples with unconjugated bilirubin concentrations above 25 mg/dL.[1]

Iron dextran treatment can result in elevated total iron results.[1]

Use of the Iron2 assay for patients undergoing treatment with deferoxamine or other iron chelating compounds is not recommended.[1]

Transiently elevated iron levels can be observed post ingestion of supplements/vitamins that contain iron.[1]

Rifampicin levels above 5 mg/L may produce artificially low results with the Iron2 assay.[1]

Substances that demonstrated interference with the Iron2 assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of the package insert.[1]

Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of the package insert.[1]

Additional interference information can be found in reagent package insert, pages 4-6.[1]

References

1. IRON2 for Alinity c Reagent Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised March 2022
2. CALIPER Reference Interval Studies, accessed October 27 2020
3. ConCC for Alinity c Calibrator Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised December 2020

4. Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis. CLSI guideline C56-A, 1st Ed, Wayne, PA: CLSI, 2012

Appendices

Not applicable.

Training Plan/Competency Assessment

CH 1.04.T1 Abbott Alinity Training
QP 2.30 Orientation and Training
QP 2.40 Competency Assessment

Historical Record

Version	Author	Effective Date	Summary
1	Matt Johnson	1/7/2026	Initial Version