| **Iron** |
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| **Purpose** | This procedure provides instructions for performing IRON ON ABBOTT INSTRUMENTATION. The Alinity c Iron assay is used for the direct colorimetric determination of iron without deproteinization in human serum or plasma on the Alinity c analyzer.  |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children’s Minnesota Laboratory. |
| **Principle** | At a pH of 4.8, iron is released from transferrin to which it is bound, and then quantitatively reduced to a ferrous state. The iron forms with Ferene-S\*, 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.*\* Ferene-S = 3-(2-pyridyl)-5,6-bis-[2-(5-furylsulfonic acid)]-1,2,4-triazine***Methodology**: FereneFor additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3. |
| **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. 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. |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)**Backup: Alinity c on the opposite campus |
| **Sunquest Test Codes** | **FE:**  Iron**FEPR**: Iron Profile |
| **Specimen** | Sample: Serum or Plasma (with or without gel barrier) **Preferred:** SST (ensure complete clot formation before centrifugation)**Alternative:** Lithium Heparin, Sodium Heparin**Minimum sample volume:** 0.6 mL blood, 0.2mL serum/plasma**Stability when separated from cells/gel:** **20 to 25°C:** 7 days**2 to 8°C:** 3 weeks**-20°C:** 1 year**Rejection criteria:** Unlabeled tube, sample type other than serum or acceptable plasma, hemolyzed samples should be redrawn whenever possible. See interferences section for more.**Preparation:** 1. Whole blood specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis.
2. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
3. Specimens should be free of particulate matter.
4. Transfer serum or plasma to a properly labeled pilot tube.
5. Architect and Alinity systems utilize a specimen level detect mechanism, so special racks specific to tube-type are not required.
6. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
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| **Reagents** | **Reagent Handling** Reagents are shipped on wet ice. Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate. If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate. Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results. Use a pipette to remove all bubbles prior to loading on the Alinity or Architect system.* Do not use reagents beyond the expiration date.
* Do not pool reagents within a kit or between kits.
* Do not use components from one lot with components from another lot.
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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Abbott Alinity c Iron Reagent Kit | 08P3920 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board**: 60 days |
| Abbott Alinity c Iron Calibrator | 04U7501 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**Opened expiration:** 7 days |

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| **Risk and Safety** | This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens.The following warnings and precautions apply to R1Warning:  Contains guanidine hydrochloride, sodium acetate, acetic acid, and thiourea.Suspected of damaging fertility or the unborn child.Does not require special disposal with normal use.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 10 to 1000 μg/dL |
| Reference Material: | Alinity c Iron Calibrator kit |
| Suggested Calibration Levels: | Lot-specific calibrator values are listed in the Alinity c Iron CalibratorKit value sheet |
| Calibration Scheme: | 1 Level Reference Method: Gravimetric |
| Calibration Frequency: | 14 days; Every new reagent lot, after maintenance to critical components, if QC values warrant calibration |
| AMR | AMR is verified twice annually using the Maine Standards GC2 Product # 1200ab by running all applicable levels in triplicate. Assay results are submitted to Maine Standards for compilation and comparison to peers. Results are reviewed and approved by the Technical Specialist. Questionable results are investigated and corrective actions documented. |

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| **Quality Control** | **QC Material**: Bio-Rad Liquichek Multiqual 1,2,3 Unassayed Control Levels 1&3**Frequency:** Two levels each day of use **Stability:** Once thawed, opened, and stored tightly capped at 2 to 8°C,product will be labeled with an expiration date equal to the shortest stability of the included analytes, which is **7 days.** **Preparation**: This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used. * To thaw the product, allow it to stand at room temperature (18° to 25°C) until completely thawed but no longer than one (1) hour for Unassayed Control and 30 minutes for Pediatric Control.
* After thawing, the products **MUST** be gently swirled and inverted several times to ensure homogeneity.
* For optimal analyte stability in the thawed state, promptly return to 2 to 8°C storage after each use and minimize the time at room temperature to no more than 20 minutes daily.
* **Before each use**, gently swirl the contents until homogeneous with no visible signs of precipitate.

**Acceptable ranges:** * Non-Bio-Rad controls will utilize manufacturer ranges and 2 SD Westgard rules.
* New lots of Bio-Rad controls should be run for 20 days in parallel with the current lot whenever possible prior to switching to the new lot.
* Refer to the Westgard Rules in Chemistry procedure for current Westgard rules in place for each analyte.
* **Acceptable ranges are current in Unity Real Time only.** Quality Control results must be rejected in Sunquest when the results cross the interface.
* In the event of a QC failure, refer to the [Unity Real Time QC Review, General User](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.17-unity-real-time-qc-review-general-user.pdf) and navigate to the QC Troubleshooting section.
* Do not load or release patients until QC is acceptable in Unity Real Time.
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| **Interferences** | **Hemolysis, Icterus & Lipemia (HIL) Index Values:**

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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”Due to the release of iron from cells during hemolysis, hemolyzed samples should be avoided whenever possible. If a redraw cannot be obtained, ensure the appropriate comment, listed above, is appended to the result. |
| **Reference Intervals** | **Female:** 0 to < 14 Years 16-12814 to < 19 Years: 20-162Adult: 50 to 170 **Male:**0 to < 14 Years: 16-12814 to < 19 Years: 31-168Adult: 65 to 175 |
| **Critical Values** | None defined. |
| **Limitations** | Use of hemolyzed samples should be avoided whenever possible. Ensure that if a redraw cannot be obtained the result has the –HP comment appended. |
| **Dilutions** |

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| Max Auto Dilution: | 1 : 6.55 |
| Maximum Manual Dilution: | None |
|  | Follow Abbott [Alinity Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) instructions for programming automated dilutions. The system will automatically calculate the concentration of the sample and report the result. If a diluted sample result is less than the lower value of the measuring interval of 10 µg/dL, do not report the result. Rerun and/or investigate for other possible causes of error. |

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| **Result Reporting** | * Results between 10 and 1000 without error messages are released
* Results below 10 without error messages are reported as < 1000.
* Results > 1000 should be diluted using the onboard automated 1:6.55 dilution. Release results without error messages following this dilution.
* Results > 6550 following automated dilution are reported as > 6550
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in a specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. Abbott Alinity c Iron Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018.
2. Abbott Alinity c Iron Calibrator Package Insert, Abbott Diagnostics Division, Abbott Park, IL USA. Revised March 2018.
3. Bio-Rad Liquichek Multiqual 1,2,3, Unassayed Control Package Insert, Bio-Rad Laboratories, Irvine CA, USA.
4. [CALIPER Reference Range Studies.](https://caliper.research.sickkids.ca/#/)  Accessed October 27, 2020.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Elauteria Earnhardt | April 21, 2020 | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Added correct Alinity in Mpls, AMR, cal ver materials, reference range, dilutions, product numbers, and references for new instrument. |