| **Unsaturated Iron Binding Capacity (UIBC)** |
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| **Purpose** | This procedure provides instructions for performing UNSATURATED IRON BINDING CAPACITY (UIBC) ON ABBOTT INSTRUMENTATION. The Alinity c UIBC assay is used for the quantitative determination of unsaturated iron-binding capacity (UIBC) in 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** | Sample is added to an alkaline buffer containing a known concentration of iron to saturate the available binding sites on transferrin. The iron that remains free after transferrin saturation is reduced to a ferrous state and then complexed by Ferene-S\* to form a stable complex, of which the color intensity is measured at 604nm. The color intensity is directly proportional to the unbound excess iron concentration and indirectly proportional to the unsaturated iron binding capacity. UIBC is therefore determined by subtracting the quantity of unbound iron from the total added quantity. *\* 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 status is used in the diagnosis and management of some hematologic and hepatic conditions. In addition to serum iron levels, several tests may be ordered including UIBC, total iron binding capacity (TIBC) and ferritin. TIBC is a surrogate for transferrin and has a direct relationship to it. TIBC = (UIBC + serum iron) UIBC and TIBC are increased in low iron states such as uncomplicated anemia and decreased in high iron conditions such as hemochromatosis. The lone exception to the preceding is the case of anemia of chronic disease where the patient may be anemic but has adequate iron reserves and a low UIBC. |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | **FEPR:** Iron Profile**UIBC:** lab orderable only |
| **Specimen** | Sample: Plasma or serum (with or without gel barrier)**Preferred:** Lithium Heparin**Alternative:** SST/Serum, Sodium Heparin**Minimum sample volume:** 0.6 mL blood, 0.2 mL 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**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. 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 8 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*** |
| Alinity c UIBC Reagent Kit  | 08P4420 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board**: 28 days |
| Alinity c UIBC Calibrator Kit | 08P4401 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**Opened expiration:** 60 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. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.The following warnings and precautions apply to: R1 and R2**WARNING** Contains methylisothiazolone. May cause an allergic skin reaction.The following warnings and precautions apply to: UBIC CalibratorC:\Users\CE154502\AppData\Local\Temp\SNAGHTML2a2fc686.PNG**WARNING** Contains hydroxylamine hydrochloride. Suspected of causing cancer. May cause an allergic skin reaction. Harmful to aquatic life.No special disposal required.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 25 μg/dL to 500 μg/dL |
| Reference Material: | UIBC Calibrator |
| Suggested Calibration Levels: | 1 level NOTE: the calibrator value must be entered as a negative value in the assay configuration. |
| Calibration Scheme: | Linear data reduction method |
| Calibration Frequency: | 7 Days |
| 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 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
* 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” |
| **Reference Intervals** | Male: 69 to 240 μg/dLFemale: 70 to 310 μg/dL |
| **Critical Values** | None specified |
| **Limitations** | Use disposable plastic pipettes.For diagnostic purposes, the test findings should always be assessed in conjunction with the patient's medical history, clinical examinations, and other findings.Significant interference may be observed with hemolyzed samples. See Interference section for additional information.The following compounds may interfere with the UIBC assay:• Gadolinium Magnetic Resonance Contrast Agents• DeferasiroxInterferences from medication or endogenous substances may affect results. |
| **Dilutions** | Do not dilute |
| **Result Reporting** | * Results between 25 and 500 without error messages are released
* Results below 25 without error messages are reported as < 25 μg/dL
* Results > 500 are reported as > 500 μg/dL.
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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 UIBC Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised March 2018.
2. Abbott Alinity c UIBC Calibrator, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018.
3. Bio-Rad Liquichek Multiqual 1,2,3, Unassayed Control Package Insert, Bio-Rad Laboratories, Irvine CA, USA.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Elauteria Earnhardt | April 23, 2020 | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Added AMR, references, number and title, reference intervals, interferences, cal ver materials, correct Alinity for Mpls. |