| **Uric Acid** |
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| **Purpose** | This procedure provides instructions URIC ACID ON ABBOTT INSTRUMENTATION. The Alinity c Uric Acid assay is used for the quantitation of uric acid in human serum, plasma, or urine 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** | The Uric Acid assay is a two-part reaction. Uric acid is oxidized to allantoin by uricase with production of hydrogen peroxide (H2O2). The H2O2 reacts with 4-aminoantipyrine (4-AAP) and *N*-(3- sulfopropyl)-3-methoxy-5-methylaniline (HMMPS) in the presence of peroxidase (POD) to yield a quinoneimine dye. The resulting change in absorbance at 604 nm is proportional to the uric acid concentration in the sample. The two-part (R1/R2) configuration of this assay allows reduction of interference from ascorbic acid by inclusion of ascorbic oxidase in the portion of the assay.C:\Users\CE154502\AppData\Local\Temp\SNAGHTML2a5a27b9.PNG**Methodology**: UricaseFor additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3. |
| **Clinical Significance** | Uric acid is a metabolite of purines, nucleic acids, and nucleoproteins. Consequently, abnormal levels may be indicative of a disorder in the metabolism of these substances. Hyperuricemia may be observed in renal dysfunction, gout, leukemia, polycythemia, atherosclerosis, diabetes, hypothyroidism, or in some genetic diseases. Decreased levels are present in patients with Wilson’s disease. |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code:SALIC)****Backup: Opposite campus** |
| **Sunquest Test Codes** |

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| **URIC** Uric acid in plasma or serum in mg/dL**URICR** Uric acid in plasma for patients given Rasburicase  |

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| **Specimen** | Sample: Preferred: Heparinized Plasma, with or without gel.Alternate sample types: Serum with or without gel, Sodium HeparinNote: Test code **URICR** must be collected on ICE**Stability of samples for patients on Rasburicase**: 2 to 8°C / 4 hours**Minimum sample volume:** 0.6 mL blood, 0.2 mL serum/plasma**Stability when separated from cells/gel:** Serum/Plasma  **20 to 25°C:** 3 days **2 to 8°C :** 7 days **-20°C:** 6 months**Rejection criteria:** Unlabeled tube, incorrect sample type, samples not collected or stored on ice for patients on Rasburicase**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 directly 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** Upon receipt, place reagent cartridges in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate. If a reagent cartridge is dropped, place in an upright position for 8 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 Uric Acid Reagent Kit  | 08P5620 | **Store at:** 2 to 8°C**Unopened:** Until printed manufacturer’s expiration date**On-board**: 60 days |
| Abbott Alinity c Multiconstituent Calibrator | 08P6001 | **Store at:** 2 to 8°C**Unopened:** Until printed manufacturer’s 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. 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****DANGER** Contains boric acid and methylchloroisothiazolinone. May cause an allergic skin reaction. May damage fertility or the unborn child. Causes mild skin irritation.*The following warnings and precautions apply to:* **R2**C:\Users\CE154502\AppData\Local\Temp\SNAGHTML2a5f77ad.PNG **WARNING** Contains methylchloroisothiazolinone. May cause an allergic skin reaction.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | Serum/plasma: 1 to 33 mg/dL |
| Reference Material: | Multiconstituent Calibrator |
| Suggested Calibration Levels: | 2 levels |
| Calibration Scheme: | Linear data reduction method |
| Calibration Frequency: | 60 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 Unassayed Multiqual 1,2,3 Level 1 and 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 and Female**: 0 to < 15 Days: 2.8-12.7 15 Days to < 1 Year: 1.6-6.31 to < 12 Years: 1.8-4.9. **Female**: 12 to < 19 Years: 2.6-5.9 Adult: 2.6 to 6.0 **Male:** 12 to < 19 Years: 2.6-7.6Adult: 3.5 to 7.2 |
| **Critical Values** | >10 mg/dLCritical values must be called according to the Critical Limit Test Value Policy. |
| **Limitations** | N-Acetyl-4-benzoquinone Imine (NAPQI), a metabolite of Acetaminophen at very high levels may lead to falsely low results. N-Acetyl-L-Cysteine at therapeutically achieved concentrations may lead to falsely low results. |
| **Dilutions** | Do not dilute |
| **Result Reporting** | * Results between 1 and 33 without error messages are released
* Results below 1 without error messages are reported as < 1 mg/dL.
* Results > 33 are reported as > 33 mg/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. [CALIPER Reference Interval Studies](https://caliper.research.sickkids.ca/#/login;next=search;queryParams=%7B%7D), accessed October 27 2020
2. Abbott Alinity c Uric Acid Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. December 2017
3. Abbott Alinity c Multiconstituent Calibrator Package Insert, Abbott Diagnostics Division, Abbott Park, IL USA. December 2017
4. Bio-Rad Liquichek Unassayed Multiqual 1,2,3, 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 24, 2020 | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Added references, corrected Mpls Alinity, AMR, cal ver materials, interferences, dilutions, etc |