Uric Acid, Serum or Plasma

Purpose

This procedure provides instructions for URIC ACID on Abbott Instrumentation. The Alinity c Uric Acid2 assay is used for the quantification of uric acid 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

Methodology: Uricase

The Uric Acid2 assay is an automated clinical chemistry assay. The Uric Acid2 assay is a 2-part reaction. Uric acid is oxidized to allantoin with the production of hydrogen peroxide (H2O2). The H2O2 reacts with 4-aminoantipyrine (4-AAP) and N, N-bis-(4-sulfobutyl)-3methlyaniline, disodium salt (TODB) in the presence of peroxidase (POD) to yield a quinonimine dye. The resulting change in absorbance at 604 nm is proportional to the uric acid concentration in the sample.[1]

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.

The Uric Acid2 assay is to be used as an aid in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.[1]

Materials

Product Description	*Product Code*	*Stability*
Uric Acid2 Reagent (640 tests per box; each box contains 4 reagent sets of 160 tests). Each reagent set consists of an R1 and R2 component. **R1:** Active Ingredient: TODB (0.847 g/L). Preservatives: ProClin 300, ProClin 950, and sodium azide. **R2:** Active ingredients: 4-aminoantipyrine (0.285 g/L), peroxidase (POD) (4.000 KU/L), uricase (2.0 KU/L). Preservatives	**MFR#** 04U0920 **CHC#** 34012	**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.

ProClin 300, ProClin 950, and sodium azide. Abbott Diagnostics		
Consolidated Chemistry Calibrator (ConCC) Each calibrator set consists of 6 lyophilized calibrator vials and 6 empty barcode labeled vials. Abbott Diagnostics	**MFR#** 04V6201 **CHC#** TBD	**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:** 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.

Special Safety Precautions

The following warnings and precautions apply to: R1 and R2. **WARNING** Contains methylisothiazolones and sodium azide. H317 May cause an allergic skin reaction. H402* Harmful to aquatic life. H412 Harmful to aquatic life with long lasting effects. EUH032 Contact with acids liberates very toxic gas. **Prevention** P261 Avoid breathing mist / vapors / spray. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves / protective clothing / eye protection. **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: 8 hours at room temperature, 3 days at 2-8 C, or up to 3 months frozen at –20 C or colder.

Stability for patients taking Rasburicase: Samples must be collected and sent on ice. Sample is stable up to 4 hours at 2-8 C. (Test code URICR).

Test Code

LIS Test code: URIC for Uric Acid in Serum or Plasma. URICR for Uric Acid Patient on Rasburicase.

Analyzer

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

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

Calibration

Calibration Information

Reference Material	ConCC; 04V6201
Calibration Frequency	Calibration is due every 30 days and with each new reagent lot.
Calibration Scheme	3-Point Calibration; 2 replicates per level. The Uric Acid2 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: 3.3 uL + 50 uL for over-aspiration and dead volume
    - Sample volume for each additional test from the same sample cup: 3.3 uL

Dilutions

Do not dilute.

Calculations

Not applicable.

Interpretation and Resulting

Results will be reported to the first decimal (xx.x).

Results between 0.3 and 37.7 mg/dL without error messages are released.
Results below 0.3 mg/dL without error messages are reported as <0.3 mg/dL.
Results greater than 37.7 mg/dL without error messages are reported as >37.7 mg/dL.

Reference Intervals

Critical Values: >10.0 mg/dL

Reference Ranges[2]

Age	*Sex*	*Reference Interval (mg/dL)*
0 to <15 days	All	2.8-12.7
15 days to 1 year	All	1.6-6.3
1 to <12 years	All	1.8-4.9
12 to 18 years	Female Male	2.6-5.9 2.6-7.6
Adult	Female Male	2.6-6.0 3.5-7.2

Method Performance Specifications

Analytical Measuring Range: 0.7-37.7 mg/dL
AMR/Calibration Verification Frequency: Not required, 3 point calibration every 30 days or less
AMR recommended verification product: Maine Standards GC2
AMR proximity budget: 2 mg/dL or 20%
AMR systematic error budget: 50%
Allowable Error: 10% (CAP)
Precision: 0.17 mg/dL SD or 3.5% 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 (mg/dL)	N/A	24	N/A	
Semi Quant	N/A	3+	N/A	

N-Acetyl-4-benzoquinone Imine (NAPQI), a metabolite of acetaminophen at very high concentrations may lead to falsely low results.[1]

Interference beyond +7% was observed at the following concentrations.[1]

- Bilirubin (conjugated or unconjugated), 24 mg/dL

Additional interference information can be found in reagent package insert, page 6.

References

1. Uric Acid2 for Alinity c Reagent Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised February 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	11/14/2025	Initial Version