Uric Acid in Plasma/Serum or Urine

Purpose

This procedure provides instructions for performing URIC ACID IN PLASMA/SERUM OR URINE. The URCA method is an *in vitro* diagnostic test for the quantitative measurement of uric acid in human serum, plasma and urine on the Dimension Vista® System.

Policy Statements

This procedure applies to all personnel responsible for testing Uric Acid on the Siemens Dimension Vista

Principle

The uric acid method is a modification of the uricase method first reported by Bulger and Johns, later modified by Kalckar. Measurement of uric acid by monitoring the loss of absorbance at 293 nm following uricase treatment is generally recognized as being more specific and less subject to interference than other, indirect methods.

Uric acid, which absorbs light at 293 nm is converted by uricase to allantoin,which is nonabsorbing at 293 nm. The change in absorbance at 293 nm due to the disappearance of uric acid is directly proportional to the concentration of uric acid in the sample and is measured using a bichromatic (293, 700 nm) endpoint technique.

Clinical Significance

Classic gout, the so-called disease of upper-class men, causes onset of a painful, swollen great toe. Gout is caused by deposition of monosodium urate crystals. Hyperuricemia can be caused by increased formation or decreased excretion. Factors contributing to increased formation include obesity, high purine diet, regular use of ethanol, and diuretic therapy. Elevations may also be observed in Lead poisoning, glucose-6-phosphatase deficiency, hereditary gout, and glycogen storage disease. Excessive cell destruction as found in neoplasia, hemolytic anemia, resolving pneumonia, and mononucleosis causes increased levels.

Decreased excretion may be caused by chronic renal failure or increased renal absorption.

Numerous drugs are known to affect uric acid concentrations.

Patients with elevated urine levels should be assessed for risk of stone formation.

Analyzer

PRIMARY METHOD: *Siemens Dimension Vista 500*

SECONDARY (BACKUP) METHOD: Siemens Dimension Vista 500 (opposite campus)

Sunquest Test Codes

URIC	Uric acid in plasma or serum in mg/dL
URICR	Uric acid in plasma for patients given Rasburicase
UUA	Urine Uric acid in mg/dL
UUAQ	Quantitative urine uric acid in mg/ 24 hr, timed collection

Specimen

Plasma (lithium heparin) preferred, or Serum

- Venipuncture should occur prior to administration of Metamizole due to the potential for falsely depressed results[7]. Metamizole is an anti-pyretic banned in most countries

Plasma (lithium heparin) **immediately placed on ice** for patients on Rasburicase
Urine: Timed (24 hour) or Random collection no preservatives. See preparation notes.

Minimum volume: 200 µL, minimum 100 µL: Actual test volume: 6.6 µL (Vista)

Stability: RT / 1 day, 2-8 °C / 3-5 days, < -20°C for 6 months, Alkaline urine samples are stable at ambient temperature for 3 – 4 days

Stability of samples for patients on Rasburicase: 2-8 °C / 4 hours

Rejection criteria: Unlabelled specimens, Rasburicase specimens not collected or stored on ice.

Preparation:

1. Random urine collections should be maintained at room temperature and analyzed immediately.
2. Cloudy specimens require adjusting a well-mixed aliquot to pH 8-9. Prior to centrifugation, add 1 drop 5% (w/v) NaOH to a 5 ml aliquot of urine. Verify pH is 8-9. A maximum of 2 more drops may be added to correct pH. (max dilution factor = <5%.) Allow to stand 15 minutes before analysis for warming and dissolution.
3. Timed urine collections are measured for total volume, and the collection date and time recorded for the start and end of the collection. Enter this information into Sunquest by ordering the test PV on the same accession number.
4. Rasburicase specimens must be immediately placed on ice, transported on ice, and analyzed within 4 hours of collection.
5. Whole blood specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis.
6. 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.
7. Lipemic samples should be ultrafuged.
8. Specimens should be free of particulate matter.
9. Transfer serum, urine or plasma to a properly labeled SSC or tube. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.

Reagents

PRIMARY METHOD:

Product Description	*Product Code*	*Stability*
URCA Flex® reagent cartridge All reagents are liquid and ready to use.	K1077	**Store at:** 2 – 8 °C **Unopened:** Refer to carton for expiration date. **On-board:** Sealed wells on the instrument are stable for 30 days. **Open well stability:** 3 days for wells 1-10, 30 days for wells 11-12
CHEM 1 CAL (Vista)	KC110	**Store at:** 2 - 8 °C. **Unopened:** Refer to carton for expiration date. **On-board:** Once the vial stopper is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista® System. **Opened**: Once the cap is removed, assigned values are stable for 7 days when recapped and stored at 2-8 C. Do not use on board the Vista.

Risk and Safety

Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion.

Safety data sheets (MSDS/SDS) available on www.siemens.com/diagnostics

For *in vitro* diagnostic use.

Calibration

PRIMARY METHOD:

Analytical Measuring Range	0.2–15.0 mg/dL
Reference Material:	CHEM 1 CAL (KC110)
Suggested Calibration Levels:	Level 1 (Calibrator A): 0 mg/dL Level 2 (Calibrator B): 18 mg/dL
Calibration Scheme:	2 levels (n=5)
Calibration Frequency:	• Every 90 days for any one lot • For each new lot of Flex® reagent cartridges • After major maintenance or service, if indicated by quality control results • As indicated in laboratory quality control procedures
Analytical Measuring Range and Calibration Verification	• Cal Verification and AMR verification are performed at least once every six (6) months. • Touch Advanced → Calibrations → Calibrations by Lot, select method “URIC” and “Order a Linearity Study” • See iGuide “Calibration by Lot” for more information.

Quality Control (Plasma/Serum)

Biorad Multiqual (Human) Levels 1 & 3

Frequency: Two levels each day of use

Stability: Stable until the date on vial when stored at -20 to -50 °C protect from light. Thawed and unopened, 7 days at 2 -8 °C. 7 days on board the Vista, and 5 days opened and stored at 2 – 8 °C

Preparation: Allow the control to stand at 18 – 25 °C for 30 minutes until completely thawed. Gently mix the vials until homogeneous to dissolve any precipitate.

Sunquest Control names: Level 1 = C-MQ1, Level 2 = C-MQ3

Quality Control (Urine)

Biorad Liquicheck Urine Chemistry Control Levels 1 & 2

Frequency: Two levels each day of use

Stability: Stable until the date on vial when stored at 2 – 8 °C, or unopened on board the Dimension Vista, and 30 days opened and stored at 2 – 8 °C

Sunquest Control names: Level 1 = C-UR1, Level 2 = C-UR2

Calculations

UUAQ = mg Uric acid/collection = $\frac{\text{urine uric acid in mg/dL} \times \text{Total Volume in mL}}{100}$

Timed Urine calculations are performed by the Laboratory computer system when all necessary information is present. Enter the measured urine uric acid in mg/dL, collection time in hours, and the total volume.

Interferences

Hemolysis, Icterus & Lipemia (HIL) Index Values:

H	I	L
-	-	-

- Xanthine has been reported to decrease the URCA result by 40%.
- Formaldehyde (formalin) has been reported to give negative interference with the uricase methods.
- Refer to the product insert for additional information on non-interfering substances.

Reference Range

Serum/Plasma:
2.0 - 5.5 mg/dL

Urine:
0 - 750 mg/24 hr

The reference values are for a 24-hour collection. Random specimens and timed specimens collected for other than a 24-hour time period are reported in units of mg/collection, for which reference values are not established.

Critical Values

>10 mg/dL: Critical values must be called according to the Critical Limit Test Value Policy.

Limitations

Linear range of detection: 0.2 – 15.0 mg/dL

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension Operator's Guide for troubleshooting.

Dilutions

Serum or Plasma:

Maximum Dilution:	1:4
Surplus Rack:	Samples with results >15.0 mg/dL reflex to a 1:4 dilution
Limited Rack:	Samples with results >15.0 mg/dL should be repeated as an Add-On Test with a 1:4 dilution.
Manual Dilution:	Do not manually dilute

Urine:

Auto Urine Dilution (AUD):	1:10
Manual Dilution:	Do not manually dilute

Result Reporting

- Results between 0.2 – 15.0 mg/dL without error messages are released
- Serum/Plasma/Urine results below 0.2 mg/dL: report as < 0.2 mg/dL.
- Serum/Plasma results > 15.0 mg/dL without error messages are reported following a maximum dilution of 1:4
- Serum/Plasma results that exceed the assay range following a maximum dilution of 1:4 are reported as >60.0 mg/dL
- Urine Uric acid results that exceed the assay range following the AUD of 1:10 are reported as >150.0 mg/dL
- Timed Urine collection results: The Laboratory Information System calculates urine uric acid on timed and random collections when all necessary information is present. Report the numerical value in Sunquest.

Specimen Storage

Promptly stopper tested specimen and store upright in specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer.

References

1. Vista URCA Flex® reagent cartridge insert sheet, Siemens Healthcare Diagnostics Inc, PN 781077.001 2014-07-28
2. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc, Hudson, OH, 5th Edition, 2001
3. Tietz Textbook of Clinical Chemistry, 3rd Edition, W.B. Saunders Company, 1999, pp. 50-51, 1245-1250
4. Biorad Multiqual (Human) Chemistry Control Product insert, Bio-Rad Laboratories Irvine, CA 92618
5. Biorad Liquichek™ Urine Chemistry Control Product insert, Bio-Rad Laboratories, Irvine, CA 92618
6. Curesearch, Children's Oncology Group, ANHL01P1 protocol for Rasburicase
7. Medical Device Correction Notice DC-16-02.A.US – March 17, 2016

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1.	Patti Yelich	March 2001	Uric Acid in Serum or Urine, Dade Dimension,
2.	L. Lichty	August 2003	Uric Acid on Dimension RxL,
3.	L. Lichty	August 2006	Uric Acid in Plasma, Serum or Urine,
4.	L. Lichty	June 1, 2011	New format, updates to product insert, renumbered from CH 3.44, added instruction for Rasburicase samples.
5.	L. Lichty	April 17, 2013	Clarify maximum dilution reporting.
6.	L. Lichty	12/17/2013	Siemens URCA CLSI procedure for Vista, Issue date, 2013-08-20
7.	D. Helfinstine	June 15, 2015	Updated for Dimension Vista
8.	L. Lichty	March 28, 2016	Metamizole interference