



URIC ACID
REF 7D76-20
30-3928/R4

ARCHITECT®

AEROSET®

URIC ACID

This package insert contains information to run the Uric Acid assay on the ARCHITECT c Systems™ and the AEROSET System.

NOTE: Changes Highlighted

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Customer Support

United States: **1-877-4ABBOTT**

Canada: **1-800-387-8378 (English speaking customers)**

1-800-465-2675 (French speaking customers)

International: Call your local Abbott representative

Symbols in Product Labeling

| | | | |
|----------------|---|------------|------------------------------|
| CAL 1-2 | Calibrators 1 and 2 | REF | Catalog number>List number |
| CONC | Concentration | SN | Serial number |
| EC REP | Authorized Representative in the European Community | | Consult instructions for use |
| INGRED | Ingredients | | Manufacturer |
| IVD | In vitro diagnostic medical device | | Temperature limitation |
| LOT | Batch code/Lot number | | Use by/Expiration date |
| R1 | Reagent 1 | | |



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EC REP

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NAME
URIC ACID

INTENDED USE

The Uric Acid assay is used for the quantitation of uric acid in human serum, plasma, or urine.

SUMMARY AND EXPLANATION OF TEST

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.^{1,2}

PRINCIPLES OF PROCEDURE

The Uric Acid assay is based on the methods of Trivedi and Kabasakalian.^{3,4} Uric acid is oxidized to allantoin by uricase with the production of hydrogen peroxide (H_2O_2). The H_2O_2 reacts with 4-aminoantipyrine (4-AAP) and 2,4,6-tribromo-3-hydroxybenzoic acid (TBHB) in the presence of peroxidase to yield a quinoneimine dye. The resulting change in absorbance at 548 nm is proportional to the uric acid concentration in the sample.

Methodology: Uricase

REAGENTS

Reagent Kit

[REF] 7D76 Uric Acid is supplied as a liquid, ready-to-use, single reagent kit which contains:

[R1] 10 x 84 mL

Estimated tests per kit: 4,497

Calculation is based on the minimum reagent fill volume per kit.

| Reactive Ingredients | Concentration |
|----------------------|---------------|
| 4-Aminoantipyrine | 0.5 mmol/L |
| TBHB | 1.75 mmol/L |
| Uricase | > 120 U/L |
| Peroxidase | > 500 U/L |
| TRIS Buffer | 50 mmol/L |

REAGENT HANDLING AND STORAGE

Reagent Handling

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate. To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration which could impact results.

Reagent Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagent stability is 26 days if the reagent is uncapped and onboard.

WARNINGS AND PRECAUTIONS

Precautions for Users

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.
4. Contains nonsterile bovine serum albumin.
5. **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens.⁵ Biosafety Level 2⁶ or other appropriate biosafety practices^{7,8} should be used for materials that contain or are suspected of containing infectious agents.

SPECIMEN COLLECTION AND HANDLING

Suitable Specimens

Serum, plasma, and urine are acceptable specimens.

- **Serum:** Use serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. When processing samples, separate serum from blood cells or gel according to the specimen collection tube manufacturer's instructions.
- Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.
- **Plasma:** Use plasma collected by standard venipuncture techniques into glass or plastic tubes. Acceptable anticoagulants are lithium heparin (with or without gel barrier) and sodium heparin. Ensure centrifugation is adequate to remove platelets. When processing samples, separate plasma from blood cells or gel according to the specimen collection tube manufacturer's instructions.
- **Urine:** 24 hour urine specimens are preferred. To preventurate precipitation and adjust the pH, add 10 mL of sodium hydroxide [500 g/L (12.5 N)] to the collection bottle before collection of the specimen.⁹

Random specimens or specimens timed over shorter intervals are also acceptable for analysis. Adjust the specimen pH to > 8.0 by dropwise addition of sodium hydroxide [500 g/L (12.5 N)]. Check the pH often during the addition of sodium hydroxide to the specimen.

NOTE: Reference ranges provided are for 24 hour excretion.

For total sample volume requirements, refer to the instrument-specific ASSAY PARAMETERS section of this package insert and Section 5 of the instrument-specific operations manual.

Specimen Storage

Serum, plasma, and urine

| Temperature | Maximum Storage | | Bibliographic Reference |
|-------------|-----------------|-------------------|-------------------------|
| | Serum/Plasma | Urine | |
| 20 to 25°C | 3 days | 4 days at pH > 8 | 10 |
| 2 to 8°C | 7 days | no recommendation | 10, 11 |
| -20°C | 6 months | no recommendation | 10 |

Guder et al.¹⁰ suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above. However, limitations of laboratory equipment make it necessary in practice for clinical laboratories to establish a range around -20°C for specimen storage. This temperature range may be established from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

PROCEDURE

Materials Provided

[REF] 7D76 Uric Acid Reagent Kit

Materials Required but not Provided

- [REF] 1E65 Multiconstituent Calibrator, [CAL 1-2] 3 x 5 mL
- Control Material
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

Assay Procedure

For a detailed description of how to run an assay, refer to Section 5 of the instrument-specific operations manual.

Specimen Dilution Procedures

The ARCHITECT cSystems and the AEROSET System have automatic dilution features; refer to Section 2 of the instrument-specific operations manual for additional information.

Serum and plasma: Specimens with uric acid values exceeding 33.1 mg/dL (1.95 mmol/L) are flagged and may be diluted using the Automated Dilution Protocol or the Manual Dilution Procedure.

Urine: Urine samples are automatically diluted 1:10 by the system using the Standard dilution option, then the system automatically corrects the concentration by multiplying the result by the appropriate dilution factor. This dilution extends urine Uric Acid linearity to 433.8 mg/dL (25.59 mmol/L). Samples exceeding this concentration are flagged and may be diluted using the Automated Dilution Protocol or the Manual Dilution Procedure.

PROCEDURE (Continued)

Automated Dilution Protocol

If using the Automated Dilution Protocol, the system performs a dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor. To set up the automatic dilution feature, refer to *Section 2* of the instrument-specific operations manual for additional information.

Manual Dilution Procedure

Manual dilutions should be performed as follows:

- Use saline (0.85% to 0.90% NaCl) to dilute the sample.
- The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor.
- If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

NOTE: If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to *Section 5* of the instrument-specific operations manual.

CALIBRATION

Calibration is stable for approximately 26 days (624 hours) and calibration is required with **each change in reagent cartridge** and reagent lot number. Verify calibration with at least two levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

The urine application uses the serum calibration.

For a detailed description of how to calibrate an assay, refer to *Section 6* of the instrument-specific operations manual.

For information on calibrator standardization, refer to the Multiconstituent Calibrator package insert.

QUALITY CONTROL

The following is the recommendation of Abbott Laboratories for quality control. As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

RESULTS

Refer to the instrument-specific operations manual for information on results calculations.

• ARCHITECT System Operations Manual—Appendix C

• AEROSET System Operations Manual—Appendix A

Representative performance data are given in the EXPECTED VALUES and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert. Results obtained in individual laboratories may vary.

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND HANDLING and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

EXPECTED VALUES

Reference Range¹²

Serum/Plasma

| | Range (mg/dL) | Range (mmol/L) |
|---------------|---------------|----------------|
| Child | 2.0 to 5.5 | 0.12 to 0.32 |
| Adult, Male | 3.5 to 7.2 | 0.21 to 0.42 |
| Adult, Female | 2.6 to 6.0 | 0.15 to 0.35 |

To convert results from mg/dL to mmol/L, multiply mg/dL by 0.059.

EXPECTED VALUES

Reference Range (Continued)

Urine

| Diet | Range (mg/day) | Range (mmol/day) |
|-------------|----------------|------------------|
| Purine-free | | |
| Male | < 420 | < 2.48 |
| Female | slightly lower | slightly lower |
| Low Purine | | |
| Male | < 480 | < 2.83 |
| Female | < 400 | < 2.36 |
| High Purine | < 1,000 | < 5.90 |
| Average | 250 to 750 | 1.48 to 4.43 |

To convert results from mg/day to mmol/day, multiply mg/day by 0.0059.

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

24 Hour Urinary Excretion

To convert results from mg/dL to mg/day (24 hour urinary excretion)

Where:

$$V = 24 \text{ hour urine volume (mL)}$$

$$c = \text{analyte concentration (mg/dL)}$$

$$\text{24 hour excretion} = [(V \times c) \div 100] \text{ mg/day}$$

To convert results from mmol/L to mmol/day (24 hour urinary excretion)

Where:

$$V = 24 \text{ hour urine volume (mL)}$$

$$c = \text{analyte concentration (mmol/L)}$$

$$\text{24 hour excretion} = [(V \times c) \div 1000] \text{ mmol/day}$$

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity

Uric Acid serum is linear up to 33.1 mg/dL (1.95 mmol/L). Uric Acid urine is linear up to 433.8 mg/dL (25.59 mmol/L). Linearity was verified using Clinical and Laboratory Standards Institute (CLSI) protocol NCCLS EP6-P.¹³

Limit of Detection (LOD)

The LOD for Uric Acid serum is 0.2 mg/dL (0.01 mmol/L). The LOD for Uric Acid urine is 5 mg/dL (0.3 mmol/L). The LOD is the mean concentration of an analyte-free sample + 2 SD, where SD = the pooled, within-run standard deviation of the analyte-free sample. A study performed on an ARCHITECT c System and an AEROSET System produced an LOD for Uric Acid serum of 0.07 mg/dL (0.005 mmol/L) and an LOD for Uric Acid urine of 0.31 mg/dL (0.019 mmol/L).

Limit of Quantitation (LOQ)

The LOQ for Uric Acid serum is 0.25 mg/dL (0.015 mmol/L). The LOQ for Uric Acid urine is 0.86 mg/dL (0.051 mmol/L). The LOQ is the analyte concentration at which the CV = 20%.

Interfering Substances¹⁴

Interference studies were conducted using CLSI protocol NCCLS EP7-P.¹⁵ Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

| Interfering Substance | Interferent Concentration | N | Target (mg/dL) | Observed (% of Target) |
|-----------------------|---------------------------|---|----------------|------------------------|
| Ascorbate | 0.375 mg/dL (21.3 µmol/L) | 4 | 5.1 | 93.6 |
| | 0.75 mg/dL (42.6 µmol/L) | 4 | 5.1 | 87.5 |
| Bilirubin | 15 mg/dL (257 µmol/L) | 4 | 5.6 | 94.7 |
| | 30 mg/dL (513 µmol/L) | 4 | 5.6 | 85.9 |
| Hemoglobin | 62 mg/dL (0.62 g/L) | 4 | 5.0 | 108.9 |
| | 125 mg/dL (1.25 g/L) | 4 | 5.0 | 120.1 |
| Intralipid | 750 mg/dL (7.5 g/L) | 4 | 5.2 | 108.7 |
| | 1,000 mg/dL (10.0 g/L) | 4 | 5.2 | 114.6 |

Ascorbate solutions at the above concentrations were prepared by addition of ascorbic acid stock to human serum pools. Bilirubin solutions at the above concentrations were prepared by addition of a bilirubin stock to human serum pools. Hemoglobin solutions at the above concentrations were prepared by addition of hemolysate to human serum pools. Intralipid solutions at the above concentrations were prepared by addition of Intralipid to human serum pools.

SPECIFIC PERFORMANCE CHARACTERISTICS

Interfering Substances (Continued)

For the urine application, glucose up to 1,000 mg/dL, protein up to 50 mg/dL, sodium oxalate up to 60 mg/dL, acetic acid (8.5N) up to 6.25 mL/dL, hydrochloric acid (6N) up to 2.5 mL/dL, nitric acid (6N) up to 5.0 mL/dL, boric acid up to 250 mg/dL, and sodium fluoride up to 400 mg/dL demonstrated less than 10% interference. Ascorbate and sodium carbonate demonstrated greater than 10% interference.

Precision

The imprecision of the Uric Acid serum assay is \leq 4% Total CV. Representative data from studies using CLSI protocol NCCLS EP5-A¹⁶ are summarized below.

Serum

| Control | Level 1 | Level 2 |
|--------------|-----------|-------------|
| N | 80 | 80 |
| Mean (mg/dL) | 4.9 | 9.6 |
| Within Run | SD %CV | 0.02 0.4 |
| Between Run | SD %CV | 0.01 0.3 |
| Between Day | SD %CV | 0.08 1.6 |
| Total | SD %CV | 0.08 1.7 |
| | | 0.10 1.1 |

The imprecision of the Uric Acid urine assay is \leq 6.1% Total CV. Representative data from studies using CLSI protocol NCCLS EP10-A¹⁷ are summarized below.

Urine

| Control | Level 1 | Level 2 |
|--------------|-----------|-------------|
| N | 50 | 50 |
| Mean (mg/dL) | 10.4 | 19.9 |
| Within Run | SD %CV | 0.26 2.5 |
| Between Run | SD %CV | 0.00 0.0 |
| Between Day | SD %CV | 0.37 3.6 |
| Total | SD %CV | 0.45 4.3 |
| | | 0.57 2.9 |

Method Comparison

Correlation studies were performed using CLSI protocol NCCLS EP9-A.¹⁸

Serum and urine results from the Uric Acid assay on the AEROSET System were compared with those from a commercially available uricase methodology.

Serum and urine results from the Uric Acid assay on an ARCHITECT cSystem were compared with the Uric Acid assay on an AEROSET System.

Serum

| | AEROSET vs. Comparative Method | ARCHITECT vs. AEROSET |
|-------------------------|-----------------------------------|--------------------------|
| N | 80 | 92 |
| Y - Intercept | 0.134 | -0.030 |
| Correlation Coefficient | 0.999 | 1.000 |
| Slope | 1.074 | 0.982 |
| Range (mg/dL)* | 1.49 to 18.06 | 3.30 to 32.20 |

*AEROSET Range

Urine

| | AEROSET vs. Comparative Method | ARCHITECT vs. AEROSET |
|-------------------------|-----------------------------------|--------------------------|
| N | 79 | 102 |
| Y - Intercept | 0.184 | -0.022 |
| Correlation Coefficient | 0.997 | 0.999 |
| Slope | 0.999 | 0.912 |
| Range (mg/dL)* | 3.35 to 64.31 | 5.99 to 421.32 |

*AEROSET Range

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TRADEMARKS

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ARCHITECT cSYSTEMS ASSAY PARAMETERS

ARCHITECT®

Uric Acid Serum/Plasma—Conventional and SI Units

| | | | | |
|--|-----------------------------------|--|---------------------------------------|--------------------------------------|
| Configure assay parameters — General | | | | |
| <input checked="" type="radio"/> General | <input type="radio"/> Calibration | <input type="radio"/> SmartWash | <input type="radio"/> Results | <input type="radio"/> Interpretation |
| Assay: Uric | Type: Photometric | Version: 1 | | |
| Number: 1010 | | | | |
| <input checked="" type="radio"/> Reaction definition | | <input type="radio"/> Reagent / Sample | <input type="radio"/> Validity checks | |
| Reaction mode: End up | | | | |
| | | Primary | Secondary | Read times |
| Wavelength: 548 | | / | 700 | Main: 24 – 26 |
| Last required read: 26 | | | | |
| Absorbance range: ___ – ___ | | | Color correction: ___ – ___ | |
| Sample blank type: None | | | | |

| O Reaction definition | | ● Reagent / Sample | | O Validity checks | | | |
|-------------------------------------|------------|--------------------|---------|-------------------|-----------------|------------------|---|
| Reagent: URIC0 | | Reagent volume: | 160 | R1 | | | |
| Diluent: Saline | | Water volume: | _____ | | | | |
| Diluent dispense mode: Type 0 | | Dispense mode: | Type 0 | | | | |
| Dilution name | Sample | Diluted sample | Diluent | Water | Dilution factor | Default dilution | |
| STANDARD : | 3.2 | _____ | _____ | _____ | = | 1:1.00 | ● |
| _____ | _____ | _____ | _____ | _____ | = | | O |
| _____ | _____ | _____ | _____ | _____ | = | | O |
| O Reaction definition | | O Reagent / Sample | | ● Validity checks | | | |
| Reaction check: | | None | | | | | |
| Maximum absorbance variation: _____ | | | | | | | |

| | | | | |
|---|--|---|---------------------------------|--|
| Configure assay parameters — Calibration | | | | |
| <input type="radio"/> General | <input checked="" type="radio"/> Calibration | <input type="radio"/> SmartWash | <input type="radio"/> Results | <input type="radio"/> Interpretation |
| Assay: Uric | Calibration method: Linear | | | |
| <input checked="" type="radio"/> Calibrators | | <input type="radio"/> Volumes | <input type="radio"/> Intervals | <input type="radio"/> Validity checks |
| Calibrator set: MCC | | Calibrator level: Blank: Water Cal 1: MCC1 Cal 2: MCC2 | | Concentration: 0 ^{††} + ++ |
| Replicates: 3 [Range 1 – 3] | | | | |

| O Calibrators | ● Volumes | O Intervals | O Validity checks |
|-----------------|------------------|-------------|-------------------|
| Calibrator: MCC | | | |
| | Calibrator level | Sample | Diluted sample |
| Blank: Water | 3.2 | — | — |
| Cal 1: MCC1 | 3.2 | — | — |
| Cal 2: MCC2 | 3.2 | — | — |

| O Calibrators | O Volumes | ● Intervals | O Validity checks |
|------------------------|--------------------|-------------|-------------------|
| Calibration intervals: | | | |
| | Full interval: 624 | (hours) | |
| Calibration type: | | | |
| | Adjust type: None | | |

| <input type="checkbox"/> Calibrators | <input type="checkbox"/> Volumes | <input type="checkbox"/> Intervals | <input checked="" type="checkbox"/> Validity checks |
|---------------------------------------|----------------------------------|------------------------------------|---|
| Blank absorbance range: _____ - _____ | | | |
| Span: Blank - Blank | | | |
| Span absorbance range: _____ - _____ | | | |
| Expected cal factor: 0.00 | | | |
| Expected cal factor tolerance %: 0 | | | |

Configure assay parameters – SmartWash

General Calibration SmartWash Results Interpretation

Assay: Uric

| COMPONENT | REAGENT / ASSAY | WASH | Volume | Replicates |
|-----------|-----------------|--------------------|--------|------------|
| Cuvette | Trig | 10% Detergent B*** | 345 | |

*** Select “Detergent B” for software prior to Version 2.2.

Uric Acid Serum/Plasma—Conventional Units

| Configure assay parameters — Results | | | | |
|--------------------------------------|-----------------------------------|---------------------------------|--|--------------------------------------|
| <input type="radio"/> General | <input type="radio"/> Calibration | <input type="radio"/> SmartWash | <input checked="" type="radio"/> Results | <input type="radio"/> Interpretation |
| | | Assay: Uric | | Result units: mg/dL |
| | Assay defaults: | | | |
| | | Low-Linearity: | 0.3 [±] | |
| | | High-Linearity: | 33.1 | |
| Gender and age specific ranges: | | | | |
| GENDER | AGE (UNITS) | NORMAL | EXTREME | |
| Male | 0 – 130 (Y) | 3.5 – 7.2 | | |
| Female | 0 – 130 (Y) | 2.6 – 6.0 | | |
| Either | 0 – 130 (Y) | 2.6 – 7.2 | | |

| Configure result units | |
|------------------------|-----------------|
| Assay: | Uric |
| Version: | 1 |
| Result units: | mg/dL |
| Decimal places: | 1 [Range 0 - 4] |
| Correlation factor: | 1.0000 |
| Intercept: | 0.0000 |

Uric Acid Serum/Plasma—SI Units

| Configure assay parameters — Results | | | | |
|---|-----------------------------------|---------------------------------|--|--------------------------------------|
| <input type="radio"/> General | <input type="radio"/> Calibration | <input type="radio"/> SmartWash | <input checked="" type="radio"/> Results | <input type="radio"/> Interpretation |
| Assay: Uric | | | Result units: mmol/L | |
| Assay defaults: | | | | |
| Low-Linearity: 0.02 High-Linearity: 1.95 | | | | |
| Gender and age specific ranges: | | | | |
| GENDER | AGE (UNITS) | NORMAL | EXTREME | |
| Male | 0 – 130 (Y) | 0.21 – 0.42 | | |
| Female | 0 – 130 (Y) | 0.15 – 0.35 | | |
| Either | 0 – 130 (Y) | 0.15 – 0.42 | | |

| Configure result units | |
|------------------------|-----------------|
| Assay: | Uric |
| Version: | 1 |
| Result units: | mmol/L |
| Decimal places: | 2 [Range 0 - 4] |
| Correlation factor: | 1.0000 |
| Intercept: | 0.0000 |

 Due to differences in instrument systems and unit configurations, version numbers may vary.

†† Displays the number of decimal places defined in the decimal places parameter field.

† Refer to concentration specified on calibrator labeling or value sheet.

The linear low value (Low-Linearity) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

ARCHITECT cSYSTEMS ASSAY PARAMETERS

ARCHITECT®

Uric Acid Urine—Conventional and SI Units

| Configure assay parameters — General | | | | |
|--|--|---|--|--|
| <input checked="" type="radio"/> General | <input type="radio"/> Calibration | <input type="radio"/> SmartWash | <input type="radio"/> Results | <input type="radio"/> Interpretation |
| Assay: Uric-U | Type: Photometric | Version: 1 | | |
| Number: 1041 | | | | |
| <input checked="" type="radio"/> Reaction definition | | <input type="radio"/> Reagent / Sample | <input type="radio"/> Validity checks | |
| Reaction mode: End up | | Primary | Secondary | Read times |
| Wavelength: 548 / 700 | | | | Main: 24 – 26 |
| Last required read: 26 | | | | |
| Absorbance range: ___ – ___ | | Color correction: ___ – ___ | | |
| Sample blank type: None | | | | |
| | | | | |
| <input type="radio"/> Reaction definition | | <input checked="" type="radio"/> Reagent / Sample | <input type="radio"/> Validity checks | |
| | | R1 | | |
| Reagent: URIC0 | | Reagent volume: 160 | | |
| Diluent: Saline | | Water volume: ___ | | |
| Diluent dispense mode: Type 0 | | Dispense mode: Type 0 | | |
| Dilution name | Sample | Diluted sample | Diluent | Water Dilution factor Default dilution |
| STD(1:10) : | 18.0 | 3.2 | 162 | ___ = 1:10.00 ● |
| _____ : | _____ | _____ | _____ | = ○ |
| _____ : | _____ | _____ | _____ | = ○ |
| | | | | |
| <input type="radio"/> Reaction definition | | <input type="radio"/> Reagent / Sample | <input checked="" type="radio"/> Validity checks | |
| Reaction check: None | | | | |
| | | | | |
| Maximum absorbance variation: ___ | | | | |
| | | | | |
| Configure assay parameters — Calibration | | | | |
| <input type="radio"/> General | <input checked="" type="radio"/> Calibration | <input type="radio"/> SmartWash | <input type="radio"/> Results | <input type="radio"/> Interpretation |
| Assay: Uric-U | Calibration method: Use Cal Factor/Blank | | | |
| Use Cal factor from: Uric | | | | |

| | | | | | |
|--|-----------------------------------|--|-------------------------------|--------------------------------------|--|
| Configure assay parameters – SmartWash | | | | | |
| <input type="radio"/> General | <input type="radio"/> Calibration | <input checked="" type="radio"/> SmartWash | <input type="radio"/> Results | <input type="radio"/> Interpretation | |
| Assay: Uric-U | | | | | |
| COMPONENT Cuvette | REAGENT / ASSAY Trig | WASH 10% Detergent B*** | Volume 345 | Replicates | |

Uric Acid Urine—Conventional Units

Configure assay parameters — Results

| | | | | |
|------------------------------------|-----------------------------------|---------------------------------|--|--------------------------------------|
| <input type="radio"/> General | <input type="radio"/> Calibration | <input type="radio"/> SmartWash | <input checked="" type="radio"/> Results | <input type="radio"/> Interpretation |
| Assay: Uric-U | | | Result units: mg/dL | |
| Assay defaults: | | | | |
| Low-Linearity: 0.1 ^{##} | | | | |
| High-Linearity: 43.3 ^{##} | | | | |
| Gender and age specific ranges: | | | | |
| GENDER | AGE (UNITS) | NORMAL | EXTREME | |

| Configure result units | |
|------------------------|-----------------|
| Assay: | Uric-U |
| Version: | 1 |
| Result units: | mg/dL |
| Decimal places: | 1 [Range 0 - 4] |
| Correlation factor: | 1.0000 |
| Intercept: | 0.0000 |

Uric Acid Urine—SI Units

Configure assay parameters — Results

| | | | | |
|------------------------------------|-----------------------------------|---------------------------------|--|--------------------------------------|
| <input type="radio"/> General | <input type="radio"/> Calibration | <input type="radio"/> SmartWash | <input checked="" type="radio"/> Results | <input type="radio"/> Interpretation |
| Assay: Uric-U | | | Result units: mmol/L | |
| Assay defaults: | | | | |
| Low-Linearity: 0.01 ^{[[} | | | | |
| High-Linearity: 2.55 ^{[[} | | | | |
| Gender and age specific ranges: | | | | |
| GENDER | AGE (UNITS) | NORMAL | EXTREME | |

| Configure result units | |
|------------------------|-----------------|
| Assay: | Uric-U |
| Version: | 1 |
| Result units: | mmol/L |
| Decimal places: | 2 [Range 0 - 4] |
| Correlation factor: | 1.0000 |
| Intercept: | 0.0000 |

† Due to differences in instrument systems and unit configurations, version numbers may vary.

The linear low value (Low-Linearity) is LOQ divided by the Standard dilution factor, then rounded up to the number of decimal places defined in the decimal places parameter field. The linear high value (High-Linearity) is Linearity divided by the Standard dilution factor.

AEROSET SYSTEM ASSAY PARAMETERS

AEROSET®

Uric Acid Serum/Plasma—Conventional Units

| Assay Configuration: Outline Page | | | | | | | |
|-----------------------------------|---------|------------------|---------------|---------|-----|----------|-----|
| Assay Name | Assay # | | | Line | | | |
| Uric | 10 | | | B-Line | | | |
| Quantitative Ranges | | | | | | | |
| Min Text | Min | Panic-L | L-Reference-H | Panic-H | Max | Max Text | * |
| * | 0.0* | 0.0 | 2.6 | 7.2 | 0.0 | 0.0* | * |
| | 0.3** | L-Linear Range-H | | 33.1 | | | |
| Reference Ranges* | | | | | | | |
| Age | | Male | | Female | | | |
| 0 Year | | 3.5 | - | 7.2 | 2.6 | - | 6.0 |
| 0 Year | | 0.0 | - | 0.0 | 0.0 | - | 0.0 |
| 0 Year | | 0.0 | - | 0.0 | 0.0 | - | 0.0 |
| 0 Year | | 0.0 | - | 0.0 | 0.0 | - | 0.0 |
| Qualitative Ranges | | N/A | | | | | |

Uric Acid Serum/Plasma—SI Units

| Assay Configuration: Outline Page | | | | | | | |
|-----------------------------------|---------|------------------|---------------|---------|------|----------|------|
| Assay Name | Assay # | | | Line | | | |
| Uric | 10 | | | B-Line | | | |
| Quantitative Ranges | | | | | | | |
| Min Text | Min | Panic-L | L-Reference-H | Panic-H | Max | Max Text | * |
| * | 0.0* | 0.0 | 0.15 | 0.42 | 0.0 | 0.0* | * |
| | 0.02** | L-Linear Range-H | | 1.95 | | | |
| Reference Ranges* | | | | | | | |
| Age | | Male | | Female | | | |
| 0 Year | | 0.21 | - | 0.42 | 0.15 | - | 0.35 |
| 0 Year | | 0.0 | - | 0.0 | 0.0 | - | 0.0 |
| 0 Year | | 0.0 | - | 0.0 | 0.0 | - | 0.0 |
| 0 Year | | 0.0 | - | 0.0 | 0.0 | - | 0.0 |
| Qualitative Ranges | | N/A | | | | | |

| Assay Configuration: Base Page | | | | | | | | | |
|--------------------------------|---------------------|------------|---------------------|-----------------|-----------|-------|--|--|--|
| Reaction Mode | Wavelength-Prim/Sec | | Read time-Main/Flex | | AbsMaxVar | | | | |
| END UP | 548 / 700 | | | 24 – 26 / 0 – 0 | | 0.0 | | | |
| Sample Blank Test | Blank Read Time | Abs Window | | Abs Limits | | | | | |
| (____) | 0 – 0 | 0 – 0 | | 0.0 – 0.0 | | | | | |
| S.Vol | DS.Vol | D.Vol | W.Vol | Rgt Name/Pos | | | | | |
| Standard | 3.2 | 0.0 | 0 | 0 | | | | | |
| Dil 1 | 3.2 | 0.0 | 0 | 0 | Diluent: | — — * | | | |
| Dil 2 | 3.2 | 0.0 | 0 | 0 | Type# | 0 | | | |
| Rgt Name/Pos | R.Vol | W.Vol | Type# | | | | | | |
| Reagent 1 | URIC061 – * 160 | 0 | 0 | | | | | | |
| Reaction Check | Read Time – A/B | Range | | Minimum | | | | | |
| | 1 – 1 / 1 – 1 | 0.0 – 0.0 | | 0.0 | | | | | |
| Factor/Intercept | Decimal Places | Units | | | | | | | |
| 1.0 / 0.0 | 1 | mg/dL | | | | | | | |

| Assay Configuration: Base Page | | | | | | | | | |
|--------------------------------|---------------------|------------|---------------------|-----------------|-----------|-------|--|--|--|
| Reaction Mode | Wavelength-Prim/Sec | | Read time-Main/Flex | | AbsMaxVar | | | | |
| END UP | 548 / 700 | | | 24 – 26 / 0 – 0 | | 0.0 | | | |
| Sample Blank Test | Blank Read Time | Abs Window | | Abs Limits | | | | | |
| (____) | 0 – 0 | 0 – 0 | | 0.0 – 0.0 | | | | | |
| S.Vol | DS.Vol | D.Vol | W.Vol | Rgt Name/Pos | | | | | |
| Standard | 3.2 | 0.0 | 0 | 0 | | | | | |
| Dil 1 | 3.2 | 0.0 | 0 | 0 | Diluent: | — — * | | | |
| Dil 2 | 3.2 | 0.0 | 0 | 0 | Type# | 0 | | | |
| Rgt Name/Pos | R.Vol | W.Vol | Type# | | | | | | |
| Reagent 1 | URIC061 – * 160 | 0 | 0 | | | | | | |
| Reaction Check | Read Time – A/B | Range | | Minimum | | | | | |
| | 1 – 1 / 1 – 1 | 0.0 – 0.0 | | 0.0 | | | | | |
| Factor/Intercept | Decimal Places | Units | | | | | | | |
| 1.0 / 0.0 | 2 | mmol/L | | | | | | | |

| Assay Configuration: Calibration Page | | | | | | | |
|---------------------------------------|-----------------|--------|---------|----------------|---------------|--|--|
| Calib Mode | Interval (H) | | | | | | |
| Linear | 624 | | | | | | |
| Blank/Calib Replicates | Extrapolation % | | Span | Span Abs Range | | | |
| 3 / 3 | 0 | | BLK – 1 | 0.0 – 0.0 | | | |
| Sample | S.Vol | DS.Vol | D.Vol | W.Vol | BLK Abs Range | | |
| BLK | Water | 3.2 | 0.0 | 0 | 0.0 – 0.0 | | |
| C1 | MCC 1 | 3.2 | 0.0 | 0 | Cal Deviation | | |
| C2 | MCC 2 | 3.2 | 0.0 | 0 | 0.0 | | |
| | | | | | FAC Limit (%) | | |
| | | | | | 10 | | |

| Assay Configuration: Calibration Page | | | | | | | |
|---------------------------------------|-----------------|--------|---------|----------------|---------------|--|--|
| Calib Mode | Interval (H) | | | | | | |
| Linear | 624 | | | | | | |
| Blank/Calib Replicates | Extrapolation % | | Span | Span Abs Range | | | |
| 3 / 3 | 0 | | BLK – 1 | 0.0 – 0.0 | | | |
| Sample | S.Vol | DS.Vol | D.Vol | W.Vol | BLK Abs Range | | |
| BLK | Water | 3.2 | 0.0 | 0 | 0.0 – 0.0 | | |
| C1 | MCC 1 | 3.2 | 0.0 | 0 | Cal Deviation | | |
| C2 | MCC 2 | 3.2 | 0.0 | 0 | 0.0 | | |
| | | | | | FAC Limit (%) | | |
| | | | | | 10 | | |

| Assay Configuration: SmartWash Page | | | | | | | |
|-------------------------------------|------------|-------|-----|--|--|--|--|
| Rgt Probe | Reagent | Wash | Vol | | | | |
| | DBILI61 | Water | 300 | | | | |
| Cuvette | Assay Name | Wash | Vol | | | | |
| | — | — | — | | | | |
| Sample Probe | Wash | | | | | | |
| | — | | | | | | |

| Assay Configuration: SmartWash Page | | | | | | | |
|-------------------------------------|------------|-------|-----|--|--|--|--|
| Rgt Probe | Reagent | Wash | Vol | | | | |
| | DBILI61 | Water | 300 | | | | |
| Cuvette | Assay Name | Wash | Vol | | | | |
| | — | — | — | | | | |
| Sample Probe | Wash | | | | | | |
| | — | | | | | | |

Refer to Assay Configuration in Section 2 of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

** The linear low value (L-Linear Range) is LOQ rounded up to the number of decimal places defined in the decimal places parameter field.

AEROSET SYSTEM ASSAY PARAMETERS

AEROSET®

Uric Acid Urine—Conventional Units

| Assay Configuration: Outline Page | | | | | | | |
|-----------------------------------|-------|------------------|---------------|---------|------|----------|-----|
| Assay Name | | Assay # | | Line | | | |
| Uric-U | | 41 | | B-Line | | | |
| Quantitative Ranges | | | | | | | |
| Min Text | Min | Panic-L | L-Reference-H | Panic-H | Max | Max Text | * |
| * | 0.0* | 0.0 | 0.0 | 0.0 | 0.0* | * | * |
| | 0.1** | L-Linear Range-H | | 43.3** | | | |
| Reference Ranges* | | | | | | | |
| Age | | Male | | Female | | | |
| 0 Year | | 0.0 | – | 0.0 | 0.0 | – | 0.0 |
| 0 Year | | 0.0 | – | 0.0 | 0.0 | – | 0.0 |
| 0 Year | | 0.0 | – | 0.0 | 0.0 | – | 0.0 |
| 0 Year | | 0.0 | – | 0.0 | 0.0 | – | 0.0 |
| Qualitative Ranges | | N/A | | | | | |

Uric Acid Urine—SI Units

| Assay Configuration: Outline Page | | | | | | | |
|-----------------------------------|--------|------------------|---------------|---------|------|----------|-----|
| Assay Name | | Assay # | | Line | | | |
| Uric-U | | 41 | | B-Line | | | |
| Quantitative Ranges | | | | | | | |
| Min Text | Min | Panic-L | L-Reference-H | Panic-H | Max | Max Text | * |
| * | 0.0* | 0.0 | 0.0 | 0.0 | 0.0* | * | * |
| | 0.01** | L-Linear Range-H | | 2.55** | | | |
| Reference Ranges* | | | | | | | |
| Age | | Male | | Female | | | |
| 0 Year | | 0.0 | – | 0.0 | 0.0 | – | 0.0 |
| 0 Year | | 0.0 | – | 0.0 | 0.0 | – | 0.0 |
| 0 Year | | 0.0 | – | 0.0 | 0.0 | – | 0.0 |
| 0 Year | | 0.0 | – | 0.0 | 0.0 | – | 0.0 |
| Qualitative Ranges | | N/A | | | | | |

| Assay Configuration: Base Page | | | | | | | |
|--------------------------------|---------------------|-------|---------------------|-----------------|------------|---------------|--------------|
| Reaction Mode | Wavelength-Prim/Sec | | Read time-Main/Flex | | AbsMaxVar | | |
| END UP | 548 / 700 | | | 24 – 26 / 0 – 0 | | 0.0 | |
| Sample Blank Test | Blank Read Time | | Abs Window | | Abs Limits | | |
| (____) | 0 – 0 | | 0 – 0 | | 0.0 – 0.0 | | |
| S.Vol | DS.Vol | D.Vol | W.Vol | | | | |
| Standard | 18.0 | 3.2 | 162 | 0 | | | Rgt Name/Pos |
| Dil 1 | 18.0 | 3.2 | 162 | 0 | Diluent: | DILUENT D-18* | |
| Dil 2 | 18.0 | 3.2 | 162 | 0 | Type# | 0 | |
| Rgt Name/Pos | R.Vol | W.Vol | Type# | | | | |
| Reagent 1 | URIC061 – ____ * | 160 | 0 | 0 | | | |
| Reaction Check | Read Time – A/B | | Range | | Minimum | | |
| | 1 – 1 / 1 – 1 | | 0.0 – 0.0 | | 0.0 | | |
| Factor/Intercept | Decimal Places | | Units | | | | |
| 1.0 / 0.0 | 1 | | mg/dL | | | | |

| Assay Configuration: Base Page | | | | | | | |
|--------------------------------|---------------------|-------|---------------------|-----------------|------------|---------------|--------------|
| Reaction Mode | Wavelength-Prim/Sec | | Read time-Main/Flex | | AbsMaxVar | | |
| END UP | 548 / 700 | | | 24 – 26 / 0 – 0 | | 0.0 | |
| Sample Blank Test | Blank Read Time | | Abs Window | | Abs Limits | | |
| (____) | 0 – 0 | | 0 – 0 | | 0.0 – 0.0 | | |
| S.Vol | DS.Vol | D.Vol | W.Vol | | | | |
| Standard | 18.0 | 3.2 | 162 | 0 | | | Rgt Name/Pos |
| Dil 1 | 18.0 | 3.2 | 162 | 0 | Diluent: | DILUENT D-18* | |
| Dil 2 | 18.0 | 3.2 | 162 | 0 | Type# | 0 | |
| Rgt Name/Pos | R.Vol | W.Vol | Type# | | | | |
| Reagent 1 | URIC061 – ____ * | 160 | 0 | 0 | | | |
| Reaction Check | Read Time – A/B | | Range | | Minimum | | |
| | 1 – 1 / 1 – 1 | | 0.0 – 0.0 | | 0.0 | | |
| Factor/Intercept | Decimal Places | | Units | | | | |
| 1.0 / 0.0 | 2 | | mmol/L | | | | |

| Assay Configuration: Calibration Page | | | | | | | |
|---------------------------------------|---------------------|--------|---------|----------------|--|--|--|
| Calib Mode | Use Cal Factor from | | | Interval (H) | | | |
| UseFac/Blk | Uric (10) | | | 0 | | | |
| Blank/Calib Replicates | Extrapolation % | | Span | Span Abs Range | | | |
| 0 / 0 | 0 | | BLK – 1 | 0.0 – 0.0 | | | |
| Sample | S.Vol | DS.Vol | D.Vol | BLK Abs Range | | | |
| BLK | 2.0 | 0.0 | 0 | 0.0 – 0.0 | | | |
| C1 | 2.0 | 0.0 | 0 | Cal Deviation | | | |
| C2 | 2.0 | 0.0 | 0 | 0.0 | | | |

| Assay Configuration: Calibration Page | | | | | | | |
|---------------------------------------|---------------------|--------|---------|----------------|--|--|--|
| Calib Mode | Use Cal Factor from | | | Interval (H) | | | |
| UseFac/Blk | Uric (10) | | | 0 | | | |
| Blank/Calib Replicates | Extrapolation % | | Span | Span Abs Range | | | |
| 0 / 0 | 0 | | BLK – 1 | 0.0 – 0.0 | | | |
| Sample | S.Vol | DS.Vol | D.Vol | BLK Abs Range | | | |
| BLK | 2.0 | 0.0 | 0 | 0.0 – 0.0 | | | |
| C1 | 2.0 | 0.0 | 0 | Cal Deviation | | | |
| C2 | 2.0 | 0.0 | 0 | 0.0 | | | |

| Assay Configuration: SmartWash Page | | | | | | | |
|-------------------------------------|------------|-------|-----|--|--|--|--|
| Rgt Probe | Reagent | Wash | Vol | | | | |
| | DBILI61 | Water | 300 | | | | |
| Cuvette | Assay Name | Wash | Vol | | | | |
| | — | — | — | | | | |
| Sample Probe | Wash | | | | | | |
| | — | | | | | | |

| Assay Configuration: SmartWash Page | | | | | | | |
|-------------------------------------|------------|-------|-----|--|--|--|--|
| Rgt Probe | Reagent | Wash | Vol | | | | |
| | DBILI61 | Water | 300 | | | | |
| Cuvette | Assay Name | Wash | Vol | | | | |
| | — | — | — | | | | |
| Sample Probe | Wash | | | | | | |
| | — | | | | | | |

Refer to **Assay Configuration** in **Section 2** of the **AEROSET System Operations Manual** for information regarding assay parameters.

* User defined or instrument defined.

** The linear low value (L-Linear Range) is LOQ divided by the Standard dilution factor, then rounded up to the number of decimal places defined in the decimal places parameter field. The linear high value (Linear Range-H) is Linearity divided by the Standard dilution factor.