Uric Acid2

FOR USE WITH
ARCHITECT

Read Highlighted Changes: Revised February 2022.

REF 04T1320
REF 04T1330

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

Uric Acid2 (also referred to as Uric2)

INTENDED USE

The Uric Acid2 assay is used for the quantitation of uric acid in human serum, plasma, or urine on the ARCHITECT c Systems.

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.

SUMMARY AND EXPLANATION OF THE 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 THE PROCEDURE

The Uric Acid2 assay is an automated clinical chemistry assay.

The Uric Acid2 assay is a two-part reaction. 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 N, N-bis-(4-sulfobutyl)-3-methylaniline, disodium salt (TODB) 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.

Methodology: Uricase

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

Uric Acid2 Reagent Kit 04T13

NOTE: Some kit sizes may not be available. Please contact your local distributor.

Volumes (mL) listed in the following table indicate the volume per cartridge.

REF	04T1320	04T1330
Tests per cartridge set	160	500
Number of cartridge sets per kit	4	4
Tests per kit	640	2000
R1	16.2 mL	44.2 mL
R2	13.5 mL	36.2 mL

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), and uricase (2.000 KU/L). Preservatives: ProClin 300, ProClin 950, and sodium azide.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[3-6]

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.

* Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Abbott

Reagent Handling

- Do not pool reagents within a kit or between kits.
- Do not use components from one lot with components from another lot.
- Do not reuse containers, caps or plugs due to the risk of contamination and the potential to compromise reagent performance.
- When either the R1 or R2 reagent cartridge becomes empty, replace both cartridges.
- Upon receipt, reagent cartridges can be used immediately or stored in an upright position.
- 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.

For a detailed discussion of reagent handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

- Do not freeze.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position.

Reagents may be stored on or off the ARCHITECT c System. If reagents are removed from the system, store at 2 to 8°C (with replacement caps) in their original boxes.

For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Uric Acid2 assay file must be installed on the ARCHITECT c System prior to performing the assay.

Installation of all the required SmartWash updates on the ARCHITECT c Systems Assay Disk Version 17.00 (or higher), and either the MULTIGENT Assay Disk Version 9.00 (or higher) or the Special Chemistry Assay Disk Version 7.00 (or higher) must be completed prior to performing the assay. See below for impacted assays:

				VERSION	
Assay Name	**Short Name**	**REF**	**Assay Number**	**Conventional Units / Alternate Units**	**SI Units / Alternate Units**
Amphetamine / Methamphetamine 1000 Qualitative	AmpQ	3L37	2849	6	6
Amphetamine / Methamphetamine Semiquantitative	AmpSQ	3L37	2848	7	7
Amphetamine / Methamphetamine 500 Qualitative	Amp5Q	3L37	2879	4	4
Magnesium	MAG	3P68	1070	6	4
Magnesium Urine	MAGU	3P68	1099	8	4

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

Alternate Result Units

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
mg/dL	0.059	mmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.

Specimen Type	Collection Vessel	Special Conditions
Serum	Serum tubes Serum separator tubes	
Plasma	Lithium heparin tubes Lithium heparin separator tubes Sodium heparin tubes	
Urine (24 hour)	Clean plastic or glass container with or without preservatives[7, 8]	24 hour urine specimens are preferred. Urate precipitation can occur with sample storage; this can be avoided by adjusting the specimen pH to between 8 and 9 by addition of sodium hydroxide.[9, 10]
Urine (random specimens or timed specimens collected over intervals shorter than 24 hours)	Clean plastic or glass container with or without preservatives[7, 8]	Random specimens or specimens timed over shorter intervals are also acceptable for analysis. Urate precipitation can occur with sample storage; this can be avoided by adjusting the specimen pH to between 8 and 9 by addition of sodium hydroxide.[9, 10]

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.

The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	Room temperature (20 to 25°C)	8 hours
	2 to 8°C	3 days
	-20°C	3 months[11]
Urine	Room temperature (20 to 25°C)	2 days[7]
	2 to 8°C	2 days[7]

Serum/Plasma: Avoid multiple freeze/thaw cycles.[11]

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.[12] The storage information provided here is based on references or data maintained by the manufacturer.

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

04T13 Uric Acid2 Reagent Kit

Materials Required but not Provided

- Uric Acid2 assay file found on www.corelaboratory.abbott
- 04V1501 Consolidated Chemistry Calibrator
- Controls containing uric acid
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the ARCHITECT System Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the ARCHITECT System Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the ARCHITECT System Operations Manual, Section 5 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 effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 3.3 µL (serum/plasma); 20.0 µL (urine).

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the ARCHITECT System Operations Manual, Section 5.
- Refer to the Consolidated Chemistry Calibrator package insert REF 04V1501 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Serum/Plasma

Sample dilutions have not been evaluated for the Uric Acid2 assay. Samples with a uric acid value exceeding > 37.7 mg/dL (> 2.22 mmol/L) are flagged with the code "> 37.7 mg/dL" ("> 2.22 mmol/L"). The standard dilution factor for the Uric Acid2 assay is 1:1.27.

Urine

Samples with a uric acid value exceeding 261.3 mg/dL (15.42 mmol/L) are flagged with the code ">261.3 mg/dL" (">15.42 mmol/L"). Additional sample dilutions have not been evaluated for the urine Uric Acid2 assay. The system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

Dilution Name	Dilution Factor
Standard	1:6.34

For details on configuring automated dilutions, refer to the ARCHITECT System Operations Manual, Section 2.

Calibration

For instructions on performing a calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Calibration is stable for approximately 30 days (720 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- At least 2 levels of controls (low and high) 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, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[13]

RESULTS

Calculation

The Uric Acid2 (Uric2) assay utilizes the Linear data reduction method to generate a calibration and results for both the serum/plasma and urine applications.

Urine sample quantification (Uric2-U) is achieved using the calibration generated with the Uric2 assay parameter file.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

Reportable Interval

Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[14]

Serum/Plasma

	mg/dL	mmol/L
Analytical Measuring Interval (AMI)[a]	0.3 - 37.7	0.02 - 2.22
Reportable Interval[b]	0.2 - 37.7	0.01 - 2.22

Urine

	mg/dL	mmol/L
Analytical Measuring Interval (AMI)[a]	2.0 - 261.3	0.12 - 15.42
Reportable Interval[b]	0.6 - 261.3	0.04 - 15.42

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in mg/dL (mmol/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] The reportable interval extends from the LoD to the upper limit of the AMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the reportable interval.

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- Substances that demonstrated interference with the Uric Acid2 assay are listed in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.
- SmartWashes for assays impacted by Uric Acid2 must be configured to avoid interference due to reagent carryover. See the INSTRUMENT PROCEDURE section of this package insert for the required assay file updates.

EXPECTED VALUES

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

Reference Range (Serum/Plasma)[10]

Age	Range (mg/dL)	Range* (mmol/L)
0 - 14 days	2.8 - 12.7	0.17 - 0.75
15 days - < 1 year	1.6 - 6.3	0.09 - 0.37
1 - < 3 years	1.8 - 4.9	0.11 - 0.29
3 - < 5 years	2.0 - 4.9	0.12 - 0.29
5 - 8 years	1.9 - 5.0	0.11 - 0.30
9 - 10 years	2.4 - 5.5	0.14 - 0.32
11 - 12 years	2.6 - 5.8	0.15 - 0.34
13 - 79 years (male)	3.7 - 7.7	0.22 - 0.45
13 - 79 years (female)	2.5 - 6.2	0.15 - 0.37

Reference Range (Urine 24-Hour)[2]

Diet	Range (mg/day)	Range* (mmol/day)
Average diet	250 - 750	1.48 - 4.43
Purine-free	< 420 (females slightly lower)	< 2.48 (females slightly lower)
Low-purine (male)	< 480	< 2.83
Low-purine (female)	< 400	< 2.36
High-purine	< 1000	< 5.90

* Alternate result units were calculated by Abbott and are not included in the citation provided.

Abbott has not evaluated reference ranges in the pediatric population.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

Precision

Within-Laboratory Precision

Serum/Plasma

A study was performed based on guidance from CLSI EP05-A3.[15] Testing was conducted using 3 lots of the Uric Acid2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Two controls and 3 human serum panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mg/dL)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	4.7	0.04	0.9	0.06 (0.05 - 0.06)	1.3 (1.1 - 1.3)
Control Level 2	80	10.2	0.05	0.5	0.08 (0.06 - 0.12)	0.8 (0.6 - 1.2)
Panel A	80	1.1	0.03	2.3	0.03 (0.03 - 0.03)	2.7 (2.6 - 3.1)
Panel B	80	7.4	0.05	0.6	0.07 (0.07 - 0.08)	0.9 (0.9 - 1.1)
Panel C	80	33.1	0.12	0.4	0.21 (0.21 - 0.32)	0.6 (0.6 - 1.0)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mmol/L)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	0.28	0.002	0.6	0.003 (0.003 - 0.005)	1.2 (0.9 - 1.7)
Control Level 2	80	0.60	0.004	0.6	0.006 (0.005 - 0.008)	1.0 (0.8 - 1.3)
Panel A	80	0.06	0.003	4.9	0.005 (0.005 - 0.005)	7.8 (7.2 - 7.8)
Panel B	80	0.44	0.003	0.7	0.004 (0.004 - 0.005)	0.9 (0.9 - 1.2)
Panel C	80	1.95	0.009	0.4	0.013 (0.013 - 0.019)	0.7 (0.7 - 1.0)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

Urine

A study was performed based on guidance from CLSI EP05-A3.[15] Testing was conducted using 3 lots of the Uric Acid2 reagent, 3 lots of the Consolidated Chemistry Calibrators, 1 lot of commercially available controls, and 3 instruments. Two controls and 3 urine panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mg/dL)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	9.1	0.10	1.1	0.13 (0.09 - 0.13)	1.4 (1.0 - 1.4)
Control Level 2	80	22.8	0.17	0.7	0.23 (0.22 - 0.23)	1.0 (1.0 - 1.0)
Panel A	80	5.3	0.08	1.6	0.13 (0.10 - 0.13)	2.5 (1.8 - 2.5)
Panel B	80	30.1	0.19	0.6	0.28 (0.23 - 0.28)	0.9 (0.8 - 0.9)
Panel C	80	213.8	1.00	0.5	2.10 (2.10 - 2.71)	1.0 (1.0 - 1.3)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (mmol/L)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	80	0.54	0.006	1.1	0.008 (0.006 - 0.008)	1.4 (1.1 - 1.5)
Control Level 2	80	1.35	0.010	0.7	0.014 (0.013 - 0.014)	1.0 (1.0 - 1.0)
Panel A	80	0.31	0.006	1.9	0.008 (0.006 - 0.008)	2.7 (2.1 - 2.7)
Panel B	80	1.78	0.011	0.6	0.017 (0.013 - 0.017)	1.0 (0.7 - 1.0)
Panel C	80	12.61	0.059	0.5	0.124 (0.124 - 0.159)	1.0 (1.0 - 1.3)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

Accuracy

A study was performed to estimate the bias of the Uric Acid2 assay relative to standard reference material (NIST SRM 913). Testing was conducted using 3 concentrations of the standard across 3 lots of the Uric Acid2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 1 instrument. The bias ranged from -3.4% to 1.8% for serum, and -6.5% to -4.0% for urine.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[16] Testing was conducted using 3 lots of the Uric Acid2 reagent kit on each of 2 instruments over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

Serum

	mg/dL	mmol/L
LoB[a]	0.1	0.01
LoD[b]	0.2	0.01
LoQ[c]	0.3	0.02

Urine

	mg/dL	mmol/L
LoB[a]	0.4	0.02
LoD[b]	0.6	0.04
LoQ[c]	2.0	0.12

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met and was determined from n ≥ 60 replicates of low-analyte level samples.

Linearity

A study was performed based on guidance from CLSI EP06-A.[17]

This assay is linear across the analytical measuring interval of 0.3 to 37.7 mg/dL (0.02 to 2.22 mmol/L) for serum, and 2.0 to 261.3 mg/dL (0.12 to 15.42 mmol/L) for urine.

Analytical Specificity

Interference

Serum/Plasma

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[18] Each substance was tested at 2 levels of the analyte (approximately 4 mg/dL and 7 mg/dL). No significant interference (interference within ± 7%) was observed at the following concentrations:

	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
Bilirubin - conjugated	12 mg/dL	142.32 µmol/L
Bilirubin - unconjugated	60 mg/dL	1026.00 µmol/L
Glucose	1000 mg/dL	55.50 mmol/L
Hemoglobin	1000 mg/dL	10.00 g/L
Total protein	15 g/dL	150.00 g/L
Triglycerides	1500 mg/dL	16.94 mmol/L

Interference beyond ± 7% [based on 95% confidence interval (CI)] was observed at the concentrations shown below for the following substances.

Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Bilirubin - conjugated	24 mg/dL	284.64 µmol/L	7 mg/dL	0.41 mmol/L	-12% (-13%, -11%)
Bilirubin - conjugated	24 mg/dL	284.64 µmol/L	4 mg/dL	0.24 mmol/L	-12% (-12%, -11%)

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[18] Each substance was tested at 2 levels of the analyte (approximately 4 mg/dL and 7 mg/dL). No significant interference (interference within ± 7%) was observed at the following concentrations:

	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
4-Acetamidoantipyrine	40 mg/L	163.08 µmol/L
4-Aminoantipyrine	40 mg/L	196.81 µmol/L
4-Formylaminoantipyrine	40 mg/L	172.97 µmol/L
4-Methylaminoantipyrine	40 mg/L	184.33 µmol/L
Acetaminophen	160 mg/L	1059.20 µmol/L
Acetylcysteine	150 mg/L	919.50 µmol/L
Acetylsalicylic acid	30 mg/L	166.50 µmol/L
Ampicillin-Na	80 mg/L	215.41 µmol/L
Ascorbic acid	60 mg/L	340.80 µmol/L
Biotin	4250 ng/mL	17.38 µmol/L
Ca-dobesilate	25 mg/L	59.75 µmol/L
Carbamazepine	5 mg/dL	211.50 µmol/L
Cefoxitin	6600 mg/L	15.44 mmol/L
Cyclosporine	2 mg/L	1.66 µmol/L
Dipyrone (or metamizole)	10 mg/dL	300.30 µmol/L
Dobutamine	4 mg/L	13.28 µmol/L
Doxycycline	20 mg/L	45.00 µmol/L
Glutathione (reduced)	100 mg/L	325.38 µmol/L
Ibuprofen	220 mg/L	1067.00 µmol/L
Levodopa	4 mg/L	20.28 µmol/L
Methyldopa	5 mg/L	23.65 µmol/L
Metronidazole	130 mg/L	759.20 µmol/L
N-Acetyl-4-benzoquinone imine (NAPQI)	20 mg/L	134.09 µmol/L
Phenylbutazone	330 mg/L	1069.20 µmol/L
Piperazine	0.5 mg/dL	58.05 µmol/L
Rifampicin	40 mg/L	48.80 µmol/L
Sodium heparin	4 U/mL	N/A
Theophylline	60 mg/L	333.00 µmol/L
Thiouric acid	2132 ng/mL	11.59 µmol/L
Xanthine	100 mg/L	657.42 µmol/L

N/A = Not applicable

Interference beyond ± 7% [based on 95% confidence interval (CI)] was observed at the concentrations shown below for the following substances.

Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Ca-dobesilate	62 mg/L	148.18 µmol/L	7 mg/dL	0.41 mmol/L	-9% (-9%, -8%)
Ca-dobesilate	40 mg/L	95.60 µmol/L	4 mg/dL	0.24 mmol/L	-7% (-8%, -6%)
Levodopa	7 mg/L	35.49 µmol/L	7 mg/dL	0.41 mmol/L	-9% (-9%, -8%)
Levodopa	5 mg/L	25.35 µmol/L	4 mg/dL	0.24 mmol/L	-7% (-8%, -6%)
Methyldopa	20 mg/L	94.60 µmol/L	7 mg/dL	0.41 mmol/L	-16% (-16%, -15%)
Methyldopa	8 mg/L	37.84 µmol/L	4 mg/dL	0.24 mmol/L	-9% (-9%, -8%)
Rifampicin	45 mg/L	54.90 µmol/L	4 mg/dL	0.24 mmol/L	-7% (-8%, -7%)
Dobutamine	7 mg/L	23.24 µmol/L	7 mg/dL	0.41 mmol/L	-7% (-8%, -7%)
Dobutamine	7 mg/L	23.24 µmol/L	4 mg/dL	0.24 mmol/L	-8% (-9%, -7%)
N-Acetyl-4-benzoquinone imine (NAPQI)	25 mg/L	167.62 µmol/L	4 mg/dL	0.24 mmol/L	-7% (-8%, -6%)

Urine

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[18] Each substance was tested at 2 levels of the analyte (approximately 12 mg/dL and 30 mg/dL). No significant interference (interference within ± 10%) was observed at the following concentrations:

	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
Albumin	50 mg/dL	0.50 g/L
Ascorbate	200 mg/dL	11.36 mmol/L
Glucose	1000 mg/dL	55.50 mmol/L

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[18] Each substance was tested at 2 levels of the analyte (approximately 12 mg/dL and 30 mg/dL). No significant interference (interference within ± 10%) was observed at the following concentrations:

	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
Acetaminophen	16 mg/dL	1059.20 µmol/L
Acetylcysteine	15 mg/dL	919.50 µmol/L
Acetylsalicylic acid	6 mg/dL	333.00 µmol/L
Biotin	4250 ng/mL	17.38 µmol/L
Boric acid	1000 mg/dL	161.73 mmol/L
Hydrochloric acid (6N)	2.5 mL/dL	150.00 mmol/L
Ibuprofen	22 mg/dL	1067.00 µmol/L

Potentially Interfering Substance	Interferent Level	
	Default Units	Alternate Units
Sodium hydroxide (2.5N)	1.0 mL/dL	25.00 mmol/L

Interferences from medication or endogenous substances may affect results.[19]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3[20] using the Passing-Bablok regression method.

Uric Acid2 vs Uric Acid on the ARCHITECT c System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	129	mg/dL	1.00	0.05	1.00	1.6 - 31.8
		(mmol/L)		(0.00)		(0.09 - 1.88)
Urine	126	mg/dL	1.00	0.29	1.03	5.5 - 243.1
		(mmol/L)		(0.02)		(0.32 - 14.34)

BIBLIOGRAPHY

1. Burtis CA, Ashwood ER, Bruns DE, editors. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics*, 4th ed. St. Louis, MO: Elsevier Saunders; 2006:803-808.
2. Wu AHB, editor. *Tietz Clinical Guide to Laboratory Tests.* 4th ed. St. Louis, MO: Elsevier Saunders; 2006.
3. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
4. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
5. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
6. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition.* CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
7. Wu W, Yang D, Tiselius HG, et al. Collection and storage of urine specimens for measurement of urolithiasis risk factors. *Urology* 2015;85:299-303.
8. Malarkey LM, McMorrow ME. *Saunders Nursing Guide to Laboratory and Diagnostic Tests*. 2nd ed. St. Louis, MO: Elsevier; 2012:34.
9. Ng RH, Menon M, Ladenson JH. Collection and handling of 24-hour urine specimens for measurement of analytes related to renal calculi. *Clin Chem* 1984;30(3):467-471.
10. Rifai N, Horvath AR, Wittwer C, editors. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics.* 6th ed. St. Louis, MO: Elsevier; 2018.
11. Cuhadar S, Koseoglu M, Atay A, et al. The effect of storage time and freeze-thaw cycles on the stability of serum samples. *Biochem Med* 2013;23(1):70-77.
12. Clinical and Laboratory Standards Institute (CLSI). *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition.* CLSI Document GP44-A4. Wayne, PA: CLSI; 2010.
13. Westgard JO. *Basic QC Practices.* 3rd ed. Madison, WI: Westgard Quality Corporation; 2010.
14. Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking.* 1st ed. CLSI Guideline EP34. Wayne, PA: CLSI; 2018.
15. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline—Third Edition.* CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.
16. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition.* CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.
17. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. CLSI Document EP06-A. Wayne, PA: CLSI; 2003.
18. Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry.* 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.
19. Young DS. Laboratory test listings. In: *Effects of Drugs on Clinical Laboratory Tests.* 5th ed. AACC Press; 2000:chap 3.
20. Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition.* CLSI Document EP09-A3. Wayne, PA: CLSI; 2013.

Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
DISTRIBUTED IN THE USA BY	Distributed in the USA by
FOR USE WITH	Identifies products to be used together
INFORMATION FOR USA ONLY	Information needed for United States of America only
PRODUCT OF IRELAND	Product of Ireland
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

Abbott Ireland
Diagnostics Division
Lisnamuck, Longford
Co. Longford
Ireland
+353-43-3331000

DISTRIBUTED IN THE USA BY

Abbott Laboratories
Abbott Park, IL 60064 USA

Customer Service: Contact your local representative or find country-specific contact information on www.corelaboratory.abbott

For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, please report it to the manufacturer and to your national authority.

Revised February 2022.

Abbott