Urea Nitrogen2

FOR USE WITH

ARCHITECT

en

Urea2
04T12
G93377R04
B4T120

Revised October 2023.

REF 04T1220

REF 04T1230

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

Urea Nitrogen2 (also referred to as Urea2)

INTENDED USE

The Urea Nitrogen2 assay is used for the quantitation of urea nitrogen in human serum, plasma, or urine on the ARCHITECT c Systems.

The Urea Nitrogen2 assay is to be used as an aid in the diagnosis and treatment of certain renal and metabolic diseases.

SUMMARY AND EXPLANATION OF THE TEST

Proteins in the body are metabolized by the liver producing ammonia as a waste product, which is converted into urea by the urea cycle. Urea, which contains nitrogen, is released into the bloodstream and is excreted by the kidneys into the urine. The relationship between urea and urea nitrogen is the factor 0.467 for converting urea mass units to those of urea nitrogen, and 2.14 for converting urea nitrogen mass units to those of urea.[1]

Increases in urea nitrogen may be due to increased production or decreased excretion. Urea nitrogen is useful in assessing renal function, especially with serum creatinine.[2]

Urea nitrogen clearance and urea nitrogen/creatinine ratio in serum are useful clinically to assess glomerular filtration rate (GFR) and volume depletion. Urea nitrogen is used before, during and after dialysis treatment to quantify an individual's urea clearance during a single dialysis.[2]

Urinary urea nitrogen provides a crude index of overall nitrogen balance and may be used as a guide to replacement in patients receiving parenteral nutrition.[1] In prerenal azotemia the fractional excretion of urea nitrogen (FE_{un}) which is used as an index of volume status, can be used when fractional excretion of sodium (FE_{Na}) cannot provide reliable diagnostic information.[3]

Urea test results can be reported as urea or urea nitrogen. The term blood urea nitrogen (BUN) continues to be used for ordering the serum urea nitrogen test.[1]

PRINCIPLES OF THE PROCEDURE

The Urea Nitrogen2 assay is an automated clinical chemistry assay.

The Urea Nitrogen2 assay is a modification of a totally enzymatic procedure.[4] The test is performed as a kinetic assay in which the initial rate of the reaction is linear for a limited period of time. Urea in the sample is hydrolyzed by urease to ammonia and carbon dioxide. The second reaction, catalyzed by glutamate dehydrogenase (GLDH), converts ammonia and α-ketoglutarate to glutamate and water with the concurrent oxidation of reduced nicotinamide adenine dinucleotide (NADH) to nicotinamide adenine dinucleotide (NAD). Two moles of NADH are oxidized for each mole of urea present. The initial rate of decrease in absorbance at 340 nm is proportional to the urea concentration in the sample.

Methodology: Urease

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

REAGENTS

Kit Contents

Urea Nitrogen2 Reagent Kit 04T12

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	04T1220	04T1230
Tests per cartridge set	350	1450
Number of cartridge sets per kit	4	4
Tests per kit	1400	5800
R1	24.8 mL	53.9 mL
R2	10.0 mL	33.1 mL

R1 Active ingredient: β-NADH (1.915 g/L). Preservative: sodium azide.

R2 Active ingredients: α-ketoglutaric acid (13.149 g/L), GLDH (60.000 KU/L), and urease (10.000 KU/L). Preservative: 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.[5-8]

The following warnings and precautions apply to: R1 and R2	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

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.

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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 and validate the system by analyzing controls.
- 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 24 hours 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

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	25 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 Urea Nitrogen2 assay file must be installed on the ARCHITECT c System prior to performing the assay.

Installation of all the required SmartWash updates on the Special Chemistry Assay Disk Version 7.00 (or higher) must be completed prior to performing the assay. See below for impacted assay:

				VERSION	
Assay Name	**Short Name**	**REF**	**Assay Number**	**Conventional Units / Alternate Units**	**SI Units / Alternate Units**
Cystatin C	CYSC	1P93	2980	4	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	0.357	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[9, 10]	24 hour timed urine specimens are preferred.[11]

- 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	Collection Vessel	Maximum Storage Time
Serum/Plasma	Room temperature (20 to 25˚C)	Serum tubes[a] Serum separator tubes Lithium heparin tubes[a] Lithium heparin separator tubes Sodium heparin tubes[a]	24 hours
	2 to 8˚C	Serum tubes[a] Lithium heparin tubes[a] Sodium heparin tubes[a]	48 hours
		Serum separator tubes Lithium heparin separator tubes	7 days
Urine	Room temperature (20 to 25˚C)	Glass or plastic container	3 days[12]
	2 to 8˚C	Glass or plastic container	3 days[12]

[a] The maximum storage time for these vessels is supported by Cuhadar, et al.[13]

Serum/Plasma: Specimens may be stored at -20˚C for up to 30 days.[14]

Avoid multiple freeze/thaw cycles.[15]

Urine: If testing will be delayed more than 3 days, store frozen.

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.[16] 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

04T12 Urea Nitrogen2 Reagent Kit

Materials Required but not Provided

- Urea Nitrogen2 assay file found on www.corelaboratory.abbott
- 04V1501 Consolidated Chemistry Calibrator
- Controls containing urea nitrogen
- 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: 2.0 µL (serum/plasma); 10.0 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

Samples with a urea nitrogen value exceeding 128 mg/dL (45.7 mmol/L) are flagged with the code "> 128 mg/dL" ("> 45.7 mmol/L") and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Serum/Plasma Automated Dilution Protocol

The system performs a dilution of the sample, relative to the standard dilution, and automatically calculates the concentration by multiplying the result by the dilution factor.

Dilution Name	Dilution Factor
Standard	1:1.64
1:5	1:8.21

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

Serum/Plasma Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl).

The operator must enter the manual dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the manual dilution factor, the result must be manually multiplied by the appropriate manual dilution factor before reporting the result. If a diluted sample result is less than 3 mg/dL (1.1 mmol/L), do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Urine

Samples with a urea nitrogen value exceeding 1995 mg/dL (712.2 mmol/L) are flagged with the code "> 1995 mg/dL" ("> 712.2 mmol/L"). The system performs a standard dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor. Additional sample dilutions have not been evaluated for the urine Urea Nitrogen2 assay.

Dilution Name	Dilution Factor
STD (1:20)	1:32.82

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 5 days (120 hours), but is required with each change in reagent cartridge. 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.
- Run both levels of control with each cartridge change.
- 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.[17]

RESULTS

Calculation

The Urea Nitrogen2 assay utilizes the Linear data reduction method to generate a calibration and results.

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.[18]

Serum/Plasma

	mg/dL	mmol/L
Analytical Measuring Interval (AMI)[a]	3 - 128	1.1 - 45.7
Extended Measuring Interval (EMI)[b]	128 - 640	45.7 - 228.5
Reportable Interval[c]	3 - 640	1.1 - 228.5

[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] EMI: The EMI extends from the ULoQ to the ULoQ × sample dilution.

[c] The reportable interval extends from the LoD to the upper limit of the EMI.

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

Urine

	mg/dL	mmol/L
Analytical Measuring Interval (AMI)[a]	40 - 1995	14.3 - 712.2
Reportable Interval[b]	17 - 1995	6.1 - 712.2

[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 analytical measuring 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 Urea Nitrogen2 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 Urea Nitrogen2 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)

Age	Urea N, mg/dL	Urea, mmol/L[a]
Pediatrics[19]		
0 - < 14 days	2.8 - 23.0	1.0 - 8.2
15 days - < 1 year	3.4 - 16.8	1.2 - 6.0
1 - < 10 years	9.0 - 22.1	3.2 - 7.9
10 - < 19 years (female)	7.3 - 19.0	2.6 - 6.8
10 - < 19 years (male)	7.3 - 21.0	2.6 - 7.5
Adult[20]	6 - 20	2.1 - 7.1
Adult > 60 years	8 - 23	2.9 - 8.2

[a] 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.

24-Hour Reference Range, Urine[20]

Urea N	Urea[a]
12 - 20 g/day	430 - 710 mmol/day

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

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.[21] Testing was conducted using 3 lots of the Urea Nitrogen2 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	15	0.3	2.1	0.4 (0.2 - 0.4)	2.4 (1.6 - 2.4)
Control Level 2	80	49	0.5	1.1	0.8 (0.8 - 0.9)	1.7 (1.6 - 1.7)
Panel A	80	4	0.2	4.7	0.2 (0.0 - 0.2)	4.7 (0.0 - 4.7)
Panel B	80	22	0.3	1.1	0.5 (0.3 - 0.6)	2.1 (1.4 - 2.7)
Panel C	80	102	0.8	0.8	1.9 (1.2 - 2.5)	1.8 (1.2 - 2.5)

[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	5.4	0.10	1.9	0.11 (0.08 - 0.11)	2.1 (1.5 - 2.1)
Control Level 2	80	17.6	0.21	1.2	0.32 (0.30 - 0.33)	1.8 (1.7 - 1.9)
Panel A	80	1.4	0.08	5.4	0.08 (0.00 - 0.08)	5.4 (0.0 - 5.4)
Panel B	80	8.0	0.07	0.9	0.14 (0.12 - 0.21)	1.8 (1.5 - 2.6)
Panel C	80	36.3	0.29	0.8	0.66 (0.45 - 0.91)	1.8 (1.2 - 2.5)

[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.[21] Testing was conducted using 3 lots of the Urea Nitrogen2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls and 3 instruments. Two controls and 3 human 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	447	3.7	0.8	7.1 (7.1 - 11.7)	1.6 (1.6 - 2.6)
Control Level 2	80	729	5.2	0.7	11.4 (11.2 - 15.4)	1.6 (1.6 - 2.1)
Panel A	80	55	2.2	4.1	2.7 (2.7 - 5.6)	5.0 (5.0 - 10.3)
Panel B	80	715	6.2	0.9	10.2 (10.2 - 15.1)	1.4 (1.4 - 2.1)
Panel C	80	1605	12.6	0.8	22.6 (22.6 - 27.8)	1.4 (1.4 - 1.8)

[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	159.5	1.32	0.8	2.54 (2.54 - 4.19)	1.6 (1.6 - 2.6)
Control Level 2	80	260.2	1.85	0.7	4.06 (3.99 - 5.52)	1.6 (1.6 - 2.1)
Panel A	80	19.5	0.78	4.0	0.97 (0.97 - 2.00)	5.0 (5.0 - 10.3)
Panel B	80	255.3	2.21	0.9	3.66 (3.66 - 5.40)	1.4 (1.4 - 2.1)
Panel C	80	572.9	4.51	0.8	8.07 (8.07 - 9.92)	1.4 (1.4 - 1.8)

[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 Urea Nitrogen2 assay relative to standard reference material (NIST SRM Standard 912). Testing was conducted using 3 concentrations of standard across 3 lots of the Urea Nitrogen2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 1 instrument. The bias ranged from 1.6% to 4.2% for serum, and -1.3% to 3.0% for urine.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[22] Testing was conducted using 3 lots of the Urea Nitrogen2 reagent 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]	1	0.4
LoD[b]	3	1.1
LoQ[c]	3	1.1

Urine

	mg/dL	mmol/L
LoB[a]	12	4.3
LoD[b]	17	6.1
LoQ[c]	40	14.3

[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.[23] This assay is linear across the analytical measuring interval of 3 to 128 mg/dL (1.1 to 45.7 mmol/L) for serum, and 40 to 1995 mg/dL (14.3 to 712.2 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.[24] Each substance was tested at 2 levels of the analyte (approximately 10 mg/dL and 30 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)		
	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
Bilirubin - conjugated	60 mg/dL	712 µmol/L
Bilirubin - unconjugated	60 mg/dL	1026 µmol/L
Hemoglobin	2000 mg/dL	20 g/L
Total protein	10 g/dL	100 g/L
Triglycerides	1500 mg/dL	17 mmol/L

Interference beyond ± 10% [based on 95% Confidence Interval (CI)] was observed at the concentrations and analyte level shown below for the following substance.

Interference Beyond ± 10% (Based on 95% CI)					
Potentially Interfering Substance	**Interferent Level**		**Analyte Level**		
	Default Units	**Alternate Units**	**Default Units**	**Alternate Units**	**% Interference (95% CI)**
Total protein	11 g/dL	110 g/L	10 mg/dL	3.6 mmol/L	11% (9%, 14%)

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[24] Each substance was tested at 2 levels of the analyte (approximately 10 mg/dL and 30 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)		
	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
3-methyl-(triazen-1-yl)imidazole-4-carboxamide (MTIC)	0.6 mg/L	3.6 µmol/L
4-methylamino-antipyrine	3.3 mg/dL	152 µmol/L
5-amino-4-imidazolecarboxamide (AIC)	3 mg/L	24 µmol/L
Acetaminophen	160 mg/L	1059 µmol/L
Acetylcysteine	150 mg/L	920 µmol/L
Acetylsalicylic acid	30 mg/L	167 µmol/L
Ampicillin-Na	80 mg/L	215 µmol/L
Ascorbic acid	60 mg/L	341 µmol/L
Biotin	4250 ng/mL	17 µmol/L
Ca-dobesilate	60 mg/L	143 µmol/L
Cefoxitin	6287 mg/L	14 712 µmol/L
Cyclosporine	2 mg/L	1.7 µmol/L
Dipyrone (metamizole)	45 mg/dL	1351 µmol/L
Doxycycline	20 mg/L	45 µmol/L
Ibuprofen	220 mg/L	1067 µmol/L
Levodopa	8 mg/L	41 µmol/L
Methyldopa	25 mg/L	118 µmol/L
Metronidazole	130 mg/L	759 µmol/L
Phenylbutazone	330 mg/L	1069 µmol/L
Rifampicin	50 mg/L	61 µmol/L
Sodium heparin	4 U/mL	N/A
Sulfapyridine	300 mg/L	1203 µmol/L
Sulfasalazine	300 mg/L	753 µmol/L
Temozolomide	20 mg/L	103 µmol/L
Theophylline	60 mg/L	333 µmol/L

N/A= Not Applicable

Interference beyond ± 10% [based on 95% Confidence Interval (CI)] was observed at the concentration shown below for the following substance.

Interference Beyond ± 10% (Based on 95% CI)					
Potentially Interfering Substance	Interferent Level		Analyte Level		% Interference (95% CI)
	Default Units	Alternate Units	Default Units	Alternate Units	
Cefoxitin	6600 mg/L	15 444 µmol/L	10 mg/dL	3.6 mmol/L	10% (6%, 14%)

Urine

Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[24] Each substance was tested at 2 levels of the analyte (approximately 700 mg/dL and 1500 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)		
	Interferent Level	
Potentially Interfering Substance	Default Units	Alternate Units
Ascorbate	200 mg/dL	11 360 µmol/L
Glucose	1000 mg/dL	56 mmol/L
Protein	50 mg/dL	0.5 g/L

Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[24] Each substance was tested at 2 levels of the analyte (approximately 700 mg/dL and 1500 mg/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

No Significant Interference (Interference within ± 10%)		
	Interferent Level	
Potentially Interfering Substance	Default Units	Alternate Units
Acetaminophen	16 mg/dL	1059 µmol/L
Acetic acid (8.5N)	6.25 mL/dL	531 mmol/L
Acetylcysteine	15 mg/dL	920 µmol/L
Biotin	4250 ng/mL	17 µmol/L
Boric acid	250 mg/dL	40 433 µmol/L
Hydrochloric acid (6N)	2.5 mL/dL	150 mmol/L
Ibuprofen	22 mg/dL	1067 µmol/L
Nitric acid (6N)	5.0 mL/dL	300 mmol/L
Sodium carbonate	1.25 g/dL	118 mmol/L
Sodium fluoride	400 mg/dL	95 mmol/L
Sodium oxalate	60 mg/dL	4478 µmol/L

Interferences from medication or endogenous substances may affect results.[25]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3[26] using the Passing-Bablok regression method.

Urea Nitrogen2 vs Urea Nitrogen on the ARCHITECT c System						
	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	124	mg/dL (mmol/L)	1.00	0.74 (0.24)	1.02	4 - 123 (1.5 - 43.9)
Urine	121	mg/dL (mmol/L)	1.00	8.95 (3.17)	1.03	41 - 1754 (14.4 - 626.1)

BIBLIOGRAPHY

1. Burtis CA, Bruns DE, editors. *Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics.* 7th ed. St Louis, MO: Saunders; 2015:370.
2. Jacobs DS, De Mott WR, Oxley DK. *Jacobs & DeMott Laboratory Test Handbook with Key Word Index.* 5th ed. Hudson (Cleveland), OH: Lexi-Comp; 2001.
3. Schafer AI, Goldman L, editors. *Goldman-Cecil Medicine.* Vol 1. 25th ed. Philadelphia, PA: Elsevier/Saunders; 2016:989.
4. Talke H, Schubert GE. *Klinische Wochenschrift* 1965;43:174.
5. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
6. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.
7. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
8. 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.
9. Feres MC, Bini R, De Martino MC, et al. Implications for the use of acid preservatives in 24-hour urine for measurements of high demand biochemical analytes in clinical laboratories. *Clin Chim Acta* 2011;412(23-24):2322–2325.
10. Malarkey LM, McMorrow ME. *Saunders Nursing Guide to Laboratory and Diagnostic Tests.* 2nd ed. St. Louis, MO: Elsevier; 2012:34.
11. Tietz NW, editor. *Clinical Guide to Laboratory Tests*, 3rd ed. Philadelphia, PA: WB Saunders; 1995:622–624.
12. van Berkel EAT, Schel O, Boer AK. Influence of the storage temperature on urine analysis timed samples. *Ned Tijdschr Klin Chem Labgeneesk* 2010;35:173-174.
13. Cuhadar S, Atay A, Koseoglu M, et al. Stability studies of common biochemical analytes in serum separator tubes with or without gel barrier subjected to various storage conditions. *Biochem Med* 2012;22(2):202-214.
14. Kachhawa K, Kachhawa P, Varma M, et al. Study of the stability of various biochemical analytes in samples stored at different predefined storage conditions at an accredited laboratory of India. *J Lab Physicians* 2017;9(1):11-15.
15. 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.
16. 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.
17. Westgard JO. *Basic QC Practices.* 3rd ed. Madison, WI: Westgard Quality Corporation; 2010.
18. 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.
19. Colantonio DA, Kyriakopoulou L, Chan MK, et al. Closing the gaps in pediatric laboratory reference intervals: a CALIPER database of 40 biochemical markers in a healthy and multiethnic population of children. *Clin Chem* 2012;58:854-868.
20. Rifai N, Horvath AR, Wittwer C, editors. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics.* 6th ed. St. Louis, MO: Elsevier; 2018:499.
21. 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.
22. 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.
23. 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.
24. Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry.* 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.
25. Young DS. Laboratory test listings. In: *Effects of Drugs on Clinical Laboratory Tests.* 5th ed. AACC Press; 2000:chap 3.
26. 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.

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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.
FOR USE WITH	Identifies products to be used together
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%).

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