Alinity c Urea Nitrogen-24

Prepared by: Yusra Othman /Director/Supervisor-Chem **Date:** May/22/2024
signature/title

Reviewed by: Jordan Dillard /Instructor **Date:** June 27 2024
signature/title

Approved by: Sanford N. Bush, M.D /Chairman **Date:** June 28 2024
signature/title

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SUPERSEDES: Procedure titled _____

INTENDED USE

The Alinity c Urea Nitrogen assay is used for the quantitation of urea nitrogen in human serum, plasma, or urine on the Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Measurements obtained by this test are used in the diagnosis of certain renal and metabolic diseases. The determination of serum urea nitrogen is a widely used test for the evaluation of kidney function. The test is frequently requested in conjunction with the serum creatinine test for the differential diagnosis of prerenal (cardiac decompensation, water depletion, increased protein catabolism), renal (glomerulonephritis, chronic nephritis, polycystic kidney,

nephrosclerosis, tubular necrosis), and postrenal (obstructions of the urinary tract) hyperuremia.

PRINCIPLES OF THE PROCEDURE

The Urea Nitrogen assay is a modification of a totally **enzymatic** procedure first described by **Talke and Schubert**. 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 (GLD) 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.*1*

Methodology: Urease

For additional information on system and assay technology, refer to the **Alinity ci-series Operations Manual, Section 3.**

REAGENTS

Kit Contents

Alinity c Urea Nitrogen Reagent Kit 08P16

NOTE: Some kit sizes are not available in all countries. Please contact your local distributor.

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

REF	08P1620	08P1630
Tests per cartridge	400	1300
Number of cartridges per kit	10	10
Tests per kit	4000	13 000
R1	12.9 mL	33.6 mL
R2	15.6 mL	43.4 mL
R1 Active ingredients: NADH (2.95 mmol/L). Preservatives: ProClin 950 (0.1%), sodium azide (0.1%).		
R2 Active ingredients: α-Ketoglutaric Acid (99.8 mmol/L), Urease (jack bean) (23.5 KU/L), GLD (beef liver) (63.5 KU/L), Adenosine Diphosphate (7.6 mmol/L). Preservative: sodium azide (0.2%).		

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 be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[2], [3], [4], [5]

The following warnings and precautions apply to: R1	
	
WARNING	Contains methylisothiazolone and sodium azide.
H317	May cause an allergic skin reaction.
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.
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.

The following warnings and precautions apply to: R2	
Contains tris hydroxymethyl aminomethane* and sodium azide.	
H316*	Causes mild skin irritation.

EUH032	Contact with acids liberates very toxic gas.
Response	
P332+P313*	If skin irritation occurs: Get medical advice / attention.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) or OSHA Hazard Communication 29 CFR 1910.1200 (HCS) 2012 have 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/and SDS folder.

For a detailed discussion of safety precautions during system operation, refer to the **Alinity ci-series Operations Manual, Section 8.**

Reagent Handling

- Reagents are shipped on wet ice.
- Upon receipt, place reagent cartridges in an upright position for 24 hours before use to allow bubbles that may have formed to dissipate.
- 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 **Alinity ci-series 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. Do not reuse original reagent caps or replacement caps due to the risk

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
			of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, **refer to the Alinity ci-series Operations Manual, Section 5.**

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- 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 **Alinity ci-series Operations Manual, Section 10.**

INSTRUMENT PROCEDURE

The Alinity c Urea Nitrogen assay file must be installed on the Alinity c analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.

For information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

Conversion formula:

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

Default Result Unit (urea nitrogen)	Conversion Factor	Alternate Result Unit (urea)

Default Result Unit (urea nitrogen)	Conversion Factor	Alternate Result Unit (urea)
mg/dL	0.357	mmol/L
g/day*	35.7	mmol/day

*** NOTE: This result unit is only used for urine samples. It is not included in the assay** parameter "Result units".

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 (with or without gel barrier)	
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin	
Urine	Clean plastic or glass container	24-hour timed urine specimens are preferred.[6]

- 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

- 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.
- For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- 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.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	20 to 25°C	7 days
	2 to 8°C	7 days
	-20°C	1 year[7], [8]
Urine*	20 to 25°C	2 days
	2 to 8°C	7 days
	-20°C	1 month

* Urine samples can be preserved **with thymol** to avoid bacterial action.[6]

Avoid multiple freeze/thaw cycles.

Guder et al. suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above.[7], [8]

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

08P16 Alinity c Urea Nitrogen Reagent Kit

Materials Required but not Provided

- Alinity c Urea Nitrogen assay file
- 08P6001 Alinity c Multiconstituent Calibrator Kit
- Commercially available 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 Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- 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 Alinity ci-series Operations Manual, Section 4.
- Refer to the Alinity c Multiconstituent Calibrator Kit package insert and commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Serum/Plasma

Samples with urea nitrogen values exceeding 125 mg/dL (44.6 mmol/L urea) are flagged with the code "> 125 mg/dL" (> 44.6 mmol/L urea) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Urine

Urine samples are automatically diluted 1:20 by the system using the Standard dilution option, then the system automatically corrects the concentration by multiplying the result by the dilution factor. This dilution extends urine urea nitrogen linearity to 1991 mg/dL (710.8 mmol/L urea). Samples exceeding this concentration are flagged with the code "> 1991 mg/dL"

(> 710.8 mmol/L urea) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

Serum/Plasma

The system performs a **1:5 dilution** of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

Urine

If using an automated dilution protocol, the system performs a dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor. For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Manual Dilution Procedure

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

The operator must enter the dilution factor in the Specimen or Control tab of the Create 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 dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. If a diluted sample result is flagged indicating it is less than the lower value of the measuring interval of 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 Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration is stable for approximately **7 days (168 hours),** but is required with each change in reagent cartridge or 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

- At least two levels of controls (normal and abnormal) are to be run every day testing performed.
- If quality control results do not meet the acceptance criteria defined laboratory quality controls procedure, sample results may be suspect. Follow the established quality control procedures to troubleshoot. Recalibration may be necessary. For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or

calibrator lot.

Commercial 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.[9]

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

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

For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

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 Alinity ci-series Operations Manual, Section 5.

Measuring Interval

Measuring interval is defined as the range of values in mg/dL (mmol/L) which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Alinity c Urea Nitrogen assay **is 3 mg/dL to 125 mg/dL** (1.1 mmol/L to 44.6 mmol/L) for the serum/plasma application and 40 mg/dL to 1991 mg/dL (14.3 mmol/L to 710.8 mmol/L) for the urine application.

LIMITATIONS OF THE PROCEDURE

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

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	Urea Nitrogen Range (mg/dL)	Urea Range (mmol/L)
Children		
1 to 3 years	5.1 to 16.8	1.8 to 6.0
4 to 13 years	7.0 to 16.8	2.5 to 6.0
14 to 19 years	8.4 to 21.0	3.0 to 7.5
Adult, Male		
< 50 years	8.9 to 20.6	3.2 to 7.4
> 50 years	8.4 to 25.7	3.0 to 9.2
Adult, Female		
< 50 years	7.0 to 18.7	2.5 to 6.7
> 50 years	9.8 to 20.1	3.5 to 7.2

Values in the cited reference were converted from urea (mg/dL) to urea nitrogen (mg/dL), and subsequently converted to SI units for urea (mmol/L).

NOTE: The Alinity c Urea Nitrogen assay reports concentrations of urea nitrogen (mg/dL) in default units and concentrations of urea (mmol/L) in SI units.

Mass Conversion of Urea Nitrogen to Urea

mg/dL urea nitrogen × 2.14 = mg/dL urea

mg/dL urea ÷ 100 = g/L urea

SI Unit Conversion of Urea

g/L urea ÷ 60.0 g/mol = mol/L urea

mol/L urea ×1000 = mmol/L urea

Urine[11]

	Urea Nitrogen Range (g/day)	Urea Range (mmol/day)
All	12 to 20	428 to 714

24-Hour Urinary Excretion

To convert results from mg/dL to g/day urea nitrogen (24-hour urinary excretion):

24-hour excretion = [(V × c) ÷ 100 000] g/day urea nitrogen

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mg/dL)

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

24-hour excretion = [(V × c) ÷ 1000] mmol/day urea

Where:

V = 24-hour urine volume (mL)

c = analyte concentration (mmol/L)

SPECIFIC PERFORMANCE CHARACTERISTICS

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

The Alinity c analyzer and the ARCHITECT c System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

Precision

Within-Laboratory Precision

Serum

A study was performed based on guidance from CLSI EP05-A2.*12* Testing was conducted using 1 lot of the Alinity c Urea Nitrogen Reagent Kit, 1 lot of the Alinity c Multiconstituent Calibrator Kit, and 1 lot of commercially available controls and 1 instrument. Three control levels and 1 panel were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

Sample	n	Mean (mg/dL)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	9	0.4	5.1	0.5	5.9
Control Level 2	120	39	0.5	1.3	0.7	1.8
Control Level 3	120	62	0.6	0.9	1.0	1.6
Panel	120	15	0.3	2.2	0.4	2.8

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

Sample	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	3.1	0.13	4.2	0.15	4.9
Control Level 2	120	13.9	0.16	1.2	0.24	1.8
Control Level 3	120	22.0	0.20	0.9	0.35	1.6
Panel	120	5.5	0.10	1.7	0.12	2.3

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

Urine

A study was performed based on guidance from CLSI EP05-A2.[12] Testing was conducted using 1 lot of the Alinity c Urea Nitrogen Reagent Kit, 1 lot of the Alinity c Multiconstituent Calibrator Kit, 1 lot of commercially available controls and 1 instrument. Two control levels were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

Sample	n	Mean (mg/dL)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	435	4.2	1.0	7.5	1.7
Control Level 2	120	978	10.0	1.0	17.0	1.7

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

Sample	n	Mean (mmol/L)	Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
			SD	%CV	SD	%CV
Control Level 1	120	155.2	1.50	1.0	2.67	1.7
Control Level 2	120	349.2	3.56	1.0	6.08	1.7

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

Lower Limits of Measurement

Serum/Plasma

A study was performed based on guidance from CLSI EP17-A2.[13] Testing was conducted using 3 lots of the Alinity c Urea Nitrogen 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.

	mg/dL	mmol/L
LoB[a]	1	0.4
LoD[b]	2	0.7
LoQ[c]	**3**	1.1

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

Urine

A study was performed based on guidance from CLSI EP17-A2.[13] Testing was conducted using 2 lots of the Alinity c Urea Nitrogen Reagent Kit on each of 2 instruments over a

minimum of 3 days. The LoB, LoD and LoQ values are summarized below. These representative data support the lower limit of the measuring interval.

	mg/dL	mmol/L
LoB[a]	11	3.9
LoD[b]	20	7.1
LoQ[c, d]	**40.0**	14.28

[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.

[d] This value represents the observed LoQ on the ARCHITECT System. The LoQ observed on the Alinity c analyzer supports this LoQ.

Linearity

A study was performed based on guidance from CLSI EP06-A.*14*

This assay is linear across the measuring interval of **3 to 125 mg/dL** (1.1 to 44.6 mmol/L) for the serum/plasma application and 40 to 1991 mg/dL (14.3 to 710.8 mmol/L) for the urine application.

Interference

This study was performed on the ARCHITECT c System.

Potentially Interfering Substances

A study was performed based on guidance from NCCLS EP7-P.*15* Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

Serum

Potentially Interfering Substance	Interferent Level		Urea Nitrogen	
	Default Units	Alternate units	Target Level mg/dL	Recovery (% of Target)
Bilirubin	30 mg/dL	513 µmol/L	20.8	99.5
	60 mg/dL	1026 µmol/L	20.8	98.2
Hemoglobin	1000 mg/dL	10.0 g/L	19.8	96.5
	2000 mg/dL	20.0 g/L	19.8	97.4
Intralipid	750 mg/dL	7.5 g/L	20.8	99.8

Potentially Interfering Substance	Interferent Level		Urea Nitrogen	
	Default Units	Alternate units	Target Level mg/dL	Recovery (% of Target)
	1000 mg/dL	10.0 g/L	20.8	99.0

The following drugs were tested on the ARCHITECT c System for interference at the concentrations indicated using an acceptance criteria of ± 10% from the target value.

Potentially Interfering Substance	Interferent Level		Urea Nitrogen		
	Default Units	Alternate units	Target Level mg/dL	Target Level mmol/L	Recovery (% of Target)
Sulfapyridine	300 mg/L	1204.8 µmol/L	8.8	3.1	100.0
Sulfasalazine	300 mg/L	753.8 µmol/L	8.8	3.1	101.4
Temozolomide	20 mg/L	103.1 µmol/L	12.1	4.3	105.4

Urine

A change in Urea Nitrogen concentration of < 10% was observed for the following potentially interfering substances up to the concentrations listed.

Potentially Interfering Substance	Interferent Level
Protein	50 mg/dL
Glucose	1000 mg/dL
Sodium Oxalate	60 mg/dL
Ascorbate	200 mg/dL
Acetic Acid (8.5 N)	6.25 mL/dL
Boric Acid	250 mg/dL
Hydrochloric Acid (6 N)	2.5 mL/dL
Nitric Acid (6 N)	5.0 mL/dL
Sodium Fluoride	400 mg/dL
Sodium Carbonate	1.25 g/dL

Interferences from medication or endogenous substances may affect results.[16]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[17]

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Urea Nitrogen vs ARCHITECT Urea Nitrogen	Serum	mg/dL	111	1.00	-0.08	1.01	7 - 125
		mmol/L	111	1.00	-0.04	1.01	2.5 - 44.5
	Urine	mg/dL	117	1.00	0.74	0.98	43 - 1926
		mmol/L	117	1.00	0.26	0.98	15.4 - 687.4

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