May 31, 2022

Abbott Ireland Diagnostics Division
Tiffini Jenkins
Regulatory Affairs Manager
Lisnamuch
Longford, Ireland

Re: K203771
Trade/Device Name: Urea Nitrogen2
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDQ
Dated: February 28, 2022
Received: March 2, 2022

Dear Tiffini Jenkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k203771

Device Name
Urea Nitrogen2

Indications for Use *(Describe)*
The Urea Nitrogen2 assay is used for the quantitation of Urea Nitrogen in human serum, plasma, or urine on the ARCHITECT c System.
The Urea Nitrogen2 assay is to used as an aid in the diagnosis and treatment of certain renal and metabolic diseases.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. 510(k) Number

k203771

II. Applicant Name

Abbott Ireland Diagnostics Division
Lisnamuck, Longford,
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Primary contact person for all communications:

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Date Summary Prepared: May 24, 2022

III. Device Name

Urea Nitrogen2

Reagents

Trade Name: Urea Nitrogen2
Device Classification: Class II
Classification Name: Urease and Glutamic Dehydrogenase, Urea Nitrogen
Governing Regulation Number: 21 CFR 862.1770
Product Code: CDQ

IV. Predicate Device

Urea Nitrogen (k981918)

V. Description of Device

A. 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.* 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

* Talke H, Schubert GE. *Klinische Wochenschrift* 1965;43:174.

B. Reagents

The various kit configurations of the Urea Nitrogen2 reagent kit are described below.

	List Number	
	04T1220	**04T1230**
Tests per cartridge set	350	1450
Number of cartridge sets per kit	4	4
Tests per kit	1400	5800
Reagent 1 (R1)	24.8 mL	53.9 mL
Reagent 2 (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.

VI. Intended Use of the Device

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

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

VII. Comparison of Technological Characteristics

The Urea Nitrogen2 assay (subject device) is an automated clinical chemistry assay for the quantitation of urea nitrogen in human serum, plasma, or urine on the ARCHITECT c System.

The similarities and differences between the subject assay and the predicate device are presented in the following table.

Comparison of Subject Device (Urea Nitrogen2) to Predicate Device (Urea Nitrogen)

Characteristics	Subject Device Urea Nitrogen2 (List No. 04T12)	Predicate Device Urea Nitrogen (k981918; List No. 7D75)
Platform	ARCHITECT c System	Same†
Intended Use and Indications for Use	The Urea Nitrogen2 assay is used for the quantitation of urea nitrogen in human serum, plasma, or urine on the ARCHITECT c System. The Urea Nitrogen2 assay is to be used as an aid in the diagnosis and treatment of certain renal and metabolic diseases.	The Urea Nitrogen assay is used for the quantitation of urea nitrogen in human serum, plasma, or urine.
Methodology	Urease	Same
Specimen Type	Human serum, plasma, urine	Same
Assay Principle / Principle of Procedure	The Urea Nitrogen2 assay is an automated clinical chemistry assay. The Urea Nitrogen2 assay is a modification of a totally enzymatic procedure.‡ 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.	The Urea Nitrogen2 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.

† In accordance with FDA Guidance Document "Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagent for Automated Analyzers", issued June 10, 1996, the assay equivalency study on ARCHITECT c System vs. the original platform, AEROSET, was performed and submitted under K980367/A004 in May 2002.

‡ Talke H, Schubert GE. *Klinische Wochenschrift* 1965;43:174.

Comparison of Subject Device (Urea Nitrogen2) to Predicate Device (Urea Nitrogen) (Continued)

Characteristics	Subject Device Urea Nitrogen2 (List No. 04T12)	Predicate Device Urea Nitrogen (k981918; List No. 7D75)
Standardization	NIST SRM 912b/Gravimetric	NIST SRM 912b/Differential Scanning Calorimetry
Use of Calibrators	Yes	Same
Use of Controls	Yes	Same
Assay Range	<u>Serum/Plasma:</u> Analytical Measuring Interval: 2 – 125 mg/dL Extended Measuring Interval: 125 – 625 mg/dL Reportable Interval: 2 – 625 mg/dL <u>Urine:</u> Analytical Measuring Interval: 16 – 1991 mg/dL Reportable Interval: 11 – 1991 mg/dL	Urea Nitrogen serum is linear from 2 to 125 mg/dL. Urea Nitrogen urine is linear from 2 to 1991 mg/dL.
Precision	<u>Serum/Plasma:</u> Samples with urea nitrogen concentrations between 4 and 102 mg/dL were evaluated. The samples demonstrated standard deviations (SDs) ≤ 0.4 mg/dL and % Coefficient of Variation (%CV) ≤ 2.7%. <u>Urine:</u> Samples with urea nitrogen concentrations between 55 and 1605 mg/dL were evaluated. The samples demonstrated SDs ≤ 11.7 mg/dL and %CV ≤ 2.1%.	<u>Serum/Plasma:</u> Samples with urea nitrogen concentrations between 15.5 and 48.0 mg/dL demonstrated %CV values ranging from 1.8 to 2.0%. <u>Urine:</u> Samples with urea nitrogen concentrations between 504.8 and 896.4 mg/dL demonstrated %CV values ranging from 3.1 to 3.8%.

Comparison of Subject Device (Urea Nitrogen2) to Predicate Device (Urea Nitrogen) (Continued)

Characteristics	Subject Device Urea Nitrogen2 (List No. 04T12)	Predicate Device Urea Nitrogen (k981918; List No. 7D75)
Lower Limits of Measurement	Serum/Plasma: Limit of Blank: 1 mg/dL Limit of Detection: 2 mg/dL Limit of Quantitation: 2 mg/dL Urine: Limit of Blank: 6 mg/dL Limit of Detection: 11 mg/dL Limit of Quantitation: 16 mg/dL	Serum/Plasma: Limit of Detection: 0.7 mg/dL Limit of Quantitation: 1.4 mg/dL Urine: Limit of Detection: 15.0 mg/dL Limit of Quantitation: 40.0 mg/dL
Tube Types	Serum: - Serum tubes - Serum separator tubes Plasma: - Lithium heparin tubes - Lithium heparin separator tubes - Sodium heparin tubes	Same

VIII. Summary of Nonclinical Performance

A. Reportable Interval

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

Serum/Plasma

	mg/dL
Analytical Measuring Interval (AMI)[a]	2 - 125
Extended Measuring Interval (EMI)[b]	125 - 625
Reportable Interval[c]	2 - 625

[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 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.

Urine

	mg/dL
Analytical Measuring Interval (AMI)[a]	16 - 1991
Reportable Interval[b]	11 - 1991

[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 that demonstrated acceptable performance for linearity, imprecision, and bias.

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

[§] Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking. 1st ed.* CLSI Document EP34. Wayne, PA: CLSI; 2018.

B. Within-Laboratory Precision

Serum/Plasma

A study was performed based on guidance from CLSI EP05-A3.** Testing was conducted using 3 lots of the Urea Nitrogen2 reagent, 3 lots of the Consolidated Chemistry Calibrator, and 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.

Sample	n	Mean (mg/dL)	Within-Run (Repeatability)		Within-Laboratory[a]	
			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.

** 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.

Urine

A study was performed based on guidance from CLSI EP05-A3.†† Testing was conducted using 3 lots of the Urea Nitrogen2 reagent, 3 lots of the Consolidated Chemistry Calibrator, and 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.

Sample	n	Mean (mg/dL)	Within-Run (Repeatability)		Within-Laboratory[a]	
			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.

†† 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.

C. Accuracy

A study was performed to estimate the bias of the Urea Nitrogen2 assay relative to standard reference material (NIST SRM Standard 912b). 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 from -1.3% to 3.0% for urine.

D. Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.‡‡ Testing was conducted using 3 lots of the Urea Nitrogen2 reagent on each of 2 instruments over a minimum of 3 days. The results of the study support limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values as summarized below.

Serum

	mg/dL
LoB[a]	1
LoD[b]	2
LoQ[c]	2

Urine

	mg/dL
LoB[a]	6
LoD[b]	11
LoQ[c]	16

[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.

‡‡ 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.

E. Linearity

A study was performed based on guidance from CLSI EP06-A.[§§] This assay is linear across the analytical measuring interval of 2 to 125 mg/dL for serum, and 16 to 1991 mg/dL for urine.

F. Potentially Interfering Endogenous and Exogenous Substances

Serum/Plasma - Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[***] 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.

Potentially Interfering Substance	Interferent Level
Bilirubin - conjugated	60 mg/dL
Bilirubin - unconjugated	60 mg/dL
Hemoglobin	2000 mg/dL
Total Protein	10 g/dL
Triglycerides	1500 mg/dL

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

Potentially Interfering Substance	Interferent Level	Analyte Level	% Interference (95% CI)
Total Protein	11 g/dL	10 mg/dL	11% (9%, 14%)

[§§] 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.

[***] Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

Serum/Plasma - Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.††† 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.

Potentially Interfering Substance	Interferent Level
3-methyl-(triazen-1-yl)imidazole-4-carboxamide (MTIC)	0.6 mg/L
4-methylamino-antipyrine	3.3 mg/dL
5-amino-4-imidazolecarboxamide (AIC)	3 mg/L
Acetaminophen	160 mg/L
Acetylcysteine	150 mg/L
Acetylsalicylic acid	30 mg/L
Ampicillin-Na	80 mg/L
Ascorbic acid	60 mg/L
Biotin	4250 ng/mL
Ca-dobesilate	60 mg/L
Cefoxitin	6287 mg/L
Cyclosporine	2 mg/L
Dipyrone (metamizole)	45 mg/dL

Potentially Interfering Substance	Interferent Level
Doxycycline	20 mg/L
Ibuprofen	220 mg/L
Levodopa	8 mg/L
Methyldopa	25 mg/L
Metronidazole	130 mg/L
Phenylbutazone	330 mg/L
Rifampicin	50 mg/L
Sodium heparin	4 U/mL
Sulfapyridine	300 mg/L
Sulfasalazine	300 mg/L
Temozolomide	20 mg/L
Theophylline	60 mg/L

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

Potentially Interfering Substance	Interferent Level	Analyte Level	% Interference (95% CI)
Cefoxitin	6600 mg/L	10 mg/dL	10% (6%, 14%)

††† Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

Urine - Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[‡‡‡] 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.

Potentially Interfering Substance	Interferent Level
Ascorbate	200 mg/dL
Glucose	1000 mg/dL
Protein	50 mg/dL

Urine - Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed.[§§§] 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.

Potentially Interfering Substance	Interferent Level
Acetaminophen	16 mg/dL
Acetic acid (8.5N)	6.25 mL/dL
Acetylcysteine	15 mg/dL
Biotin	4250 ng/mL
Boric acid	250 mg/dL
Hydrochloric acid (6N)	2.5 mL/dL
Ibuprofen	22 mg/dL
Nitric acid (6N)	5.0 mL/dL
Sodium carbonate	1.25 g/dL
Sodium fluoride	400 mg/dL
Sodium oxalate	60 mg/dL

[‡‡‡] Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

[§§§] Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

G. Method Comparison

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

Urea Nitrogen2 vs Urea Nitrogen on the ARCHITECT c System						
	Units	**n**	**Correlation Coefficient**	**Intercept**	**Slope**	**Concentration Range**
Serum	mg/dL	124	1.00	0.74	1.02	4 - 123
Urine	mg/dL	121	1.00	8.95	1.03	41 - 1754

H. Tube Type

A study was performed to evaluate the suitability of specific blood collection tube types for use with Urea Nitrogen2 assay. Samples were collected from a minimum of 40 donors and evaluated across tube types. The following blood collection tube types were determined to be acceptable for use with the Urea Nitrogen2 assay:

Serum

- Serum tubes
- Serum separator tubes

Plasma

- Lithium heparin tubes
- Lithium heparin separator tubes
- Sodium heparin tubes

[****] 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.

I. Dilution Verification

A study was performed to evaluate the performance of the Urea Nitrogen2 automated dilution protocol relative to the manual dilution procedure on the ARCHITECT c System. Five human serum samples were created by spiking urea stock solution into Serasub (a synthetic serum) to target concentration values of 150, 214, 278, 342, and 405 mg/dL. Each sample was divided into multiple aliquots. An aliquot of each sample was tested using the 1:5 automated dilution protocol on the ARCHITECT c System. The additional aliquots were divided such that 2 technicians each prepared 3 manual dilutions (1:5 dilution) of each sample using saline. Each sample preparation from a given technician was tested in a separate run.

The samples were tested in replicates of 5 using 1 lot each of reagents, calibrators, and controls on 2 instruments. The % difference values for the automated dilution protocol versus the manual dilution procedure ranged from -2.8% to -1.3% and therefore, demonstrated acceptable performance.

IX. Summary of Clinical Performance

This section does not apply.

X. Conclusion Drawn from Nonclinical Laboratory Studies

The similarities and differences between the subject device and predicate device are presented in Section 5-VII.

There is no known potential adverse effect to the operator when using this *in vitro* device according to the Urea Nitrogen2 reagent package insert instructions.