March 22, 2022

Abbott Ireland Diagnostics Division
Magdalena Suszko
Associate Director Regulatory Affairs
Lisnamuck, Longford
Ireland

Re: K210452
Trade/Device Name: Creatinine2
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: CGX
Dated: December 6, 2021
Received: December 8, 2021

Dear Magdalena Suszko:

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 and Part 809); 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
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

k210452

Device Name
Creatinine2

Indications for Use *(Describe)*

The Creatinine2 assay is used for the quantitation of creatinine in human serum, plasma, or urine on the ARCHITECT c System.

The Creatinine2 assay is to be used as an aid in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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

k210452

II. Applicant Name

Abbott Ireland Diagnostics Division
Lisnamuck, Longford
Longford, IE

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Date Summary Prepared: December 6, 2021

III. Device Name

Creatinine2

Reagents

Trade Name: Creatinine2
Device Classification: Class II
Classification Name: Creatinine test system
Governing Regulation Number: 21 CFR 862.1225
Product Code: CGX

IV. Predicate Device

Creatinine (k083809)

V. Description of Device

A. Principles of the Procedure

The Creatinine2 assay is an automated clinical chemistry assay. At an alkaline pH, creatinine in the sample reacts with picric acid to form a creatinine-picrate complex that absorbs at 500 nm. The rate of increase in absorbance is directly proportional to the concentration of creatinine in the sample.

Methodology: Kinetic Alkaline Picrate

B. Reagents

The configuration of the Creatinine2 reagent kit is described below.

	List Number
	04S9520
Tests per cartridge set	450
Number of cartridge sets per kit	8
Tests per kit	3600
Reagent 1 (R1)	53.9 mL
Reagent 2 (R2)	21.4 mL

Reagent 2 Active ingredient: picric acid 5.500 g/L.

VI. Intended Use of the Device

The Creatinine2 assay is used for the quantitation of creatinine in human serum, plasma, or urine on the ARCHITECT c System.

The Creatinine2 assay is to be used as an aid in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

VII. Comparison of Technological Characteristics

The Creatinine2 assay (subject device) is an automated clinical chemistry assay for the quantitation of creatinine in human serum, plasma, or urine on the ARCHITECT c System.

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

Comparison of Subject Device (Creatinine2) to Predicate Device (Creatinine)

Characteristics	Subject Device Creatinine2 (List No. 04S95)	Predicate Device Creatinine (k083809; List No. 3L81)
Platform	ARCHITECT c System	Same
Intended Use and Indications for Use	The Creatinine2 assay is used for the quantitation of creatinine in human serum, plasma, or urine on the ARCHITECT c System. The Creatinine2 assay is to be used as an aid in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.	The Creatinine assay is used for the quantitation of creatinine in human serum, plasma, or urine.
Methodology	Kinetic Alkaline Picrate	Same
Specimen Type	Human serum, plasma, urine	Same
Assay Principle / Principle of Procedure	The Creatinine2 assay is an automated clinical chemistry assay. At an alkaline pH, creatinine in the sample reacts with picric acid to form a creatinine-picrate complex that absorbs at 500 nm. The rate of increase in absorbance is directly proportional to the concentration of creatinine in the sample.	At an alkaline pH, creatinine in the sample reacts with picrate to form a creatinine-picrate complex. The rate of increase in absorbance at 500 nm due to the formation of this complex is directly proportional to the concentration of creatinine in the sample.
Standardization	NIST SRM 967 for serum/plasma NIST SRM 914 for urine	Same
Use of Calibrators	Yes	Same
Use of Controls	Yes	Same

NIST - National Institute of Standards and Technology
SRM - Standard Reference Materials

Comparison of Subject Device (Creatinine2) to Predicate Device (Creatinine) (Continued)

Characteristics	Subject Device Creatinine2 (List No. 04S95)	Predicate Device Creatinine (k083809; List No. 3L81)
Assay Range	Serum/Plasma: Analytical Measuring Interval: 0.09 – 37.34 mg/dL Reportable Interval: 0.04 – 37.34 mg/dL Urine: Analytical Measuring Interval: 2.54 – 740 mg/dL Reportable Interval: 1.24 – 740 mg/dL	Serum/Plasma: Creatinine serum is linear from 0.20 to 37.00 mg/dL. Urine: Creatinine urine is linear from 5.00 to 740.00 mg/dL.
Precision	Serum/Plasma: Samples with creatinine concentrations between 0.25 and 36.36 mg/dL were evaluated. The samples demonstrated % coefficients of variation (%CV) ≤ 3.5% and standard deviations (SD) ≤ 0.011 mg/dL. Urine: Samples with creatinine concentrations between 5.25 and 701.12 mg/dL were evaluated. The samples demonstrated %CV ≤ 2.4% and SD ≤ 0.294 mg/dL.	Serum/Plasma: Samples with creatinine concentrations between 1.20 and 4.66 mg/dL demonstrated %CV values ranging from 3.18 to 4.95%. Urine: Samples with creatinine concentrations between 61.95 and 145.48 mg/dL demonstrated %CV values ranging from 1.27 to 1.34%.
Lower Limits of Measurement	Serum/Plasma: Limit of Blank: 0.02 mg/dL Limit of Detection: 0.04 mg/dL Limit of Quantitation: 0.09 mg/dL Urine: Limit of Blank: 0.93 mg/dL Limit of Detection: 1.24 mg/dL Limit of Quantitation: 2.54 mg/dL	Serum/Plasma: Limit of Detection: 0.05 mg/dL Limit of Quantitation: 0.10 mg/dL Urine: Limit of Detection: 4.00 mg/dL Limit of Quantitation: 5.00 mg/dL

Comparison of Subject Device (Creatinine2) to Predicate Device (Creatinine) (Continued)

Characteristics	Subject Device Creatinine2 (List No. 04S95)	Predicate Device Creatinine (k083809; List No. 3L81)
Tube Types	Serum: - Serum tubes - Serum separator tubes Plasma: - Dipotassium EDTA tubes - Lithium heparin tubes - Lithium heparin separator tubes - Sodium heparin tubes	Serum: - Glass or plastic tubes with or without gel barrier Plasma: - Glass or plastic lithium heparin tubes (with or without gel barrier) - Glass or plastic EDTA tubes - Glass or plastic sodium heparin tubes

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]	0.09 - 37.34
Reportable Interval[b]	0.04 - 37.34

[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.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the analytical measuring interval. Samples with a creatinine value below LoQ are reported as "<0.09 mg/dL" ("<8.0 µmol/L").

Urine

	mg/dL
Analytical Measuring Interval (AMI)[a]	2.54 - 740
Reportable Interval[b]	1.24 - 740

[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.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the analytical measuring interval. Samples with a creatinine value below LoQ are reported as "<2.54 mg/dL" ("<0.225 mmol/L").

* 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 Creatinine2 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	1.42	0.015	1.0	0.050 (0.016 - 0.050)	3.5 (1.1 - 3.5)
Control Level 2	80	5.91	0.035	0.6	0.147 (0.047 - 0.147)	2.5 (0.8 - 2.5)
Panel A	80	0.25	0.008	3.1	0.011 (0.010 - 0.011)	4.5 (3.9 - 4.5)
Panel B	80	26.00	0.121	0.5	0.588 (0.185 - 0.588)	2.3 (0.7 - 2.3)
Panel C	80	36.36	0.130	0.4	0.777 (0.260 - 0.777)	2.1 (0.7 - 2.1)

[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 Creatinine2 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	57.77	0.491	0.9	1.194 (0.781 - 1.194)	2.1 (1.4 - 2.1)
Control Level 2	80	132.61	1.165	0.9	3.158 (1.860 - 3.158)	2.4 (1.4 - 2.4)
Panel A	80	5.37	0.233	4.3	0.294 (0.221 - 0.294)	5.5 (4.2 - 5.5)
Panel B	80	278.12	1.958	0.7	5.003 (2.671 - 5.003)	1.8 (1.0 - 1.8)
Panel C	80	701.12	3.303	0.5	12.844 (7.631 - 12.844)	1.8 (1.1 - 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

Serum/Plasma

A study was performed to estimate the bias of the Creatinine2 assay relative to material standardized to the Certified Reference Material NIST SRM 967a.

Testing was conducted using 3 lots of the Creatinine2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 1 instrument. The bias ranged from -4.1% to 0.4% across all instruments, calibrator and reagent lots.

Urine

A study was performed to estimate the bias of the Creatinine2 assay relative to material standardized to the Certified Reference Material NIST SRM 914a.

Testing was conducted using 3 concentrations of standard across 3 lots of the Creatinine2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 1 instrument. The bias ranged from -4.8% to 3.3% across all concentrations of standard, instruments, calibrator and reagent lots.

D. Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[§] Testing was conducted using 3 lots of the Creatinine2 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/Plasma

	mg/dL
LoB[a]	0.02
LoD[b]	0.04
LoQ[c]	0.09

Urine

	mg/dL
LoB[a]	0.93
LoD[b]	1.24
LoQ[c]	2.54

[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.

E. Linearity

A study was performed based on guidance from CLSI EP06-A.[**] This assay demonstrated linearity across the analytical measuring interval of 0.09 to 37.34 mg/dL for the serum application, and 2.54 to 740 mg/dL for the urine application.

[§] 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.

[**] 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.

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 0.6 mg/dL and 2.0 mg/dL).

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

Potentially Interfering Substance	Interferent Level	Analyte Level
Acetoacetate	20 mg/dL	0.6 mg/dL 2.0 mg/dL
Bilirubin - conjugated	20 mg/dL 40 mg/dL	0.6 mg/dL 2.0 mg/dL
Bilirubin - unconjugated	8 mg/dL 40 mg/dL	0.6 mg/dL 2.0 mg/dL
Glucose	250 mg/dL 750 mg/dL	0.6 mg/dL 2.0 mg/dL
Hemoglobin	1000 mg/dL	0.6 mg/dL 2.0 mg/dL
Triglycerides	750 mg/dL 1500 mg/dL	0.6 mg/dL 2.0 mg/dL
Total protein	5.4 g/dL to 8.4 g/dL* 11.0 g/dL**	0.6 mg/dL 2.0 mg/dL

* Interference relative to a reference protein sample at 7.0 g/dL.
** Interference relative to a reference protein sample at 5.7 g/dL.

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

Interference beyond ± 10% [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)
Bilirubin - conjugated	40 mg/dL	0.6 mg/dL	-14% (-16%, -13%)
Bilirubin - unconjugated	10 mg/dL	0.6 mg/dL	-11% (-12%, -9%)
Glucose	1000 mg/dL	0.6 mg/dL	42% (41%, 44%)
Glucose	1000 mg/dL	2.0 mg/dL	13% (13%, 14%)
Total protein	6.8 g/dL	0.6 mg/dL	17% (15%, 18%)
Triglycerides	1000 mg/dL	0.6 mg/dL	11% (9%, 12%)
Total protein	5.0 g/dL* 9.1 g/dL* 15.3 g/dL**	0.6 mg/dL 0.6 mg/dL 2.0 mg/dL	-14% (-15%, -14%) 12% (11%, 12%) 20% (19%, 21%)

* Interference relative to a reference protein sample at 7.0 g/dL.
** Interference relative to a reference protein sample at 5.7 g/dL.

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 0.6 mg/dL and 2.0 mg/dL).

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

Potentially Interfering Substance	**Interferent Level**
Acetaminophen	160 mg/L
Acetohexamide	0.5 mg/dL
Acetylcysteine	150 mg/L
Acetylsalicylic acid	30 mg/L
Ampicillin-Na	80 mg/L
Ascorbic acid	60 mg/L
Azlocillin	7 g/L
Biotin	4250 ng/mL
Ca-dobesilate	60 mg/L
Cefotaxime	53 mg/dL
Cefoxitin	47 mg/L
Cephalothin	11 mg/dL
Cyclosporine	2 mg/L
Doxycycline	20 mg/L
Eltrombopag	10 mg/L
Hydroxocobalamin (Cyanokit)	187 mg/L

Potentially Interfering Substance	**Interferent Level**
Ibuprofen	220 mg/L
Levodopa	8 mg/L
Methyldopa	100 mg/L
Metronidazole	130 mg/L
Nitrofurantoin	0.3 mg/dL
Nitroglycerin	0.015 mg/L
Norfenefrine	4 mg/L
Phenylbutazone	330 mg/L
Rifampicin	50 mg/L
Sodium heparin	4 U/mL
Sulbactam	240 mg/L
Sulfamethoxazole	40 mg/dL
Sulfapyridine	30 mg/dL
Sulfasalazine	500 mg/L
Theophylline (1.3-dimethylxanthine)	60 mg/L
Trimethoprim	5 mg/dL

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

Interference beyond ± 10% [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)
Acetohexamide	1.5 mg/dL	0.6 mg/dL	18% (16%, 20%)
Acetohexamide	2 mg/dL	2.0 mg/dL	10% (10%, 11%)
Cefoxitin	71 mg/L	0.6 mg/dL	14% (12%, 16%)
Cefoxitin	119 mg/L	2.0 mg/dL	13% (12%, 14%)
Cephalothin	180 mg/dL	0.6 mg/dL	193% (190%, 196%)
Cephalothin	180 mg/dL	2.0 mg/dL	56% (55%, 57%)
Eltrombopag	300 mg/L	0.6 mg/dL	53% (51%, 55%)
Eltrombopag	25 mg/L	2.0 mg/dL	-12% (-12%, -11%)
Hydroxocobalamin (Cyanokit)	375 mg/L	0.6 mg/dL	16% (14%, 18%)
Hydroxocobalamin (Cyanokit)	2259 mg/L	2.0 mg/dL	19% (19%, 20%)
Methyldopa	200 mg/L	0.6 mg/dL	-17% (-18%, -15%)

Urine - Potentially Interfering Endogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed[§§] / CLSI EP37, 1st ed.[***] Each substance was tested at 2 levels of the analyte (approximately 15 mg/dL and 400 mg/dL).

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

Potentially Interfering Substance	**Interferent Level**
Acetoacetate	480 mg/dL
Ascorbate	220 mg/dL
Glucose	1000 mg/dL
Protein	50 mg/dL
Urobilinogen	40 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). *Supplemental Tables for Interference Testing in Clinical Chemistry*. 1st ed. CLSI supplement EP37. Wayne, PA: CLSI; 2018.

Urine - Potentially Interfering Exogenous Substances

A study was performed based on guidance from CLSI EP07, 3rd ed[†††] / CLSI EP37, 1st ed.[‡‡‡] Each substance was tested at 2 levels of the analyte (approximately 15 mg/dL and 400 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
Cefoxitin	100 mg/dL
Cephalothin	180 mg/dL
Homogentisic acid	3.5 g/L
Hydrochloric acid (6N)	2.5 mL/dL
Hydroxocobalamin (Cyanokit)	180 mg/L

Potentially Interfering Substance	Interferent Level
Ibuprofen	22 mg/dL
Levodopa	700 mg/L
Methyldopa	20 mg/L
Nitric acid (6N)	5.0 mL/dL
Nitrofurantoin	150 mg/L
Nitrofurazone	3 mg/L
Sodium carbonate	1.25 g/dL
Sodium fluoride	400 mg/dL
Sodium oxalate	60 mg/dL

Interference beyond ± 10% [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)
Cefoxitin	400 mg/dL	15 mg/dL	26% (24%, 27%)
Levodopa	1000 mg/dL	15 mg/dL	15% (13%, 16%)

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

[†††] 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). *Supplemental Tables for Interference Testing in Clinical Chemistry*. 1st ed. CLSI supplement EP37. Wayne, PA: CLSI; 2018.

[§§§] Young DS. *Effects of Drugs on Clinical Laboratory Tests.* 5th ed. Washington, DC: AACC Press; 2000:182-206

G. Method Comparison

A study was performed based on guidance from CLSI EP09-A3[****] using the Passing-Bablok regression method. The study compared the Creatinine2 assay to the Creatinine assay (List Number 3L81).

Creatinine2 vs Creatinine on the ARCHITECT c System						
	n	**Units**	**Correlation Coefficient**	**Intercept**	**Slope**	**Concentration Range**
Serum	128	mg/dL	1.00	-0.01	0.96	0.47 - 35.72
Urine	129	mg/dL	1.00	-1.23	1.01	6.65 - 727.61

H. Tube Type

A study was performed to evaluate the suitability of specific blood collection tube types for use with the Creatinine2 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 Creatinine2 assay:

Serum

- Serum tubes
- Serum separator tubes

Plasma

- Dipotassium EDTA tubes
- 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.

IX. Summary of Clinical Performance

This section does not apply.

X. Conclusion Drawn from Nonclinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the performance of the subject device, Creatinine2 (List No. 04S95), is substantially equivalent to the predicate device, Creatinine (List No. 3L81, k083809).

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 Creatinine2 reagent package insert instructions.