December 4, 2024

Siemens Healthcare Diagnostics Inc.
Elisha Caban
Regulatory Affairs Professional
511 Benedict Ave
Tarrytown, New York 10591

Re: K242685
Trade/Device Name: Atellica® CH Creatinine_3 (Crea3)
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: CGX
Dated: September 6, 2024
Received: September 6, 2024

Dear Elisha Caban:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Division 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242685

Device Name

Atellica® CH Creatinine_3 (Crea3)

Indications for Use *(Describe)*

The Atellica® CH Creatinine_3 (Crea3) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin, dipotassium EDTA, and sodium heparin), and urine using the Atellica® CH Analyzer. Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.

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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510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

The assigned 510(k) Number is:K242685

1. Date Prepared

November 7, 2024

2. Applicant Information

Manufacturer Name: Siemens Healthcare Diagnostics, Inc.

Contact: Elisha Caban

Regulatory Affairs Professional

Address: 511 Benedict Ave
Tarrytown, NY 10591 USA

Email: elisha.caban@Siemens-Healthineers.com

3. Regulatory Information

Information	**Atellica® CH Creatinine_3 (Crea3)**
Trade Name	Atellica® CH Creatinine_3 (Crea3)
Device	Alkaline Picrate, Colorimetry, Creatinine
Regulation Description	Creatinine test system
FDA Device Classification	Class II
Review Panel	Clinical Chemistry
Product Code	CGX
Regulation Number	21 CFR 862.1225

4. Predicate Device Information

Candidate Device	Predicate Device	Predicate 510(k) Clearance#
Atellica® CH Creatinine_3 (Crea3)	Atellica® CH Creatinine_2 (Crea_2)	K161494

5. Intended Use / Indications For Use

Product	Intended Use
Atellica® CH Creatinine_3 (Crea3)	The Atellica® CH Creatinine_3 (Crea3) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin, dipotassium EDTA, and sodium heparin), and urine using the Atellica® CH Analyzer. Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.

Special Conditions for Use Statement(s): For Prescription Use Only.

6. Device Description

Product	Device Description
Atellica® CH Creatinine_3 (Crea3)	The Atellica CH Crea3 assay is based on the reaction of picrate with creatinine in an alkaline The Atellica CH Crea3 assay reacts with picrate in an alkaline medium to produce a red chromophore creatinine picrate complex. The rate of complex formation is measured at 505/571 nm and is proportional to the creatinine concentration. The Atellica CH Crea3 assay is a modification of the Jaffe method, using rate blanking and intercept correction. Rate blanking is used to minimize bilirubin interference. Also, because non-specific serum/plasma protein interactions with this reagent have been found to produce a positive bias of approximately0.3 mg/dL (26.5 µmol/L), serum/plasma measurements are automatically corrected by subtracting 0.3 mg/dL (26.5 µmol/L) from each result.

7. Purpose of Submission

The purpose of this submission is a premarket notification for the new devices:

- Atellica® CH Creatinine_3 (Crea3) assay

8. Comparison of Candidate Device and Predicate Device

8.1 Atellica® CH Creatinine_3 (Crea3) assay

The table below describes the similarities and differences between the Atellica® CH Creatinine_3 (Crea3) assay (Candidate Device), and the Atellica® CH Creatinine_2 (Crea_2) assay (Predicate Device).

The performance and accuracy of the Candidate Device are substantially equivalent to those of the Predicate Device. The method comparison of the Candidate Device and the Predicate Device demonstrates acceptable correlation between the two methods.

Table 1: Comparison Table of Candidate Device and Predicate Device

Feature	Candidate Device	Predicate Device
	Atellica® CH Creatinine_3 (Crea3)	**Atellica® CH Creatinine_2 (Crea_2)**
Intended Use	The Atellica® CH Creatinine_3 (Crea3) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin, dipotassium EDTA, and sodium heparin), and urine using the Atellica® CH Analyzer.	The Atellica® CH Creatinine_2 (Crea_2) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin), and urine using the Atellica® CH Analyzer.
Indications for Use	Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.	Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.
Sample Type	Serum, lithium heparin plasma, dipotassium EDTA plasma, sodium heparin plasma, urine	Serum, Plasma (Lithium Heparin), urine.
Units of Measure	mg/dL	Same
Assay Range / Measuring Interval	Serum 0.15 mg/dL to 30.00 mg/dL Urine 3.00 mg/dL to 245.00 mg/dL	Same
Expected Values	Serum/plasma Adult Males: 0.70 – 1.30 mg/dL Adult Females: 0.55 – 1.02 mg/dL Urine Adult Males 950 – 2490 mg/day Adult Female 600 – 1800 mg/day	Same
Assay Principle	Enzymatic	Same
Standardization	NIST SRM 967	Same
Calibration	Single point	Same
Calibrators	Atellica® CH CHEM CAL (CHEM CAL)	Same

9. Standard/Guidance Document References

The following recognized standards from Clinical Laboratory Standards Institute (CLSI) were used as a basis of the study procedures described in this submission for both the Atellica® CH Creatinine_3 (Crea3) assay.

- Evaluation of Precision of Quantitative Measurement Procedures–Third Edition. (CLSI EP05-A3).
- Interference Testing in Clinical Chemistry, 3rd Edition (CLSI EP07-ED3).
- Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition (CLSI EP09C-ED3).
- Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition (EP17-A2).
- Evaluation of Stability of In Vitro Diagnostic Medical Laboratory Test Reagents,2nd Edition (CLSI EP25-ED2).
- Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Third Edition. (CLSI EP28-A3C).
- Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, 1st Edition (CLSI EP34-ED1).
- Evaluation of the Linearity of Quantitative Measurement Procedures, 2nd st Edition (CLSI EP06-ED2).
- EP32-R Metrological Traceability and its Implementation

10. Performance Characteristics for Atellica® CH Creatinine_3 (Crea3) Assay

10.1 Detection Capability

10.1.1 Atellica® CH Creatinine_3 (Crea3)

The Limit of Blank (LoB) corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have an LoB ≤ Limit of Detection (LoD) for serum and urine samples.

The Limit of Detection (LoD) corresponds to the lowest concentration of Creatinine that can be detected with a probability of 95%. The assay is designed to have an LoD ≤ 0.15 mg/dL for serum/plasma and ≤ 3.00 mg/dL for urine.

The Limit of Quantitation (LoQ) corresponds to the lowest concentration of Creatinine in a sample at which the within lab imprecision is ≤ 20%CV for serum and plasma. The assay is designed to have an LoQ) ≤ 0.15 mg/dL for serum/plasma with ≤ 0.10 mg/dL total analytical error and ≤ 3.00 mg/dL for urine with ≤ 1.50 mg/dL total analytical error.

Detection capability was determined in accordance with CLSI Document EP17-A2.

The following results were obtained:

Table 2: Crea3 Instructions for Use Detection Capability Claims

Specimen Type	Detection Capability	Result mg/dL
Serum/plasma	LoB	0.05
	LoD	0.10
	LoQ	0.15
Urine	LoB	0.50
	LoD	1.00
	LoQ	3.00

10.2 Precision

10.2.1 Atellica® CH Creatinine_3 (Crea3)

Precision was determined in accordance with CLSI Document EP05-A3. Samples were assayed on the Atellica® CH Analyzer in duplicate in 2 runs per day for 20 days. The following results were obtained:

Table 3: Crea3 Instructions for Use Precision Claims

Specimen Type	N[a]		Repeatability		Within-Lab	
		Mean	SD[b]	CV[c]	SD	CV
		mg/dL	mg/dL	(%)	mg/dL)	(%)
Serum 1	80	0.38	0.006	1.6	0.012	3.2
Serum 2	80	0.73	0.023	3.2	0.029	4.0
Serum 3	80	0.73	0.006	0.8	0.019	2.6
Serum 4	80	1.18	0.007	0.6	0.019	1.6
Serum QC 1	80	1.85	0.007	0.4	0.024	1.3
Serum QC 2	80	6.21	0.011	0.2	0.067	1.1
Serum 5	80	17.39	0.035	0.2	0.189	1.1
Serum 6	80	28.54	0.056	0.2	0.317	1.1
Urine 1	80	56.74	0.102	0.2	0.746	1.3
Urine 2	80	135.80	0.206	0.2	1.601	1.2
Urine QC 1	80	195.79	0.253	0.1	2.376	1.2

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

10.3 Reproducibility

10.3.1 Atellica® CH Creatinine_3 (Crea3)

Reproducibility was determined in accordance with CLSI Document EP05-A3. Samples were assayed n=5 in 1 run for 5 days using 3 instruments and 3 reagent lots. The data were analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained:

Table 4: Atellica® CH Creatinine_3 (Crea3) Instructions for Use Reproducibility Claims

		Mean		Repeatability			Between-DAY			Between-LOT			Between-SYSTEM			Reproducibility		
				SD[b]		%CV[c]	SD		%CV	SD		%CV	SD		%CV	SD		%CV
Sample	N[a]	mg/dL	µmol/L	mg/dL	µmol/L	%CV	mg/dL	µmol/L	%CV	mg/dL	µmol/L	%CV	mg/dL	µmol/L	%CV	mg/dL	µmol/L	%CV
Serum 1	225	0.40	35	0.014	1.2	3.5	0.007	0.6	1.8	0.011	1.0	2.8	0.006	0.5	1.5	0.020	1.8	5.0
Serum 2	225	0.72	64	0.015	1.3	2.1	0.021	1.9	2.9	0.007	0.6	1.0	0.014	1.2	1.9	0.030	2.7	4.2
Serum 3	225	1.21	107	0.009	0.8	0.7	0.015	1.3	1.2	0.013	1.1	1.1	0.013	1.1	1.1	0.025	2.2	2.1
Serum QC 1	225	1.90	168	0.011	1.0	0.6	0.021	1.9	1.1	0.006	0.5	0.3	0.014	1.2	0.7	0.028	2.5	1.5
Serum QC 2	225	6.31	558	0.030	2.7	0.5	0.052	4.6	0.8	0.023	2.0	0.4	0.040	3.5	0.6	0.076	6.7	1.2
Serum 4	225	17.62	1558	0.048	4.2	0.3	0.113	10.0	0.6	0.000	0.0	0.0	0.090	8.0	0.5	0.152	13.4	0.9
Serum 5	225	28.76	2542	0.105	9.3	0.4	0.192	17.0	0.7	0.079	7.0	0.3	0.153	13.5	0.5	0.278	24.6	1.0
Urine 1	225	57.23	5059	0.213	18.8	0.4	0.475	42.0	0.8	0.177	15.6	0.3	0.681	60.2	1.2	0.875	77.4	1.5
Urine 2	225	137.89	12189	0.511	45.2	0.4	0.842	74.4	0.6	0.385	34.0	0.3	1.577	139.4	1.1	1.898	167.8	1.4
Urine QC 1	225	199.45	17631	0.913	80.7	0.5	1.659	146.7	0.8	0.655	57.9	0.3	2.398	212.0	1.2	3.125	276.3	1.6

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

10.4 Assay Comparison

Atellica® CH Creatinine_3 (Crea3)

The Atellica® CH Creatinine_3 (Crea3) assay (y) was designed to have a correlation coefficient of ≥ 0.950 and a slope of 1.00 ± 0.05 for serum samples and correlation coefficient of ≥ 0.950 and a slope of 0.000 ± 3.00 for urine samples, compared to the Atellica CH Creatinine_2 (Crea_2) assay on the Atellica CH analyzer. Assay comparison was determined using the Weighted Deming regression model in accordance with CLSI Document EP09C-ED3. The following results were obtained:

Table 5: Atellica® CH Creatinine_3 (Crea3) Instructions for Use Method Comparison Claims

Specimen Type	Comparison Assay (x)	Regression Equation	Sample Range mg/dL	N[a]	r[b]
Serum	Atellica CH Creatinine_2 (Crea_2)	y = 1.00x - 0.04 mg/dL	0.44 to 28.64	151	1.000
Urine	Atellica CH Creatinine_2 (Crea_2)	y = 1.00x + 0.14 mg/dL	12.60 to 237.06	113	1.000

[a] Number of samples tested.

[b] Correlation coefficient.

10.5 Specimen Equivalence

10.5.1 Atellica® CH Creatinine_3 (Crea3)

The specimen equivalency was determined using the Weighted Deming regression model in accordance with CLSI Document EP09-A3. The following results were obtained:

Table 6: Atellica® CH Creatinine_3 (Crea3) Instructions for Use Specimen Equivalence Claims

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Range mg/dL (µmol/L)	N[a]	r[b]
Sodium Heparin	Serum	y = 1.00x + 0.00 mg/dL	0.60 to 27.26	50	0.999
		y = 1.00x + 0 µmol/L	(53) to (2410)		
Lithium Heparin	Serum	y = 0.99x + 0.06 mg/dL	0.60 to 27.26	50	0.999
		y = 0.99x + 5 µmol/L	(53) to (2410)		
Dipotassium EDTA	Serum	y = 0.98x + 0.04 mg/dL	0.60 to 27.26	50	0.998
		y = 0.98x + 4 µmol/L	(53) to (2410)		

[a] Number of samples tested.

[b] Correlation Coefficient.

10.6 Interferences

10.6.1.1 Atellica® CH Creatinine_3 (Crea3)

10.6.1.2 Hemolysis, Icterus, and Lipemia (HIL)

Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. The Atellica® CH Crea3 assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Bias > 10% or 0.15 mg/dL whichever is greater for serum/plasma is considered interference. Analyte results should not be corrected based on this bias.

Interference testing was performed in accordance with CLSI Document EP07-ED3. The following results were obtained:

Table 7: Atellica® CH Creatinine_3 (Crea3) Instructions for Use Interference HIL Claims

Substance	Substance Concentration (mg/dL)	Analyte Concentration (mg/dL)	Bias
Hemoglobin	1000	0.65	0.14 mg/dL
Hemoglobin	1000	2.05	6.3%
Conjugated Bilirubin	45	0.59	-0.14 mg/dL
Conjugated Bilirubin	40	2.03	-8.5%
Unconjugated Bilirubin	45	0.59	-0.07 mg/dL
Unconjugated Bilirubin	60	2.07	-6.8%
Lipemia (from Intralipid®)	2250	0.62	-0.06 mg/dL
Lipemia (from Intralipid®)	3000	1.92	8.3%
Lipemia (from Triglyceride Fraction)	3000	0.54	0.00 mg/dL
Lipemia (from Triglyceride Fraction)	3000	1.79	0.0%

10.6.1.3 Non-Interfering Substances

The following substances do not interfere with the Atellica® CH Creatinine_3 (Crea3) assay when present in serum, plasma and urine at the concentrations indicated in the tables below. Bias due to these substances is ≤ 10% or ±0.15 mg/dL for Serum and plasma and ≤ 10% for Urine.

Table 8: Atellica® CH Creatinine_3 (Crea3) Non-Interfering Substance for Serum

Substance	Substance Concentration	Analyte Concentration (mg/dL)	Bias (%)
Acetaminophen	160 mg/L	0.60	0.00 mg/dL
Acetaminophen	160 mg/L	2.08	-0.5%
Acetoacetate	20 mg/dL	0.63	0.01 mg/dL
Acetoacetate	20 mg/dL	2.13	-0.5%
Acetylcysteine (N-Acetylcysteine)	150 mg/L	0.60	0.00 mg/dL
Acetylcysteine (N-Acetylcysteine)	150 mg/L	2.05	0.5%
Acetylsalicylic Acid	30 mg/L	0.60	0.01 mg/dL
Acetylsalicylic Acid	30 mg/L	2.08	0.5%
Ampicillin-Na	80 mg/L	0.60	0.01 mg/dL
Ampicillin-Na	80 mg/L	2.03	-0.5%
Ascorbic Acid	60 mg/L	0.60	0.01 mg/dL
Ascorbic Acid	60 mg/L	2.08	0.0%
Azlocillin	7 g/L	0.55	0.00 mg/dL
Azlocillin	7 g/L	1.98	-1.0%
Biotin	4250 ng/mL	0.63	-0.01 mg/dL
Biotin	4250 ng/mL	2.12	-0.5%
Ca-Dobesilate	60 mg/L	0.60	0.01 mg/dL
Ca-Dobesilate	60 mg/L	2.03	-0.5%
Cefotaxime	53 mg/dL	0.63	0.01 mg/dL
Cefotaxime	53 mg/dL	2.13	0.0%
Cyclosporine	2 mg/L	0.64	0.02 mg/dL
Cyclosporine	2 mg/L	2.04	1.5%
Doxycycline	20 mg/L	0.62	-0.01 mg/dL
Doxycycline	20 mg/L	2.13	0.5%
Eltrombopag	300 mg/L	0.59	0.15 mg/dL
Eltrombopag	300 mg/L	2.08	1.4%
Ibuprofen	220 mg/L	0.64	0.00 mg/dL
Ibuprofen	220 mg/L	2.14	0.0%
Levodopa	700 mg/L	42.01	-1.4%
Levodopa	700 mg/L	186.99	-1.6%
Methyldopa	100 mg/L	0.63	0.03 mg/dL
Methyldopa	100 mg/L	2.09	-2.9%
Metronidazole	130 mg/L	0.60	0.02 mg/dL
Metronidazole	130 mg/L	2.03	1.0%
Nitrofurantoin	0.3 mg/dL	0.64	0.01 mg/dL
Nitrofurantoin	0.3 mg/dL	2.04	1.0%
Nitroglycerin	0.015 mg/L	0.65	0.01 mg/dL

Substance	Substance Concentration	Analyte Concentration (mg/dL)	Bias (%)
Nitroglycerin	0.015 mg/L	2.13	0.0%
Norfenefrine	4 mg/L	0.63	-0.02 mg/dL
Norfenefrine	4 mg/L	2.13	0.5%
Phenylbutazone	330 mg/L	0.64	0.03 mg/dL
Phenylbutazone	330 mg/L	2.14	0.0%
Rifampicin	50 mg/L	0.60	0.01 mg/dL
Rifampicin	50 mg/L	2.05	1.5%
Sodium Heparin	4 U/mL	0.65	-0.04 mg/dL
Sodium Heparin	4 U/mL	2.13	0.0%
Sulbactam	240 mg/L	0.60	0.05 mg/dL
Sulbactam	240 mg/L	2.03	1.5%
Sulfamethoxazole	40 mg/dL	0.64	0.00 mg/dL
Sulfamethoxazole	40 mg/dL	2.14	-0.5%
Sulfapyridine	30 mg/dL	0.63	-0.04 mg/dL
Sulfapyridine	30 mg/dL	2.12	0.0%
Sulfasalazine	500 mg/L	0.64	-0.07 mg/dL
Sulfasalazine	500 mg/L	2.14	-7.9%
Theophylline (1.3-dimethylxanthine)	60 mg/L	0.60	0.02 mg/dL
Theophylline (1.3-dimethylxanthine)	60 mg/L	2.03	-0.5%
Trimethoprim	5 mg/dL	0.64	0.00 mg/dL
Trimethoprim	5 mg/dL	2.14	0.0%

Interference beyond ±10% for Serum

Substance	Substance Concentration	Analyte Concentration (mg/dL)	Bias
Cefoxitin	23.5 mg/L	0.62	0.07 mg/dL
	47 mg/L	2.13	7.5%
	1650 mg/L	0.58	5.37 mg/dL
	1650 mg/L	2.11	243.6%
	6600 mg/L	0.58	20.85 mg/dL
	6600 mg/L	2.11	947.9 %
Cephalothin	135 mg/dL	0.60	0.64 mg/dL
	11 mg/dL	2.13	2.3%
	45 mg/dL	0.60	0.20 mg/dL
	45 mg/dL	2.07	11.1%
	180 mg/dL	0.60	0.87 mg/dL
	180 mg/dL	2.07	44.0 %
Glucose	250 mg/dL	0.59	0.14 mg/dL
	250 mg/dL	2.09	5.7%
	500 mg/dL	0.59	0.27 mg/dL
	500 mg/dL	2.09	11.5%
	1000 mg/dL	0.59	0.51 mg/dL
	1000 mg/dL	2.09	22.5 %
Total Protein	10 g/dL	0.68	0.13 mg/dL
	10 g/dL	2.23	2.2%
	15 g/dL	2.30	5.7%
	15 g/dL	0.65	0.45 mg/dL
Acetohexamide	1.0 mg/dL	0.59	0.11 mg/dL
	1.5 mg/dL	2.11	7.6%
	2.0 mg/dL	0.59	0.22 mg/dL
	2.0 mg/dL	2.11	10.4%
Hydroxocobalamin (Cyanokit)	250 mg/L	0.62	0.11 mg/dL
	250 mg/L	2.14	7.9%
	500 mg/L	0.62	0.22 mg/dL
	2259 mg/L	0.59	1.13 mg/dL
	500 mg/L	2.14	14.5%
	2259 mg/L	2.07	49.3%

Table 9: Atellica® CH Creatinine_3 (Crea3) Non-Interfering Substance for Urine

Substance	Substance Concentration	Analyte Concentration (mg/dL)	Bias (%)
6N HCL	0.01%	42.42	-0.4
6N HCL	0.01%	169.55	-0.1
6N Nitric Acid	0.60%	42.42	-0.5
6N Nitric Acid	0.60%	169.55	-0.1
Acetaminophen	200 mg/dL	42.48	0.0
Acetaminophen	200 mg/dL	170.03	-0.8
Acetic Acid	25 mL/24-hr collection	45.85	-0.8

Substance	Substance Concentration	Analyte Concentration (mg/dL)	Bias (%)
Acetic Acid	25 mL/24-hr collection	182.56	-0.2
Ascorbate	3.0 mg/dL	42.52	-0.4
Ascorbate	3.0 mg/dL	170.02	-1.0
Boric Acid	1% w/v	44.86	-1.5
Boric Acid	1% w/v	177.59	-1.0
Conjugated Bilirubin	50 mg/dL	42.52	-0.5
Conjugated Bilirubin	50 mg/dL	170.02	-1.1
Ethanol	1 g/dL	39.18	2.7
Ethanol	1 g/dL	160.56	-1.2
Gamma Globulin	0.5 g/dL	41.29	-0.1
Gamma Globulin	0.5 g/dL	163.63	0.2
Glucose	2000 mg/dL	42.52	0.8
Glucose	2000 mg/dL	170.02	-1.3
Hemoglobin	100 mg/dL	42.39	0.1
Hemoglobin	100 mg/dL	169.04	0.2
Human Serum Albumin	0.5 g/dL	41.29	-0.5
Human Serum Albumin	0.5 g/dL	163.63	0.2
Ibuprofen	500 mg/dL	42.44	-0.3
Ibuprofen	500 mg/dL	164.10	-0.1
Levodopa	700 mg/L	42.81	-1.4
Levodopa	700 mg/L	186.99	-1.6
N-Acetyl-Cysteine	2 mg/dL	42.42	-0.5
N-Acetyl Cysteine	2 mg/dL	169.55	0.0
Oxalic Acid	0.1 g/dL	42.52	-0.4
Oxalic Acid	0.1 g/dL	170.02	-1.3
pH 4	pH 4	43.89	-3.3
pH 4	pH 4	176.86	-0.2
pH 9	pH 9	43.89	0.0
pH 9	pH 9	176.86	-0.6
Sodium Carbonate	5 g/24-hr collection	44.44	-0.4
Sodium Carbonate	5 g/24-hr collection	177.50	0.1

Interference beyond ±10% for Urine

Substance	Substance Concentration	Analyte Concentration (mg/dL)	Bias %
Cefoxitin	3300 mg/L	42.55	7.3%
	6600 mg/L	188.03	7.7%
	4950 mg/L	42.55	11.3%
	6600 mg/L	42.55	15.4%

11. Clinical Study

11.1.1 Atellica® CH Creatinine_3 (Crea3)

Not applicable.

11.2 Expected Values

11.2.1 Atellica® CH Creatinine_3 (Crea3)

Table 10: Atellica® CH Creatinine_3 (Crea3) Instructions for Use for Expected Values

Group	Sample Type	Reference Interval
Males	Serum/Plasma	0.70 - 1.30 mg/dL (62 – 115 µmol/L)
Females	Serum/Plasma	0.55 - 1.02 mg/dL (49 – 90 µmol/L)
Males	Urine	950 – 2490 mg/day (8.4 – 22.0 mmol/day)
Females	Urine	600-1800 mg/day (5.3 – 15.9 mmol/day)

12. Standardization

12.1.1 Atellica® CH Creatinine_3 (Crea3) Atellica® CH Crea3

The assay shall be traceable to the reference material SRM967, from the National Institute of Standards and Technology (NIST).

13. Clinical Cut-off

13.1.1 Atellica® CH Creatinine_3 (Crea3)

Not applicable.

14. Conclusion

14.1 Atellica® CH Creatinine_3 (Crea3)

The results from the performance studies support that the Candidate Device**,** Atellica® CH Creatinine_3 (Crea3) assay, is substantially equivalent to the Predicate Device, Atellica CH Creatinine_2 (Crea_2) assay (K161494).