November 24, 2021

Siemens Healthcare Diagnostics Inc.
Ian Thompson
Regulatory Clinical Affairs Specialist
511 Benedict Avenue
Tarrytown, New York 10591

Re: K212223
Trade/Device Name: Atellica® CH Enzymatic Creatinine_3 (ECre3)
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: JFY
Dated: July 15, 2021
Received: July 16, 2021

Dear Ian Thompson:

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)*
K212223

Device Name
Atellica® CH Enzymatic Creatinine_3 (ECre3)

Indications for Use *(Describe)*
The Atellica® CH Enzymatic Creatinine_3 (ECre3) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin and dipotassium EDTA), 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

This 510(k) Summary 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: K212223

1. Date Prepared

July 15, 2021

2. Applicant Information

Contact:	Ian Thompson Regulatory Clinical Affairs Specialist
Address:	511 Benedict Avenue Tarrytown, NY 10591-5097
Email:	ian_thompson@siemens-healthineers.com

3. Regulatory Information

Atellica® CH Enzymatic Creatinine_3 (ECre3) assay

Trade Name:	Atellica® CH Enzymatic Creatinine_3 (ECre3)
Common Name:	Enzymatic Method, Creatinine
Classification Name:	Creatinine test system
FDA Classification:	Class II
Review Panel:	Clinical Chemistry
Product Code:	JFY
Regulation Number:	21 CFR 862.1225

4. Predicate Device Information

Predicate Device Name: ADVIA® Chemistry Enzymatic Creatinine_2 (ECRE_2)

510(k) Number: K070727

5. Intended Use / Indications For Use

The Atellica® CH Enzymatic Creatinine_3 (ECre3) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin and dipotassium EDTA), 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

The Atellica CH ECre3 assay measures the concentration of creatinine through a series of coupled enzymatic reactions and is based upon the method developed by Masaru and Mitsutaka.

The Atellica CH ECre3 assay uses a series of coupled enzymatic reactions. In a “pretreatment” reaction, endogenous creatine and sarcosine are removed from a test sample by creatinase and sarcosine oxidase. The level of creatinine in a test sample is then determined through coupled enzymatic reactions. First, creatinine is enzymatically converted by creatininase into creatine. Creatine is then enzymatically converted to sarcosine by creatinase. This is followed by the oxidation of sarcosine by sarcosine oxidase to produce hydrogen peroxide. In the presence of peroxidase, the hydrogen peroxide allows for the oxidative condensation of 4-aminoantipyrine and N-ethyl-N-(3-methylphenyl)-N’-succinyl-ethylenediamine to produce a reddish purple quinone pigment. The absorbance of this quinone pigment is measured as an endpoint reaction at 545/694 nm.545 / 694 nm.

7. Purpose of Submission

The purpose of this submission is a premarket notification for a new device:
Atellica CH Enzymatic Creatinine_3 (ECre3) assay.

8. Comparison of Candidate Device and Predicate Device

The table below describes the similarities and differences between the Atellica CH Enzymatic Creatinine_3 (ECre3) assay (Candidate Device), and the ADVIA® Chemistry Enzymatic Creatinine_2 (ECRE_2) (Predicate Device).

Substantial equivalence was demonstrated by testing several performance characteristics including measuring interval, expected values reference interval, precision, method comparison, interference, and specimen equivalence by method comparison. The performance studies gave acceptable results compared to the Predicate Device.

Feature	**Candidate Device**	**Predicate Device**
	Atellica® CH Enzymatic Creatinine_3 (ECre3)	**ADVIA Chemistry Enzymatic Creatinine_2 (ECRE_2)**
Intended Use	The Atellica CH Enzymatic Creatinine_3 (ECre3) assay is for in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin and dipotassium EDTA), and urine using the Atellica CH Analyzer.	For in vitro diagnostic use in the quantitative determination of creatinine in human serum, plasma (lithium heparin and potassium EDTA), and urine on ADVIA Chemistry systems.
Indications for Use	Such measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis.	Same
Sample Type	Serum, plasma (lithium heparin and dipotassium EDTA), urine	serum, plasma (lithium heparin, potassium EDTA), urine
Units of Measure	mg/dL	Same

Feature	Candidate Device	Predicate Device
	Atellica® CH Enzymatic Creatinine_3 (ECre3)	**ADVIA Chemistry Enzymatic Creatinine_2 (ECRE_2)**
Assay Range / Measuring Interval	Serum/Plasma: 0.15–30.00 mg/dL Urine: 2.00–245.00 mg/dL	Serum/Plasma: 0.10–30.00 mg/dL Urine: 1.00–245.00 mg/dL
Expected Values Serum/Plasma	Males: 0.73–1.18 mg/dL Females: 0.55–1.02 mg/dL	Males: 0.6–1.1 mg/dL Females: 0.5–0.8 mg/dL
Expected Values Urine	Males: 800–2000 mg/day Females: 600–1800 mg/day	Same
Assay Principle	Enzymatic (Creatininase)	Same
Standardization	NIST SRM 967	Same
Calibration	Single point	Same
Calibrators	Atellica CH Chemistry Calibrator (CHEM CAL)	ADVIA Chemistry Calibrator (K050374)

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:

- Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline–Third Edition. (CLSI EP05-A3).
- Interference Testing in Clinical Chemistry (CLSI EP07-ED3).
- Measurement Procedure Comparison and Bias Estimation Using Patient Samples (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 Reagents; Approved Guideline (CLSI EP25-A).
- Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition (CLSI EP28-A3c).
- Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking (CLSI EP34-ED1).

10. Performance Characteristics for Atellica® CH Enzymatic Creatinine_3 (ECre3) Assay

10.1 Detection Capability

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).

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 ≤ Limit of Quantitation (LoQ).

The Limit of Quantitation (LoQ) corresponds to the lowest concentration of creatinine in a sample at which the total analytical error is ≤ 0.10 mg/dL for serum and plasma and ≤ 1.50 mg/dL for urine. The assay is designed to have an LoQ ≤ 0.15 mg/dL (13 µmol/L) for serum and plasma and ≤ 2.00 mg/dL (177 µmol/L) for urine.

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

The study supports the following detection capability claims:

Specimen Type	Detection Capability	mg/dL (µmol/L)
Serum/plasma	LoB	0.05 (4)
	LoD	0.10 (9)
	LoQ	0.15 (13)
Urine	LoB	0.15 (13)
	LoD	0.50 (44)
	LoQ	2.00 (177)

10.2 Precision

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:

Specimen Type	N[a]	Mean mg/dL (µmol/L)	Repeatability		Within-Lab	
			SD[b] mg/dL (µmol/L)	CV[c] (%)	SD mg/dL (µmol/L)	CV (%)
Serum 1	80	0.41 (36)	0.009 (0.8)	2.2	0.013 (1.1)	3.2
Serum 2	80	0.75 (66)	0.008 (0.7)	1.1	0.015 (1.3)	2.0
Serum 3	80	1.29 (114)	0.010 (0.9)	0.8	0.030 (2.7)	2.3
Serum QC 1	80	1.91 (169)	0.012 (1.1)	0.6	0.024 (2.1)	1.3
Serum QC 2	80	3.11 (275)	0.009 (0.8)	0.3	0.026 (2.3)	0.8
Serum 4	80	8.89 (786)	0.021 (1.9)	0.2	0.055 (4.9)	0.6
Serum 5	80	18.52 (1637)	0.039 (3.4)	0.2	0.093 (8.2)	0.5
Serum 6	80	26.49 (2342)	0.054 (4.8)	0.2	0.121 (10.7)	0.5
Urine 1	80	42.82 (3785)	0.064 (5.7)	0.1	0.322 (28.5)	0.8
Urine QC 1	80	86.41 (7639)	0.156 (13.8)	0.2	0.497 (43.9)	0.6
Urine 2	80	185.06 (16,359)	0.320 (28.3)	0.2	0.831 (73.5)	0.4

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

10.3 Reproducibility

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:

Specimen Type	N[a]	Mean mg/dL (µmol/L)	Repeatability		Between-Day		Between-Lot		Between-Instrument		Total Reproducibility	
			SD[b] mg/dL (µmol/L)	CV[c] (%)	SD mg/dL (µmol/L)	CV (%)	SD mg/dL (µmol/L)	CV (%)	SD mg/dL (µmol/L)	CV (%)	SD mg/dL (µmol/L) CV	CV (%)
Serum 1	225	0.44 (39)	0.008 (0.8)	1.9	0.005 (0.4)	1.1	0.008 (0.7)	1.9	0.000 (0.0)	0.0	0.013(1.1)	2.9
Serum QC 1	225	0.79 (70)	0.011 (0.9)	1.3	0.004 (0.3)	0.5	0.008 (0.7)	1.0	0.000 (0.0)	0.0	0.014(1.2)	1.7
Serum 2	225	0.95 (84)	0.014 (1.2)	1.4	0.034 (3.0)	3.5	0.000 (0.0)	0.0	0.007 (0.6)	0.7	0.037 (3.3)	3.9
Serum QC 2	225	1.88 (166)	0.011 (1.0)	0.6	0.008 (0.7)	0.4	0.009 (0.8)	0.5	0.000 (0.0)	0.0	0.016 (1.4)	0.8
Serum QC 3	225	6.82 (603)	0.016 (1.4)	0.2	0.022 (1.9)	0.3	0.000 (0.0)	0.0	0.017 (1.5)	0.2	0.032 (2.8)	0.5
Serum 3	225	7.96 (703)	0.021 (1.8)	0.3	0.034 (3.0)	0.4	0.000 (0.0)	0.0	0.019 (1.7)	0.2	0.045 (3.9)	0.6
Serum 4	225	26.86 (2374)	0.051 (4.5)	0.2	0.105 (9.3)	0.4	0.039 (3.5)	0.1	0.082 (7.2)	0.3	0.148 (13.1)	0.6
Urine 1	225	42.30 (3739)	0.106 (9.3)	0.2	0.102 (9.0)	0.2	0.000 (0.0)	0.0	0.171 (15.1)	0.4	0.225 (19.9)	0.5
Urine 2	225	189.56 (16,757)	0.379 (33.5)	0.2	0.401 (35.4)	0.2	0.503 (44.5)	0.3	1.024 (90.5)	0.5	1.267 (112.0)	0.7

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

10.4 Assay Comparison

The Atellica CH ECre3 assay (y) was designed to have a correlation coefficient of ≥ 0.950 and a slope of 1.00 ± 0.05 compared to the ADVIA Chemistry ECRE_2 assay. Assay comparison for serum was determined using the Deming regression model and for urine using the Weighted Deming regression model in accordance with CLSI Document EP09c. The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	ADVIA Chemistry ECRE_2	y = 0.99x + 0.02 mg/dL (y = 0.99x + 2 µmol/L)	0.18–28.41 mg/dL (16–2511 µmol/L)	105	1.000
Urine	ADVIA Chemistry ECRE_2	y = 0.98x + 0.05 mg/dL (y = 0.98x + 4 µmol/L)	4.71–240.47 mg/dL (416–21,258 µmol/L)	102	0.999
Serum/Plasma	Isotope Dilution Mass Spectrometry (IDMS)	y = 1.01x + 0.01 mg/dL (y = 1.01x + 1 µmol/L)	0.35–26.70 mg/dL (31–2360 µmol/L)	47	0.991

[a] Number of samples tested.
[b] Correlation coefficient.

10.5 Specimen Equivalency

The specimen equivalency was determined using the Deming regression model in accordance with CLSI Document EP09c. The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Lithium heparin plasma	Serum	y = 0.99x + 0.00 mg/dL (y = 0.99x + 0 µmol/L)	0.50–26.91 mg/dL (44–2379 µmol/L)	55	1.000
Dipotassium EDTA plasma	Serum	y = 0.97x + 0.02 mg/dL (y = 0.97x + 2 µmol/L)	0.50–26.91 mg/dL (44–2379 µmol/L)	55	0.998

[a] Number of samples tested.
[b] Correlation Coefficient.

10.6 Interferences

10.6.1 Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH ECre3 assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. 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. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

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

Substance	Substance Concentration Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	Bias %
Hemoglobin	200 mg/dL (2.0 g/L)	1.00 mg/dL (88 µmol/L)	6.0
	1000 mg/dL (10.0 g/L)	8.25 mg/dL (729 µmol/L)	-3.2

Bilirubin, conjugated	25 mg/dL (427.5 µmol/L)	0.97 mg/dL (86 µmol/L)	-6.2
	25 mg/dL (427.5 µmol/L)	8.76 mg/dL (774 µmol/L)	-3.1
Bilirubin, unconjugated	25 mg/dL (427.5 µmol/L)	0.97 mg/dL (86 µmol/L)	-4.1
	25 mg/dL (427.5 µmol/L)	8.66 mg/dL (766 µmol/L)	-1.6
Lipemia (Intralipid®)	2000 mg/dL (20.0 g/L)	1.06 mg/dL (94 µmol/L)	-3.8
	2000 mg/dL (20.0 g/L)	8.06 mg/dL (713 µmol/L)	-2.6

10.6.2 Non-Interfering Substances

The following substances do not interfere with the Atellica CH ECre3 assay when present in serum, lithium heparin plasma, dipotassium EDTA plasma, and urine at the concentrations indicated in the tables below. Bias due to these substances is ≤ 10% at an analyte concentration of 1.00 mg/dL and 8.00 mg/dL for serum and 40.00 mg/dL and 180.00 mg/dL for urine.

Serum

Substance	Highest Concentration Tested with No Interference Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	%
Acetaminophen	200 µg/mL (1.3 mmol/L)	0.94 mg/dL (83 µmol/L)	1.1
	200 µg/mL (1.3 mmol/L)	8.32 mg/dL (735 µmol/L)	-0.2
Calcium dobesilate (Dexium)	0.38 mg/dL (9.1 µmol/L)	1.02 mg/dL (90 µmol/L)	-6.9
	0.38 mg/dL (9.1 µmol/L)	8.74 mg/dL (773 µmol/L)	-2.1
Cefoxitin	6600 µg/mL (15.4 mmol/L)	1.04 mg/dL (92 µmol/L)	-8.7
	6600 µg/mL (15.4 mmol/L)	7.44 mg/dL (658 µmol/L)	-1.1
Cephalexin	200 µg/mL (575.7 µmol/L)	0.92 mg/dL (81 µmol/L)	1.1
	200 µg/mL (575.7 µmol/L)	7.90 mg/dL (698 µmol/L)	-0.4
Dicynone (Etamsylate)	0.59 mg/dL (22.4 µmol/L)	1.01 mg/dL (89 µmol/L)	-8.9
	0.59 mg/dL (22.4 µmol/L)	8.64 mg/dL (764 µmol/L)	-2.1
DL-proline	11.5 mg/dL (998.9 µmol/L)	0.98 mg/dL (87 µmol/L)	3.1
	11.5 mg/dL (998.9 µmol/L)	8.49 mg/dL (751 µmol/L)	0.2
Dobutamine	5 µg/mL (16.6 µmol/L)	0.98 mg/dL (87 µmol/L)	-5.1
	5 µg/mL (16.6 µmol/L)	8.62 mg/dL (762 µmol/L)	-2.3
Dopamine	10 µg/mL (65.3 µmol/L)	1.02 mg/dL (90 µmol/L)	-6.9
	10 µg/mL (65.3 µmol/L)	8.74 mg/dL (773 µmol/L)	-2.1
Ethylglycine (N-ethylglycine)	6 µg/mL (58.2 µmol/L)	1.01 mg/dL (89 µmol/L)	0.0
	6 µg/mL (58.2 µmol/L)	8.66 mg/dL (766 µmol/L)	-0.2
Fluorocytosine	200 µg/mL (1549 µmol/L)	1.07 mg/dL (95 µmol/L)	-0.9
	200 µg/mL (1549 µmol/L)	7.94 mg/dL (702 µmol/L)	-0.1
Levodopa (L-dopa)	15 µg/mL (76.1 µmol/L)	1.03 mg/dL (91 µmol/L)	-4.9
	15 µg/mL (76.1 µmol/L)	8.63 mg/dL (763 µmol/L)	-2.3
Metamizole (Sulpyrine)	25 mg/L (750 µmol/L)	0.97 mg/dL (86 µmol/L)	-5.2
	25 mg/L (750 µmol/L)	8.37 mg/dL (740 µmol/L)	-4.2

Serum

Substance	Highest Concentration Tested with No Interference Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	%
Methyl dopa	11.3 µg/mL (53.5 µmol/L)	1.02 mg/dL (90 µmol/L)	-8.8
	11.3 µg/mL (53.5 µmol/L)	7.47 mg/dL (660 µmol/L)	-4.3
N-acetyl-p-benzoquinine imine (NAPQI)	0.4 mg/L (26.8 µmol/L)	1.02 mg/dL (90 µmol/L)	-2.9
	0.4 mg/L (26.8 µmol/L)	8.72 mg/dL (771 µmol/L)	-0.3
N-Acetyl Cysteine (NAC)	37.5 mg/dL (2.3 mmol/L)	0.98 mg/dL (87 µmol/L)	-7.1
	37.5 mg/dL (2.3 mmol/L)	8.36 mg/dL (739 µmol/L)	-0.7
Phenindione[a]	5 mg/dL (225 µmol/L)	0.97 mg/dL (86 µmol/L)	-5.2
	5 mg/dL (225 µmol/L)	7.76 mg/dL (686 µmol/L)	-4.3
Phenylbutazone	321 µg/mL (1040.9 µmol/L)	0.99 mg/dL (88 µmol/L)	-3.0
	321 µg/mL (1040.9 µmol/L)	8.43 mg/dL (745 µmol/L)	-1.5
Rifampicin	2.4 mg/dL (29.2 µmol/L)	1.02 mg/dL (90 µmol/L)	-2.0
	2.4 mg/dL (29.2 µmol/L)	8.57 mg/dL (758 µmol/L)	-0.6
Salicylate	200 µg/mL (1448 µmol/L)	0.99 mg/dL (88 µmol/L)	1.0
	200 µg/mL (1448 µmol/L)	8.41 mg/dL (743 µmol/L)	-0.2

[a] Use of this assay is not recommended for patients being treated with phenindione due to the reported falsely depressed results from phenindione metabolites. Sankaralingam A, Karim Y, Swaminathan R. Phenindione interferes with measurement of creatinine. Clin Biochem. 2013;46(18):1912–1913.

Urine

Substance	Highest Concentration Tested with No Interference Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	%
6N HCl	0.01%	41.72 mg/dL (3688 µmol/L)	0.3
	0.01%	188.42 mg/dL (16,656 µmol/L)	-0.6
pH 4	4.0 pH	42.73 mg/dL (3777 µmol/L)	-3.9
	4.0 pH	191.39 mg/dL (16,919 µmol/L)	-2.3
pH 9	9.0 pH	42.73 mg/dL (3777 µmol/L)	-5.4
	9.0 pH	190.45 mg/dL (16,836 µmol/L)	-3.8
Acetaminophen	200 mg/dL (13.2 mmol/L)	40.36 mg/dL (3568 µmol/L)	1.2
	200 mg/dL (13.2 mmol/L)	183.14 mg/dL (16,190 µmol/L)	2.5
Acetic Acid	25 mL/24 hr collection	41.92 mg/dL (3706 µmol/L)	-0.6
	25 mL/24 hr collection	187.47 mg/dL (16,572 µmol/L)	-0.6
Albumin	0.5 g/dL (5 g/L)	42.50 mg/dL (3757 µmol/L)	-0.5
	0.5 g/dL (5 g/L)	192.04 mg/dL (16,976 µmol/L)	0.4
Ascorbate	3 mg/dL (199.9 µmol/L)	41.94 mg/dL (3707 µmol/L)	0.0
	3 mg/dL (199.9 µmol/L)	190.30 mg/dL (16,823 µmol/L)	-0.4
Boric acid	1% w/v	42.69 mg/dL (3774 µmol/L)	-0.4
	1% w/v	190.59 mg/dL (16,848 µmol/L)	-0.6
Conjugated bilirubin	50 mg/dL (855 µmol/L)	37.01 mg/dL (3272 µmol/L)	-0.9
	50 mg/dL (855 µmol/L)	168.09 mg/dL (14,859 µmol/L)	-0.5
Ethanol	1 g/dL (216.9 mmol/L)	41.43 mg/dL (3662 µmol/L)	0.2
	1 g/dL (216.9 mmol/L)	187.49 mg/dL (16,574 µmol/L)	-0.3
Gamma Globulin	0.5 g/dL (5 g/L)	42.71 mg/dL (3776 µmol/L)	-0.5
	0.5 g/dL (5 g/L)	192.42 mg/dL (17,010 µmol/L)	-0.5
Glucose	2000 mg/L (111.1 mmol/L)	40.31 mg/dL (3563 µmol/L)	0.6

	2000 mg/L (111.1 mmol/L)	181.95 mg/dL (16,084 µmol/L)	0.7
Hemoglobin	100 mg/L (0.1 g/L)	40.34 mg/dL (3566 µmol/L)	-0.3
	100 mg/L (0.1 g/L)	178.21 mg/dL (15,754 µmol/L)	0.6
Ibuprofen	500 mg/dL (24.3 mmol/L)	40.34 mg/dL (3566 µmol/L)	0.7
	500 mg/dL (24.3 mmol/L)	183.38 mg/dL (16,211 µmol/L)	0.4
N-Acetylcysteine	2 mg/dL (122.6 µmol/L)	40.06 mg/dL (3541 µmol/L)	-0.1
	2 mg/dL (122.6 µmol/L)	180.00 mg/dL (15,912 µmol/L)	0.1
Nitric Acid	0.6%	42.49 mg/dL (3756 µmol/L)	-0.2
	0.6%	187.60 mg/dL (16,584 µmol/L)	0.3
Oxalic acid	0.1 g/dL (11.1 mmol/L)	40.31 mg/dL (3563 µmol/L)	-0.3
	0.1 g/dL (11.1 mmol/L)	182.59 mg/dL (16,141 µmol/L)	-0.3
Sodium carbonate	5 g/24 hr collection	40.15 mg/dL (3549 µmol/L)	-0.6
	5 g/24 hr collection	180.93 mg/dL (15,994 µmol/L)	-0.2

11. Clinical Study

Not applicable.

11.1 Expected Values

Siemens Healthineers has verified the reference interval for serum, plasma and urine for the Atellica CH ECre3 assay, in accordance with CLSI Document EP28-A3c.

Group Specimen Type	Reference Interval	Conventional Units (SI Units)
Males[a]	Serum/plasma	0.73–1.18 mg/dL (65–104 µmol/L)
Females[a]	Serum/plasma	0.55–1.02 mg/dL (49–90 µmol/L)
Males	Urine[b]	800–2000 mg/day
Females	Urine[b]	600–1800 mg/day

[a] These data were verified on the Atellica CH Analyzer.

[b] Wu, AHB. Tietz Clinical Guide to Laboratory Tests. 4th ed. Philadelphia, PA: WB Saunders Company; 2006:316.

12. Linearity

Linearity testing was performed in accordance with CLSI Document EP06-A.

The assay is linear for the measuring interval from 0.15–30.00 mg/dL (13–2652 µmol/L) for Serum/plasma and from 2.00–245.00 mg/dL (177–21,658 µmol/L) for Urine.

13. Standardization

The assay is traceable to the National Institute of Standards and Technology (NIST) Standard Reference Material SRM967.

Assigned values for calibrators are traceable to this standardization.

14. Clinical Cut-off

Not applicable.

15. Conclusion

The results from the performance studies support that the Candidate Device**,** Atellica CH Enzymatic Creatinine_3 (ECre3) assay, is substantially equivalent to the Predicate Device, ADVIA Chemistry Enzymatic Creatinine_2 (ECRE_2) assay (K070727).