Siemens Healthcare Diagnostics Inc.
Joy Anoop
Clinical Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, NY 10591

Re: K222439
Trade/Device Name: Atellica® CH Vancomycin (Vanc), Atellica® CH Phencyclidine (Pcp)
Regulation Number: 21 CFR 862.3950
Regulation Name: Vancomycin Test System
Regulatory Class: Class II
Product Code: LEH, LCM
Dated: January 16, 2023
Received: January 17, 2023

Dear Joy Anoop:

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,

Joseph A. Kotarek -S

Digitally signed by Joseph A. Kotarek -S
Date: 2023.08.08 17:50:18 -04'00'

Joseph Kotarek, Ph.D.
Branch Chief
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222439

Device Name
Atellica® CH Phencyclidine (Pcp)
Atellica® CH Vancomycin (Vanc)

Indications for Use *(Describe)*
The Atellica® CH Phencyclidine (Pcp) assay is for in vitro diagnostic use in the qualitative or semiquantitative analyses of phencyclidine in human urine using the Atellica® CI Analyzer, using a cutoff of 25 ng/mL. The Pcp assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass spectrometry (GC-MS) or liquid chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.
Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

The Atellica® CH Vancomycin (Vanc) assay is for in vitro diagnostic use in the quantitative measurement of vancomycin in human serum and plasma (lithium heparin) using the Atellica® CI Analyzer. Vanc test results may be used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.

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

The assigned 510(k) Number: K222439

1. APPLICANT

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue,
Tarrytown, NY 10591 USA

Contact: Anoop Joy
Clinical Regulatory Affairs Specialist
Phone: (516) 232-3307
E-mail: anoop.joy@siemens-healthineers.com

Date Prepared: March 28, 2023

2. Regulatory Information

Assay: Atellica CH Phencyclidine (Pcp)

Classification Name: Enzyme Immunoassay, Phencyclidine
Regulation Section: unclassified
Trade Name: Atellica® CH Phencyclidine (Pcp)
Classification: Unclassified, 510(k) required
Product Code: LCM
Panel: Toxicology

Assay: Atellica CH Vancomycin (Vanc)

Classification Name: Vancomycin test system
Regulation Section: 21 CFR 862.3950
Trade Name: Atellica® CH Vancomycin (Vanc)
Classification: Class II
Product Code: LEH
Panel: Toxicology

3. PREDICATE DEVICE INFORMATION

Predicate Device	Candidate Device	510(k) #	Class	Code
Atellica CH Phencyclidine (Pcp)	Atellica CH Phencyclidine (Pcp)	K163220	unclassified	LCM
Trinidad CH Vancomycin (Vanc)	Atellica CH Vancomycin (Vanc)	K160202	Class II	LEH

4. DEVICE DESCRIPTION

4.1. Atellica CH Pcp

The Atellica CH Pcp assay is a homogenous enzyme immunoassay based on competition between drug in the specimen and drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. G6PDH activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD+) to NADH in the presence of glucose-6-phosphate (G6P), resulting in an absorbance change that is measured spectrophotometrically at 340/410 nm. Endogenous G6PDH does not interfere because the coenzyme NAD+ functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.

4.2. Atellica CH Vanc

The Atellica CH Vanc assay is based on a homogeneous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique which uses a synthetic particle-vancomycin conjugate (PR) and monoclonal vancomycin specific antibody (Ab). Vancomycin present in the sample competes with vancomycin on the particles for available antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of vancomycin in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 545 and 694 nm.

5. INTENDED USE

5.1 Atellica CH Pcp

The Atellica® CH Phencyclidine (Pcp) assay is for in vitro diagnostic use in the qualitative or semiquantitative analyses of phencyclidine in human urine using the Atellica® CI Analyzer, using a cutoff of 25 ng/mL. The Pcp assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. The semi-quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass spectrometry (GC-MS) or liquid chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

5.2 Atellica CH Vanc

The Atellica® CH Vancomycin (Vanc) assay is for in vitro diagnostic use in the quantitative measurement of vancomycin in human serum and plasma (lithium heparin) using the Atellica® CI Analyzer. Vanc test results may be used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.

6. INDICATIONS FOR USE

Same as Intended use

7. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table provides a comparison between the predicate and candidate device.

7.1. Atellica CH Pcp

Below is a features comparison for the Atellica CH Pcp assay on the Atellica CI Analyzer and the predicate device Atellica IM Analyzer

Feature	**Predicate Device:** Atellica CH Phencyclidine (Pcp) on Atellica CH Analyzer	**New Device:** Atellica CH Phencyclidine (Pcp) on Atellica CI Analyzer
Intended Use :	The Atellica CH Phencyclidine (Pcp) assay is for *in vitro* diagnostic use in the qualitative or semiquantitative analyses of phencyclidine in human urine using the Atellica CH Analyzer, using a cutoff of 25 ng/mL. The Pcp assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. The semi-	The Atellica CH Phencyclidine (Pcp) assay is for *in vitro* diagnostic use in the qualitative or semiquantitative analyses of phencyclidine in human urine using the Atellica CI Analyzer, using a cutoff of 25 ng/mL. The Pcp assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. The semi-

	quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass-spectrometry (GC-MS) or liquid chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures. Clinical consideration and professional judgment should be applied to any drug-of- abuse test result, particularly when preliminary positive results are used.	quantitative mode is for purposes of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass spectrometry (GC-MS) or liquid chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used
Type of Product:	Analytical Reagents	Same
Measured Analyte:	Pcp	Same
Test Matrix:	Urine	Same
Device Technology:	Enzyme Immunoassay	Same
Materials:	Matched lots of polyclonal antibody reactive to phencyclidine and phencyclidine labeled with glucose-6-phosphate dehydrogenase are used in this Syva® Emit® II Plus methodology.	Same

Cutoff Levels:	25 ng/mL PCP	Same
Confirmatory Method:	Gas Chromatography/mass spectrometry	Same
Calibration Frequency:	60 days	130 days

7.2. Atellica CH Vanc

Below is a features comparison for the Atellica CH Vanc assay on the Atellica CI Analyzer and the predicate device Atellica IM Analyzer

Feature	**Predicate Device:** Trinidad CH Vancomycin (Vanc) on Trinidad CH System	**New Device:** Atellica CH Vancomycin (Vanc) on Atellica CI Analyzer
Intended Use :	The Trinidad CH Vancomycin (Vanc) assay is for *in vitro* diagnostic use in the quantitative measurement of vancomycin in human serum and plasma (lithium heparin) using the Trinidad CH System.	The Atellica CH Vancomycin (Vanc) assay is for *in vitro* diagnostic use in the quantitative measurement of vancomycin in human serum and plasma (lithium heparin) using the Atellica CI Analyzer.
Indications for Use:	Vanc test results may be used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.	Same
Device Technology:	Homogeneous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique	Same

Sample Type:	Serum/ Lithium Heparin plasma	Same
Therapeutic Interval:	Peak Intervals: Samples from adult volunteers drawn two hours after the completion of a 60-minute infusion of vancomycin ranged from 18 – 26 µg/mL. Samples drawn one hour after the completion of a 60 minute vancomycin infusion ranged from 25 – 40 µg/mL. Samples drawn 30 minutes after the completion of a 60 minute infusion of vancomycin ranged from 30 – 40 µg/mL. Trough Intervals: Samples should be drawn just before the next dose. A trough interval of 5 – 10 µg/mL is generally considered to be effective.	Same
Standardization:	Traceable to United States Pharmacopeia (USP) standards.	Same
Calibration Frequency:	30 days	Same
Analytical Measuring Interval:	3.0 – 50.0 µg/mL	Same

Interferences:	Bilirubin (Conjugated & Unconjugated) – 20 mg/dL Lipemia (Intralipid®) – 1000 mg/dL Hemoglobin – 600 mg/dL	Bilirubin (Conjugated & Unconjugated) – 30 mg/dL Lipemia (Intralipid®) – 2000 mg/dL Hemoglobin – 1000 mg/dL
Calibrators:	Atellica CH Drug CAL II	Same

8. PERFORMANCE CHARACTERISTICS DATA

8.1. Atellica CH Pcp

Assay Comparison

Qualitative and Semiquantitative Results

A total of one-hundred fifty-seven (157) phencyclidine samples were analyzed using the Atellica CH Pcp assay and the reference method GC/MS. All assays used a 25 ng/mL cutoff. Thirty-four (34) samples were within ± 50% of the cutoff by GC/MS. The agreement of the assay may vary depending on the study design, comparative assay, and sample population.

Qualitative and Semiquantitative Accuracy Summary of Atellica CH Pcp Assay versus GC/MS

		GC/MS Results				
		LOW NEG < 50% below the cutoff (< 13 ng/mL)	NEG Within 50% below the cutoff (13–24 ng/mL)	POS Within 50% above the cutoff (25–38 ng/mL)	HIGH POS > 50% above the cutoff (> 38 ng/mL)	% Agreement
Qualitative Summary						
Atellica CH	POS	0	3	19	81	95
	NEG	42	7	5	0	94
Semiquantitative Summary						
Atellica CH	POS	0	3	19	81	95
	NEG	42	7	5	0	94

Discordant Result Summary between Atellica CH Pcp Assay and GC/MS

Sample #	Atellica CI Pcp (ng/mL)	GC/MS Phencyclidine (ng/mL)	Atellica CI Pcp vs GC/MS (POS/NEG)
47	27	18.0	+/-
51	30	24.2	+/-
52	26	24.8	+/-
53	21	25.8	-/+
54	20	26.7	-/+
56	22	27.6	-/+
57	24	27.8	-/+
58	24	28.5	-/+

Precision

Precision was determined in accordance with CLSI Document EP05-A3. Repeatability and within-lab precision were determined by assaying negative urine pools spiked with phencyclidine at nine different levels. The assay is designed to classify the levels as positive or negative relative to the cutoff for the spiked sample pools. Samples were assayed on an Atellica CI Analyzer in duplicate in 2 runs per day for 20 days (n = 80 for each sample). The results in the qualitative mode and semi-quantitative mode are identical. The results are summarized below.

Precision Qualitative and Semi-Quantitative Analysis							
Urine Pool (ng/mL)	% of Cutoff	# of Results	Mean (ng/mL)	Repeatability		Within-Lab	
				SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)
0	-100	80	0	0.1	N/A	0.20	N/A
6.25	-75	80	6	0.4	6.7	0.6	10.0
12.5	-50	80	12	0.4	3.3	0.6	5.0
18.75	-25	80	18	0.4	2.2	0.8	4.4
25	Cutoff	80	25	0.6	2.4	1.1	4.4
31.25	25	80	32	0.9	2.8	1.7	5.3
37.5	50	80	39	0.9	2.3	2.3	5.9
43.75	75	80	43	1.1	2.6	2.5	5.8
50	100	80	52	1.7	3.3	3.7	7.1

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:

			Repeatability		Between-Day		Between-Instrument		Between-Lot		Total Reproducibility	
Sample	N[a]	Mean (ng/mL)	SD[b] (ng/mL)	CV[c] (%)	SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)	SD (ng/mL)	CV (%)
Urine QC 1	225	18	0.5	2.8	0.6	3.3	0.3	1.7	0.7	3.9	1.1	6.1
Urine QC 2	225	24	0.5	2.1	0.9	3.8	0.7	2.9	0.6	2.5	1.4	5.8
Urine QC 3	225	34	0.8	2.4	1.5	4.4	1.2	3.5	0.8	2.4	2.2	6.5

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

Recovery

Recovery of Pcp samples were prepared by spiking known amounts of phencyclidine into negative urine pools. Each spiked sample was analyzed using the Atellica CH Pcp assay. Results of recovery are shown below.

Target Concentration (ng/mL)	Mean Measured Concentration (ng/mL)	Mean Recovery %
0	0	N/A
4	4	101
5	5	100
10	9	90
15	15	100
20	19	95
25	24	96
30	30	100
40	43	107
60	64	107
80	82	103

Endogenous Substances

The protocol used follows the CLSI Document, EP07. The endogenous substances were evaluated qualitatively at the concentrations listed below. The substances were spiked into two levels of controls at ±25% (19 ng/mL and 31 ng/mL) of the cutoff concentration. At the stated concentration, the sample did not give a false response relative to the 25 ng/mL cutoff.

Compound	Concentration Tested	-25% Cutoff Pool Result (19 ng/mL)	+25% Cutoff Pool Result (31 ng/mL)
Acetone	1.0 g/dL	Negative	Positive
Ascorbic Acid	0.75 g/dL	Negative	Positive
Conjugated bilirubin	0.25 mg/dL	Negative	Positive
Creatinine	0.5 g/dL	Negative	Positive
Ethanol	1.0 g/dL	Negative	Positive
Gamma Globulin	0.5 g/dL	Negative	Positive
Galactose	0.01 g/dL	Negative	Positive
Glucose	2.0 g/dL	Negative	Positive
Hemoglobin	115 mg/dL	Negative	Positive
Human Serum Albumin	0.5 g/dL	Negative	Positive
Oxalic Acid	0.1 g/dL	Negative	Positive
Riboflavin	7.5 mg/dL	Negative	Positive

Sodium Azide	1% (w/v)	Negative	Positive
Sodium Chloride	1.5 g/dL	Negative	Positive
Sodium Fluoride	1% (w/v)	Negative	Positive
Urea	6.0 g/dL	Negative	Positive

Specificity

Interference was determined in accordance with CLSI Document EP07. The interference of structurally unrelated compounds and common over the counter drugs was evaluated qualitatively at the concentrations listed below. The compounds were spiked into two levels of controls at ±25% (19 ng/mL and 31 ng/mL) of the cutoff concentration. At the stated concentration, the sample did not give a false response relative to the 25 ng/mL cutoff.

Structurally Unrelated Compounds

Compound	Concentration Tested	-25% Cutoff Pool Result (19 ng/mL)	+25% Cutoff Pool Result (31 ng/mL)
Acetaminophen	500,000 ng/mL	Negative	Positive
l-α-Acetylmethadol (LAAM)	25,000 ng/mL	Negative	Positive
N-Acetyl procainamide (NAPA)	100,000 ng/mL	Negative	Positive
Acetylsalicylic Acid	500,000 ng/mL	Negative	Positive
Amitriptyline	8,750 ng/mL	Negative	Positive
S-(+)-Amphetamine	100,000 ng/mL	Negative	Positive
Benzoylecgonine	100,000 ng/mL	Negative	Positive
Boric Acid	1% (w/v)	Negative	Positive
Buprenorphine	100,000 ng/mL	Negative	Positive
Caffeine	500,000 ng/mL	Negative	Positive
Cannabinol	100,000 ng/mL	Negative	Positive
Carbamazepine	100,000 ng/mL	Negative	Positive
Chlordiazepoxide	100,000 ng/mL	Negative	Positive
Cimetidine	100,000 ng/mL	Negative	Positive
Clonidine	100,000 ng/mL	Negative	Positive
Codeine	25,000 ng/mL	Negative	Positive
Cotinine	100,000 ng/mL	Negative	Positive
Desipramine	75,000 ng/mL	Negative	Positive
Dextrorphan	781 ng/mL	Negative	Positive
Diazepam	100,000 ng/mL	Negative	Positive
Digoxin	100,000 ng/mL	Negative	Positive
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	12,500 ng/mL	Negative	Positive
EMDP	100,000 ng/mL	Negative	Positive
1R,2S-Ephedrine	100,000 ng/mL	Negative	Positive

Compound	Concentration Tested	-25% Cutoff Pool Result (19 ng/mL)	+25% Cutoff Pool Result (31 ng/mL)
1S,2R-Ephedrine	100,000 ng/mL	Negative	Positive
Fluoxetine	75,000 ng/mL	Negative	Positive
Flurazepam	50,000 ng/mL	Negative	Positive
Glutethimide	100,000 ng/mL	Negative	Positive
Haloperidol	100,000 ng/mL	Negative	Positive
Heroin	25,000 ng/mL	Negative	Positive
Hydrocodone	25,000 ng/mL	Negative	Positive
Ibuprofen	500,000 ng/mL	Negative	Positive
Ketamine	75,000 ng/mL	Negative	Positive
Ketorolac Tromethamine	100,000 ng/mL	Negative	Positive
Lidocaine	100,000 ng/mL	Negative	Positive
Lorazepam	100,000 ng/mL	Negative	Positive
Lormetazepam	100,000 ng/mL	Negative	Positive
LSD	100,000 ng/mL	Negative	Positive
MDMA	100,000 ng/mL	Negative	Positive
Meperidine	1,563 ng/mL	Negative	Positive
Methadone	50,000 ng/mL	Negative	Positive
S(+) - Methamphetamine	100,000 ng/mL	Negative	Positive
Methaqualone	100,000 ng/mL	Negative	Positive
Morphine	75,000 ng/mL	Negative	Positive
Naproxen	100,000 ng/mL	Negative	Positive
Nordiazepam	100,000 ng/mL	Negative	Positive
Nortriptyline	75,000 ng/mL	Negative	Positive
Oxazepam	100,000 ng/mL	Negative	Positive
Oxycodone	100,000 ng/mL	Negative	Positive
Phenobarbital	100,000 ng/mL	Negative	Positive
Phenylephrine	100,000 ng/mL	Negative	Positive
Phenytoin	100,000 ng/mL	Negative	Positive
Promethazine	3,125 ng/mL	Negative	Positive
Propoxyphene	100,000 ng/mL	Negative	Positive
Propranolol	100,000 ng/mL	Negative	Positive
Protriptyline	75,000 ng/mL	Negative	Positive
R,R - Pseudoephedrine	100,000 ng/mL	Negative	Positive
S,S - Pseudoephedrine	100,000 ng/mL	Negative	Positive
Ranitidine	100,000 ng/mL	Negative	Positive
Ritalinic Acid	100,000 ng/mL	Negative	Positive
Salicylic Acid	100,000 ng/mL	Negative	Positive

Compound	Concentration Tested	-25% Cutoff Pool Result (19 ng/mL)	+25% Cutoff Pool Result (31 ng/mL)
Scopolamine	100,000 ng/mL	Negative	Positive
Secobarbital	100,000 ng/mL	Negative	Positive
Tapentadol	50,000 ng/mL	Negative	Positive
11-nor-Δ9-THC-9-COOH	100,000 ng/mL	Negative	Positive
Tramadol	50,000 ng/mL	Negative	Positive
Trazodone	100,000 ng/mL	Negative	Positive
Tyramine	100,000 ng/mL	Negative	Positive
Verapamil	60,000 ng/mL	Negative	Positive
Zidovudine (AZT)	100,000 ng/mL	Negative	Positive
Zolpidem	100,000 ng/mL	Negative	Positive

Structurally Related Compounds

Compound	Concentration Tested (ng/mL)	Mean Observed Pcp Response (ng/mL)	Cross-Reactivity %
Chloropromazine	100,000	24.0	0.0
Clomipramine	100,000	20.8	0.0
Cyclobenzaprine	25,000	7.0	0.0
Dextromethorphan	80,000	22.6	0.0
Diphenhydramine	100,000	10.8	0.0
Doxepin	90,000	13.2	0.0
Imipramine	100,000	16.2	0.0
Methoxetamine	36,000	14.0	0.0
4-Methoxyphencyclidine	700	59.4	8.5
Thioridazine	100,000	48.4	0.0
Venlafaxine	100,000	7.2	0.0
PCP	25	24.2	96.8
1-(4-Hydroxypiperidino)phenylcyclohexane	419	26.0	6.2
1-(1-Phenylcyclohexyl)pyrrolidine (PCPy) (Rolicyclidine)	54	83.4	154.4
1-[1-(2-Thienyl)-cyclohexyl]piperidine (TCP) (Tenocyclidine)	37	7.0	18.9
trans-4-phenyl-4-Piperidinocyclohexanol	32	59.0	184.4

Specific Gravity and pH

Negative urine pools with specific gravity values ranging from 1.000–1.030 and pH values ranging from 3–10 were tested in the presence of two levels of controls at ±25% of the cutoff concentration (19 ng/mL and 31 ng/mL). No interference was observed.

Standardization

The Atellica CH Pcp assay is traceable to the Emit Calibrators/Controls which are referenced to gravimetrically prepared standards. These standards are qualified by GC/MS from an independent laboratory and must quantitate within ±10% of nominal.

8.2. Atellica CH Vanc

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2. The assay is designed to have a limit of blank (LoB) < LoD, a limit of detection (LoD) ≤ 1.0 µg/mL, and a limit of quantitation (LoQ) ≤ 3.0 µg/mL . Assay results obtained at individual laboratories may vary from the data presented.

The LoD corresponds to the lowest concentration of vancomycin that can be detected with a probability of 95%. The LoD for the Atellica CH Vanc assay is 1.0 µg/mL (0.7 µmol/L), and was determined using 450 determinations, with 225 blank and 225 low level replicates, and a LoB of 0.6 µg/mL (0.4 µmol/L). Assay results obtained at individual laboratories may vary from the data presented.

The LoQ corresponds to the lowest amount of analyte in a sample that can be accurately quantitated with a total allowable error ≤ 20%. The LoQ of the Vanc assay is 3.0 µg/mL (2.1 µmol/L), and was determined using n=5 replicates per sample that were assayed using 3 reagent lots, over a period of 3 days, using total analytical error definition of bias + 2SD.

Precision

Precision was determined in accordance with CLSI Document EP05-A3. Samples were assayed on an Atellica CI Analyzer in duplicate in 2 runs per day for at least 20 days (N ≥ 80 for each sample). The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Sample Type	N	Mean µg/mL (µmol/L)	SD[a] µg/mL (µmol/L)	CV[b] (%)	SD[a] µg/mL (µmol/L)	CV[b] (%)
Serum QC 1	80	6.1 (4.2)	0.14 (0.10)	2.3	0.17 (0.12)	2.8
Serum 1	80	13.4 (9.2)	0.13 (0.09)	1.0	0.20 (0.14)	1.5
Serum QC 2	80	19.5 (13.5)	0.15 (0.10)	0.8	0.33 (0.23)	1.7
Serum QC 3	80	32.6 (22.5)	0.34 (0.23)	1.0	0.61 (0.42)	1.9
Serum 2	80	46.1 (31.8)	0.54 (0.37)	1.2	0.89 (0.61)	1.9

[a] Standard deviation.
[b] Coefficient of variation.

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:

			Repeatability		Between-Day		Between-Instrument		Between-Lot		Total Reproducibility	
Sample	N[a]	Mean µg/mL (µmol/L)	SD[b] µg/mL (µmol/L)	CV[c] (%)	SD µg/mL (µmol/L)	CV (%)	SD µg/mL (µmol/L)	CV (%)	SD µg/mL (µmol/L)	CV (%)	SD µg/mL (µmol/L)	CV (%)
Serum QC 1	225	6.0 (4.1)	0.11 (0.1)	1.8	0.18 (0.1)	3.0	0.09 (0.1)	1.5	0.07 (0.0)	1.2	0.24 (0.2)	4.0
Serum 1	225	13.4 (9.2)	0.12 (0.1)	0.9	0.14 (0.1)	1.0	0.03 (0.0)	0.2	0.19 (0.1)	1.4	0.27 (0.2)	2.0
Serum QC 2	225	19.7 (13.6)	0.16 (0.1)	0.8	0.29 (0.2)	1.5	0.10 (0.1)	0.5	0.15 (0.1)	0.8	0.38 (0.3)	1.9
Serum QC 3	225	32.9 (22.7)	0.22 (0.2)	0.7	0.49 (0.3)	1.5	0.29 (0.2)	0.9	0.09 (0.1)	0.3	0.62 (0.4)	1.9
Serum 2	225	45.9 (31.7)	0.36 (0.2)	0.8	0.50 (0.3)	1.1	0.48 (0.3)	1.0	0.25 (0.2)	0.5	0.81 (0.6)	1.8

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

Assay Comparison

The Atellica CH Vanc assay is designed to have a correlation coefficient of ≥ 0.980 and a slope of 1.00 ± 0.10 compared to Atellica CH Vanc on Atellica CH Analyzer. Assay comparison was determined using the 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	Atellica CH Vanc on Atellica CH Analyzer	y = 0.97x + 0.3 µg/mL (y = 0.97x + 0.2 µmol/L)	4.1–45.9 µg/mL (2.8–38.6 µmol/L)	107	0.999

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

Specimen Equivalency

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]
Plasma (Lithium Heparin)	Serum	y = 1.00x - 0.1 µg/mL (y = 1.00x - 0.7 µmol/L)	4.5–43.9 µg/mL (3.1–30.3 µmol/L)	50	0.996

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

Interferences

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH Vanc assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07 using the Atellica CH Vanc assay. 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.

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration µg/mL (µmol/L)	Percent Bias[a]
Hemoglobin	1000 mg/dL (10.0 g/L)	9.4 (6.5)	2
	1000 mg/dL (10.0 g/L)	38.1 (26.3)	6
Bilirubin, conjugated	30 mg/dL (513 µmol/L)	9.2 (6.3)	0
	30 mg/dL (513 µmol/L)	37.1 (25.6)	1
Bilirubin, unconjugated	30 mg/dL (513 µmol/L)	9.5 (6.6)	-2
	30 mg/dL (513 µmol/L)	39.1 (27.0)	-1
Lipemia (Intralipid®)	2000 mg/dL (20.0 g/L)	9.7 (6.7)	8
	2000 mg/dL (20.0 g/L)	37.1 (25.6)	6
Lipemia (from trig fraction)	2000 mg/dL (20.0 g/L)	9.9 (6.8)	6
	2000 mg/dL (20.0 g/L)	38.4 (26.5)	8

[a] Analyte results should not be corrected based on this bias.

Non-Interfering Substances

The following substances do not interfere with the Atellica CH Vanc assay when present in serum and lithium plasma at the concentrations indicated in the table below. Bias due to these substances is ≤ 10% at an analyte concentration of 10.0 and 40.0 µg/mL (6.9 and 27.6 µmol/L).

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Acetaminophen	20 mg/dL (1323 µmol/L)	≤ 10%
Acetylsalicylic Acid	50 mg/dL (2778 µmol/L)	≤ 10%
Amikacin	100 µg/mL (171 µmol/L)	≤ 10%

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Amobarbital	10 mg/dL (442 µmol/L)	≤ 10%
Ampicillin	5 mg/dL (143 µmol/L)	≤ 10%
Ascorbic Acid	3 mg/dL (170.3 µmol/L)	≤ 10%
Caffeine	10 mg/dL (515 µmol/L)	≤ 10%
Carbamazepine	12 mg/dL (508 µmol/L)	≤ 10%
Cefazolin	500 µg/mL (1100 µmol/L)	≤ 10%
Cefotaxime	1000 µg/mL (2195 µmol/L)	≤ 10%
Chloramphenicol	100 µg/mL (309 µmol/L)	≤ 10%
Chlordiazepoxide	2 mg/dL (67 µmol/L)	≤ 10%
Chlorpromazine	5 mg/dL (157 µmol/L)	≤ 10%
Cimetidine	10 mg/dL (396 µmol/L)	≤ 10%
Clindamycin	300 µg/dL (675 µmol/L)	≤ 10%
Codeine	10 mg/dL (334 µmol/L)	≤ 10%
Creatinine	30 mg/dL (2652 µmol/L)	≤ 10%
Dextran 40	6000 mg/dL (1500 µmol/L)	≤ 10%
Dextran 70	2500 mg/dL (357 µmol/L)	≤ 10%
Diazepam	4 mg/dL (140 µmol/L)	≤ 10%
Digoxin	5 ng/dL (6.4 nmol/L)	≤ 10%
Erythromycin	20 mg/dL (273 µmol/L)	≤ 10%
Ethanol	350 mg/dL (76 mmol/L)	≤ 10%
Ethosuximide	30 mg/dL (2125 µmol/L)	≤ 10%
Furosemide	2 mg/dL (61 µmol/L)	≤ 10%
Fusidic Acid	500 µg/mL (968 µmol/L)	≤ 10%
Gentamicin	12 mg/dL (25 µmol/L)	≤ 10%
Heparin (Porcine)	8000 U/L (8000 U/L)	≤ 10%
Ibuprofen	40 mg/dL (1939 µmol/L)	≤ 10%

Substance	Substance Test Concentration Common Units (SI Units)	Percent Bias
Lidocaine	6 mg/dL (256 µmol/L)	≤ 10%
Lithium	3.5 mg/dL (5.04 mmol/L)	≤ 10%
Methicillin	500 µg/mL (1318 µmol/L)	≤ 10%
Netilmicin	500 µg/mL (1050 µmol/L)	≤ 10%
Nicotine	2 mg/dL (123 µmol/L)	≤ 10%
Penicillin V	80 mg/dL (2247 µmol/L)	≤ 10%
Pentobarbital	10 mg/dL (442 µmol/L)	≤ 10%
Phenobarbital	15 mg/dL (646 µmol/L)	≤ 10%
Phenytoin	10 mg/dL (396 µmol/L)	≤ 10%
Primidone	10 mg/dL (458 µmol/L)	≤ 10%
Propoxyphene	0.4 mg/dL (12 µmol/L)	≤ 10%
Protein - Albumin	12 g/dL (120 g/L)	≤ 10%
Protein - IgG	5 g/dL (50 g/L)	≤ 10%
Protein – Total	12 g/dL (120 g/L)	≤ 10%
Rheumatoid Factor	1465 IU/L (1465 IU/L)	≤ 10%
Rifampin	50 µg/mL (61 µmol/L)	≤ 10%
Salicylic Acid	50 mg/dL (3.62 mmol/L)	≤ 10%
Secobarbital	5 mg/dL (209.8 µmol/L)	≤ 10%
Sodium Fluoride	1 mg/dL (0.24 mmol/L)	≤ 10%
Sulfamethoxazole	25 µg/mL (99 µmol/L)	≤ 10%
Theophylline	25 mg/dL (1388 µmol/L)	≤ 10%
Tobramycin	100 µg/mL (214 µmol/L)	≤ 10%
Trimethoprim	25 µg/mL (86 µmol/L)	≤ 10%
Urea	500 mg/dL (83.3 mmol/L)	≤ 10%
Uric Acid	20 mg/dL (1.2 mmol/L)	≤ 10%
Valproic Acid	50 mg/dL (3467 µmol/L)	≤ 10%

Standardization

The Atellica CH Vanc assay is traceable to United States Pharmacopeia (USP) material. Assigned values for calibrators are traceable to this standardization

9. CONCLUSION

The candidate devices are substantially equivalent to the Predicate devices and yields substantially equivalent Performance Characteristics. The performance data demonstrates that the devices provide consistent, reproducible, and accurate results and raises no concerns about Safety and Effectiveness.