510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K222439

B Applicant

Siemens Healthcare Diagnostics Inc.

C Proprietary and Established Names

Atellica® CH Phencyclidine (Pcp), Atellica® CH Vancomycin (Vanc)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LEH	Class II	21 CFR 862.3950 - Vancomycin Test System	TX - Clinical Toxicology
LCM	Unclassified		

II Submission/Device Overview:

A Purpose for Submission:
Modification to a previously cleared device

B Measurand:
Vancomycin (Vanc)
Phencyclidine (Pcp)

C Type of Test:
Pcp test- qualitative or semiquantitative immunoassay
Vanc test- quantitative particle enhanced turbidimetric inhibition immunoassay (PETINIA)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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® 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The device is intended for in vitro diagnotic use only.

D Special Instrument Requirements:

Atellica® CI Analyzer

IV Device/System Characteristics:

A Device Description:

The Atellica® CH Pcp assay is comprised of the following:

Pack 1 (P1) contains two wells of Atellica CH Pcp Reagent 1:
Antibodies to phencyclidine (polyclonal sheep); G6P (5.5 mmol/L); NAD+ (3.5 mmol/L); bovine serum albumin; stabilizers; preservatives.
Pack 2 (P2) contains two wells of Atellica CH Pcp Reagent 2:
Phencyclidine labeled with bacterial G6PDH; Tris buffer; bovine serum albumin; stabilizers; preservatives.

The assay uses previously cleared Emit Calibrator/Control materials (k993755) that are not supplied in this kit.

The Atellica® CH Vanc assay is comprised of the following:

Pack 1 (P1):
Atellica CH Vanc Reagent 1 (Well 1): Particle reagent
Atellica CH Vanc Reagent 3 (Well 2): Buffer

Pack 2 (P2):
One well of Atellica CH Vanc Reagent 2: Antibody (mouse monoclonal)
Materials needed but not supplied with the reagent kit include Atellica CH DRUG CAL II calibrators, level 1, level 2, level 3, level 4, and level 5.

B Principle of Operation:
The Atellica® CH Pcp assay is a homogeneous enzyme immunoassay based on competition between drug present in the specimen and drug labeled-glucose-6-phosphate dehydrogenase (PCP-G6PDH) for antibodies raised to PCP. PCP-G6PDH activity decreases upon binding to the anti-PCP antibodies and free PCP in the specimen competitively prevents this binding, so that PCP-G6PDH enzyme activity is proportional to drug concentration in the specimen. Active PCP-G6PDH enzyme converts nicotinamide adenine dinucleotide (NAD+) to NADH in the presence of glucose-6-phosphate, resulting in an absorbance change that is measured spectrophotometrically at 340/410 nm.

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.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Trinidad CH Vancomycin (Vanc), Atellica CH Phencyclidine (Pcp)

B Predicate 510(k) Number(s):
K160202, K163220

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222439	K160202
Device Trade Name	Atellica® CH Vancomycin (Vanc) assay	Trinidad CH Vancomycin (Vanc)
General Device Characteristic Similarities		
Intended Use/Indications For Use	For in vitro diagnostic use in the quantitative measurement of vancomycin in human serum and plasma.	same
Sample type	Serum/ Lithium Heparin plasma	same
Calibration Frequency	30 days	same
Analytical Measuring Interval	3.0 – 50.0 µg/mL	same

Device Technology	Homogeneous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique	same
General Device Characteristic Differences		
Instrument	Atellica CI Analyzer	Trinidad CH system

Device & Predicate Device(s):	K222439	K163220
Device Trade Name	The Atellica® CH Pcp assay	Atellica CH Phencyclidine (PCP)
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative or semiquantitative analysis of phencyclidine in human urine.	same
Test Matrix	Urine	same
Device Technology	Enzyme Immunoassay	same
General Device Characteristic Differences		
Instrument	Atellica CI analyzer	Atellica CH analyzer

VI Standards/Guidance Documents Referenced:

Clinical and Laboratory Standards Institute (CLSI) EP05-A3 – Evaluation of Precision of Quantitative Measurement Procedures, Third Edition;
CLSI EP06-A – Evaluation of Linearity of Quantitative Measurement Procedures, Second Edition;
CLSI EP09c – Measurement Procedure Comparison and Bias Estimation Using Patient Samples, Third Edition;
CLSI EP28-A3c – Defining Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline, Third Edition;
CLSI EP17-A2 – Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition;
CLSI EP07 – Interference Testing in Clinical Chemistry, Third Edition;
CLSI EP34 – Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, First Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Atellica CH Pcp Precision

Precision studies were conducted based upon recommendations in CLSI EP05-A3. Total precision was tested in 2 runs (minimal interval of 2 hours between run), 2 replicates per run

per day, for 20 days, for a total of 80 results per sample 9 samples for with 1 reagent lot on 1 Atellica CI Analyzer.

Semi-Quantitative analysis of Atellica CH Pcp (N=2x2, 20 days)						
Urine Pool (ng/ml)	% of Cutoff	Mean (ng/ml)	Repeatability		Within-lab	
			SD (ng/ml)	%CV	SD (ng/ml)	%CV
0	-100	0	0.1	N/A	0.2	N/A
6.25	-75	6	0.4	6.7	0.6	10.0
12.5	-50	12	0.4	3.3	0.6	5.0
18.75	-25	18	0.4	2.2	0.8	4.4
25	Cutoff	25	0.6	2.4	1.1	4.4
31.25	+25	32	0.9	2.8	1.7	5.3
37.5	+50	39	0.9	2.3	2.3	5.9
43.75	+75	43	1.1	2.6	2.5	5.8
50	+100	52	1.7	3.3	3.7	7.1

The precision data are summarized below.

Qualitative analysis of Atellica CH Pcp			
Urine Pool (ng/ml)	% of Cutoff	Repeatability Results	Within-Lab Results
0	-100	80 Negative	80 Negative
6.25	-75	80 Negative	80 Negative
12.5	-50	80 Negative	80 Negative
18.75	-25	80 Negative	80 Negative
25	Cutoff	50 Positive, 30 Negative	50 Positive, 30 Negative
31.25	+25	80 Positive	80 Positive
37.5	+50	80 Positive	80 Positive
43.75	+75	80 Positive	80 Positive
50	+100	80 Positive	80 Positive

Atellica CH Vanc Precision

Precision studies were conducted based upon recommendations in CLSI EP05-A3. Total precision was tested in 2 runs (minimal interval of 2 hours between each run) with 2 replicates per run per day, for 20 days, for a total of 80 results per sample using 5 samples with 1 reagent lot on 1 Atellica CI Analyzer.

The precision data are summarized below.

Atellica CH Vanc Precision (n=2x2, 20 days)					
	Mean	Repeatability		Within-lab	
Sample	(µg/ml)	SD (µg/ml)	%CV	SD (µg/ml)	%CV
Serum QC1	6.1	0.14	2.3	0.17	2.8
Serum 1	13.4	0.13	1.0	0.2	1.5
Serum QC2	19.5	0.15	0.8	0.33	1.7
Serum QC3	32.6	0.34	1.0	0.61	1.9
Serum 2	46.1	0.54	1.2	0.89	1.9

Atellica CH Pcp and Atellica CH Vanc Reproducibility

Reproducibility was performed using 3 samples for Pcp and 5 samples for Vanc with 5 replicates per day, over 5 days, using 3 reagent lots, on 3 Atellica CI Analyzers, for a total of 225 replicates per sample based upon the recommendation in CLSI EP05-A3. Repeatability, Between-Day, Between-Instrument (Site), Between-Reagent Lot, and Total Reproducibility were evaluated and the data for reproducibility studies are summarized below.

Atellica CH Pcp Reproducibility (n=225)											
Serum Sample ID	Mean (ng/ml)	Repeatability		Between-Day		Between-Instrument		Between-Lot		Total Reproducibility	
		SD (ng/ml)	% CV	SD (ng/ml)	% CV	SD (ng/ml)	% CV	SD (ng/ml)	% CV	SD (ng/ml)	% CV
Urine QC1	18	0.5	2.8	0.6	3.3	0.3	1.7	0.7	3.9	1.1	6.1
Urine QC2	24	0.5	2.1	0.9	3.8	0.7	2.9	0.6	2.5	1.4	5.8
Urine QC3	34	0.8	2.4	1.5	4.4	1.2	3.5	0.8	2.4	2.2	6.5

Atellica CH Vanc Reproducibility (n=225)											
Serum Sample ID	Mean (ng/ml)	Repeatability		Between-Day		Between-Instrument		Between-Lot		Total Reproducibility	
		SD (µg/ml)	% CV	SD (µg/ml)	% CV	SD (µg/ml)	% CV	SD (µg/ml)	% CV	SD (µg/ml)	% CV
Serum QC1	6.0	0.11	1.8	0.18	3.0	0.09	1.5	0.07	1.2	0.24	4.0
Serum 1	13.4	0.12	0.9	0.14	1.0	0.03	0.2	0.19	1.4	0.27	2.0
Serum QC2	19.7	0.16	0.8	0.29	1.5	0.1	0.5	0.15	0.8	0.38	1.9
Serum QC3	32.9	0.22	0.7	0.49	1.5	0.29	0.9	0.09	0.3	0.62	1.9
Serum 2	45.9	0.36	0.8	0.50	1.1	0.48	1.0	0.25	0.5	0.81	1.8

2. Linearity:

Atellica CH Pcp

Urine samples were spiked with Pcp concentrations ranging from 4.0 - 80.0 ng/mL and tested with 6 replicates in the same analytical run using one reagent lot. For each known concentration, drug recovery was calculated using the mean concentration of the replicates. The data support the semi-quantitative reportable range of 5 - 75 ng/mL. The data are summarized below.

Targeted Pcp (ng/ml)	Test Mean Pcp (ng/mL)	% 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%

Atellica CH Vanc

Linearity was evaluated based upon recommendations in CLSI EP06-A, second edition using 9 serum samples which spanned the assay measuring interval (2.5, 9.1, 15.7, 22.3, 29.0, 35.6, 42.2, 48.8, 55.4 µg/mL), 5 replicates per sample and 1 reagent lot. The mean of these replicates was used for the ordinary linear regression analysis. The deviation from linearity did not exceed 10% for each level. The result of the linear regression analysis is summarized below.

y= 0.9977x+0.1988, r=0.9998

The results support the Atellica CH Vanc assay is linear from 3.0-50 µg/mL.

3. Analytical Specificity/Interference:

Specific Gravity and pH for Pcp

The specific gravity of drug-free urine samples was adjusted to obtain the following values: 1.000, 1.002, 1.005, 1.010, 1.015, 1.020, 1.025 and 1.030 in the presence of Pcp at +/- 25% of the cutoff concentration (19 ng/mL and 31 ng/mL, respectively). No interference was observed in the urine samples with the tested specific gravity range from 1.000 to 1.030.

The pH of drug-free urine was titrated from 3.0 to 11.0 (+/- 0.2) in increments of 1 pH unit in the presence of Pcp at +/- 25% of the cutoff concentration (19 ng/mL and 31 ng/mL, respectively). The pH range tested from 3 to 10 did not affect the results of the Atellica CH Pcp. A pH of 11 led to negative results of the Atellica CH Pcp at +25% of the cutoff.

Interference Testing for Pcp

Pcp interference testing was conducted using 1 instrument, 2 reagent lots, spiked human urine samples (+/- 25% cutoff), 6 replicates per sample based upon recommendations in CLSI EP07 (3rd Edition).

The results of Pcp interference testing of endogenous substances are shown below. No positive or negative interference was observed at the indicated concentrations.

Endogenous Substances for Pcp assay	**Highest interferent concentration tested that showed no significant interference**
Acetone	1.0 g/dL
Ascorbic acid	0.75 g/dL
Conjugated bilirubin	0.25 mg/dL
Creatinine	0.5 g/dL
Ethanol	1.0 g/dL
Gamma globulin	0.5 g/dL
Galactose	0.01 g/dL
Glucose	2.0 g/dL
Hemoglobin	115 mg/dL
Human Serum Albumin	0.5 g/dL
Oxalic Acid	0.1 g/dL
Riboflavin	7.5 mg/dL
Sodium Azide	1% (w/v)
Sodium Chloride	1.5 g/dL
Sodium Fluoride	1% (w/v)
Urea	6.0 g/dL

The results of Pcp interference testing of structurally unrelated compounds are shown below. No positive or negative interference was observed at the indicated concentrations.

Structure Unrelated Compound Summary for Pcp assay	**Highest interferent concentration tested that showed no significant interference**
Acetaminophen	500,000 ng/ml
I-α-Acetylmethadol (LAAM)	25,000 ng/ml
N-Acetyl Procainamide (NAPA)	100,000 ng/ml
Acetylsalicylic Acid	500,000 ng/ml
Amitriptyline	8,750 ng/ml
S-(+)-Amphetamine	100,000 ng/ml
Benzoylecgonine	100,000 ng/ml
Boric Acid	1% (w/v)
Buprenorphine	100,000 ng/ml
Caffeine	500,000 ng/ml
Cannabinol	100,000 ng/ml
Carbamazepine	100,000 ng/ml
Chlordiazepoxide	100,000 ng/ml
Cimetidine	100,000 ng/ml
Clonidine	100,000 ng/ml

Codeine	25,000 ng/ml
Cotinine	100,000 ng/ml
Desipramine	75,000 ng/ml
Dextrorphan	781 ng/ml
Diazepam	100,000 ng/ml
Digoxin	100,000 ng/ml
2-Ethylidene-1,5-dimethyl- 3,3-diphenylpyrrolidine (EDDP)	12,500 ng/ml
EMDP	100,000 ng/ml
1R,2S-Ephedrine	100,000 ng/ml
1S,2R-Ephedrine	100,000 ng/ml
Fluoxetine	75,000 ng/ml
Flurazepam	50,000 ng/ml
Glutethimide	100,000 ng/ml
Haloperidol	100,000 ng/ml
Heroin	25,000 ng/ml
Hydrocodone	25,000 ng/ml
Ibuprofen	500,000 ng/ml
Ketamine	75,000 ng/ml
Ketorolac Tromethamine	100,000 ng/ml
Lidocaine	100,000 ng/ml
Lorazepam	100,000 ng/ml
Lormetazepam	100,000 ng/ml
LSD	100,000 ng/ml
MDMA	100,000 ng/ml
Meperidine	1,563 ng/ml
Methadone	50,000 ng/ml
S(+) - Methamphetamine	100,000 ng/ml
Methaqualone	100,000 ng/ml
Morphine	75,000 ng/ml
Naproxen	100,000 ng/ml
Nordiazepam	100,000 ng/ml
Nortriptyline	75,000 ng/ml
Oxazepam	100,000 ng/ml
Oxycodone	100,000 ng/ml
Phenobarbital	100,000 ng/ml
Phenylephrine	100,000 ng/ml
Phenytoin	100,000 ng/ml
Promethazine	3,125 ng/ml
Propoxyphene	100,000 ng/ml
Propranolol	100,000 ng/ml
Protriptyline	75,000 ng/ml
R,R - Pseudoephedrine	100,000 ng/ml
S,S - Pseudoephedrine	100,000 ng/ml
Ranitidine	100,000 ng/ml
Ritalinic Acid	100,000 ng/ml
Salicylic Acid	100,000 ng/ml

Scopolamine	100,000 ng/ml
Secobarbital	100,000 ng/ml
Tapentadol	50,000 ng/ml
11-nor-Δ9-THC-9-COOH	100,000 ng/ml
Tramadol	50,000 ng/ml
Trazodone	100,000 ng/ml
Tyramine	100,000 ng/ml
Verapamil	60,000 ng/ml
Zidovudine (AZT)	100,000 ng/ml
Zolpidem	100,000 ng/ml

Cross-reactivity was evaluated by spiking the structurally similar compounds described below into drug free urine. The results are summarized in the table below.

Test Compound for Pcp assay	**Concentration (ng/mL)**	**Mean Observed Pcp Response (ng/mL)**	**% Cross-Reactivity**
Chlorpromazine	100000	24.0	0.0
Clomipramine	100000	20.8	0.0
Cyclobenzaprine	25000	7.0	0.0
Dextromethorphan	80000	22.6	0.0
Diphenhydramine	100000	10.8	0.0
Doxepin	90000	13.2	0.0
Imipramine	100000	16.2	0.0
Methoxetamine	36000	14.0	0.0
4-Methoxyphencyclidine	700	59.4	8.5
Thioridazine	100000	48.4	0.0
Venlafaxine	100000	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-Piperidinocyclohexanol	32	59.0	184.4

Vanc Cross Reactivity

Cross reactivity testing were conducted with 5, 10, 15 and 20 µg/mL Vancomycin crystalline degradation product (CDP-1) using 1 instrument, 1 reagent lot, drug free and spiked human serum samples at two levels of Vancomycin (10ug/ml ±10%, 40ug/ml ± 10%), 5 replicates per sample in accordance with CLSI EP07 (3rd Edition). No cross-activity was observed.

Interference Test for Vanc

Interference testing was conducted using 1 instrument, 3 reagent lots, spiked human serum samples at two levels of Vancomycin (10ug/ml ±10%, 40ug/ml ± 10%), 5 replicates per sample based upon recommendations in CLSI EP07 (3rd Edition). Interference was not considered to be significant unless the difference between the samples with and without a potential interferent was greater than 10.0%.

The results of Vanc interference testing of endogenous substances and structurally unrelated compounds are shown below. No significant interference was observed after testing the following substances at the indicated concentrations.

Endogenous Substances for Vanc assay	**Highest interferent concentration tested that showed no significant interference**
Hemoglobin	1000 mg/dL
Conjugated bilirubin	30 mg/dL
Unconjugated bilirubin	30 mg/dL
Lipemia (from Intralipid)	2000 mg/dL
Lipemia (from Trig Fraction)	2000 mg/dL

Structure Unrelated Compounds for Vanc assay	**Highest interferent concentration tested that showed no significant interference**
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	50 mg/dL
Amikacin	100 µg/mL
Amobarbital	10 mg/dL
Ampicillin	5 mg/dL
Ascorbic Acid	3 mg/dL
Caffeine	10 mg/dL
Carbamazepine	12 mg/dL
Cefazolin	500 µg/mL
Cefotaxime	1000 µg/mL
Chloramphenicol	100 µg/mL
Chlordiazepoxide	2 mg/dL
Chlorpromazine	5 mg/dL
Cimetidine	10 mg/dL
Clindamycin	300 µg/dL
Codeine	10 mg/dL
Creatinine	30 mg/dL
Dextran 40	6000 mg/dL
Dextran 70	2500 mg/dL
Diazepam	4 mg/dL
Digoxin	5 ng/dL
Erythromycin	20 mg/dL
Ethanol	350 mg/dL
Ethosuximide	30 mg/dL
Furosemide	2 mg/dL
Fusidic Acid	500 µg/mL

Gentamicin	12 mg/dL
Heparin (Porcine)	8000 U/L
Ibuprofen	40 mg/dL
Lidocaine	6 mg/dL
Lithium	3.5 mg/dL
Methicillin	500 µg/mL
Netilmicin	500 µg/mL
Nicotine	2 mg/dL
Penicillin V	80 mg/dL
Pentobarbital	10 mg/dL
Phenobarbital	15 mg/dL
Phenytoin	10 mg/dL
Primidone	10 mg/dL
Propoxyphene	0.4mg/dL
Protein-Albumin	12 g/dL
Protein-IgG	5 g/dL
Protein-Total	12 g/dL
Rheumatoid Factor	1465 IU/L
Rifampin	50 µg/mL
Salicylic Acid	50 mg/dL
Secobarbital	5 mg/dL
Sodium Fluoride	1 mg/dL
Sulfamethoxazole	25 µg/mL
Theophylline	25 mg/dL
Tobramycin	100 µg/mL
Trimethoprim	25 µg/mL
Urea	500 mg/dL
Uric Acid	20 mg/dL
Valproic Acid	50 mg/dL

4. Assay Reportable Range:

Atellica CH Vanc

See Section A.2. – Linearity above, measuring interval for Vanc is 3.0-50 µg/mL. Dilution studies are based upon recommendations in CLSI EP34. Manual dilution of 2x increases the upper end of the measuring interval from 50.0 µg/mL to 100.0 µg/L for 5 human spiked serum samples. Using CH Diluent, 2-fold manual dilutions of serum samples above the extended assay range were processed with 20 replicates across two independent operators in one instrument using one reagent lot. For automated dilution studies, the dilution recovery results with 2-fold dilution demonstrate an extended measuring interval up to 100.0 µg/mL using the automated dilution routine with 5 replicates per sample in 1 reagent lot, 2 instruments. Data support an extended measuring interval of 3.0 - 100.0 µg/mL.

Data from the dilution studies are summarized below.

Serum sample for Vanc	Manual Dilution Studies			Automated Dilution Studies		
	Expected	Test (2X dilution)	% Recovery	Expected	Test	% Recovery
1	54.9	25.5	93%	54.9	50.3	92%
2	65.1	34.8	107%	65.1	65	100%
3	74.9	35.7	95%	74.9	70.1	94%
4	85.0	39.6	93%	85.0	78.7	93%
5	94.8	44.2	93%	94.8	87.9	93%

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
Traceability

The Atellica CH Pcp assay is traceable to commercially available standards.
The Atellica CH Vanc assay is traceable to United States Pharmacopeia (USP) material.

6. Detection Limit:

Limit of Blank (LoB) and Limit of Detection (LoD) were tested based upon recommendations in CLSI guideline EP17-A2. The LoB study was performed by testing 5 drug free serum samples with 5 replicates per sample on 3 reagent lots for 3 days, on 1 instrument. LoB was determined using the 95% nonparametric percentile of the replicates for each of three reagent lots. The claimed LoB for the Atellica CH Vanc assay is 0.6 µg/mL (0.4 µmol/L).

For LoD, 5 low samples were prepared from a base serum spiked with a vancomycin spiking solution. Samples were processed with 5 replicates per sample on 3 reagent lots for 3 days, on 1 instrument. LoD was determined parametrically using the pooled standard deviation (SD_L) for all samples from a given reagent lot. The maximum observed LoD across the 3 lots was 0.7 µg/mL and the claimed LoD for the Atellica CH Vanc assay is 1.0 µg/mL (0.7 µmol/L).

For LoQ, 5 spiked serum samples were used with 5 replicates per sample on 3 reagent lots for 3 days, on 1 instrument. The LoQ corresponds to the lowest amount of analyte in a sample that can be accurately quantitated with a total allowable error of ≤ 20%. The maximum observed LoQ across all reagent lots was determined to be 2.7 µg/mL and the claimed LoQ for the Atellica CH Vanc assay is 3.0 µg/mL (2.1 µmol/L).

7. Assay Cut-Off:
The Atellica® CH Phencyclidine (Pcp) assay in the qualitative analysis's mode uses a cutoff of 25 ng/mL.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Atellica Pcp Assay

For the Pcp assay, a total of 157 native samples were analyzed using the Atellica CH Pcp assay on the Atellica CH Analyzer (predicate device), on the Atellica CI Analyzer (candidate device), and confirmed by GC/MS. Results obtained as positive or negative relative to the 25 ng/mL assay cutoff (qualitative mode) or in analyte units (semi-quantitative mode) from the Atellica CH Phencyclidine (Pcp) assay on the Atellica CI analyzer were compared to results from the reference method (GC/MS).

The table below summarizes the data using urine samples:

	GC/MS Result			
Atellica Pcp	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 Pos (> 38 ng/mL)
Qualitative				
POS	0	3	19	81
NEG	42	7	5	0
Semi-Quantitative				
POS	0	3	19	81
NEG	42	7	5	0

Atellica Vanc assay

For Vanc assay, method comparison studies were conducted with 1 Atellica CH Vanc reagent lot based upon recommendations in CLSI EP09c using a total of 107 native samples. Each sample was tested on the Atellica CH Analyzer (predicate device) and on the Atellica CI Analyzer (candidate device). Slope and Y-intercept results were generated for serum using Deming regression.

The table below summarizes the method comparison data:

Atellica CH Vanc on Atellica CI					
Specimen Type	**Comparison Assay (x)**	**Regression Equation**	**Sample Range**	**N**	**r**
serum	Atellica CH Vanc on Atellica CH	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

2. Matrix Comparison:

For the Atellica CH Vanc, specimen equivalence was conducted with 50 matched serum and lithium heparin plasma samples spanning the assay measuring interval (4.5-43.9 µg/mL) with 2 replicates per sample, 1 Atellica CH reagent lot based upon recommendations in CLSI EP09c, and only the first replicate was used in the analysis. Slope and Y-intercept results were generated using Deming regression.

The table below summarizes the matrix comparison data:

Atellica CH Vanc on Atellica CI					
Specimen Type	**Reference Type**	**Regression Equation**	**Sample Range**	**N**	**r**
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

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Reference range information for the Vanc test was reviewed in K160202 and remains unchanged.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.