510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k161954

B. Purpose for Submission:

Addition of previously cleared test systems to new sample handling and sample transport platform.

C. Measurand:

Sodium, potassium, chloride, albumin, thyroid stimulating hormone, and vancomycin

D. Type of Tests:

Ion selective sensors for sodium, potassium, and chloride
Quantitative, photometry for albumin
Quantitative, chemiluminescence immunoassay for thyroid stimulating hormone
Quantitative, turbidimetric immunoassay for vancomycin

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

Atellica™ Solution
Atellica™ A-LYTE Integrated Multisensor (Na, K, Cl)
Atellica™ CH Albumin BCP Reagent (Alb_P)
Atellica™ IM Thyroid Stimulating Hormone (TSH) assay
Atellica™ CH Vancomycin (Vanc) assay

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JGS	Class II	21 CFR 862.1665 Sodium Test System	Clinical Chemistry (75)
CEM		21 CFR 862.1600 Potassium Test System	
CGZ		21 CFR 862.1170 Chloride Test System	
CJW		21 CFR 862.1035 Albumin Test System	
JLW		21 CFR 862.1690 Thyroid Stimulating Hormone Test System	
LEH		21 CFR 862.3950 Vancomycin Test System	
JJE	Class I	21 CFR 862.2160 Discrete Photometric Analyzer Chemistry For Clinical Use	

H. Intended Use:

1. Intended use(s):

   See Indications for use below

2. Indication(s) for use:

   The Siemens Atellica™ Solution is a multi-component system for in vitro diagnostic testing of clinical specimens. The system is intended for the qualitative and quantitative analysis of various body fluids, using photometric, turbidimetric, chemiluminescent, and integrated ion selective electrode technology for clinical use.

   The Atellica™ A-LYTE Integrated Multisensor (Na, K, Cl) is intended for in vitro diagnostic use in the quantitative determination of sodium, potassium, and chloride (Na, K, Cl) in human serum, plasma, and urine using the Atellica™ CH system. Measurements of sodium obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Measurements of potassium obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

   The Atellica™ CH Albumin BCP Reagent (Alb_P) is intended for in vitro diagnostic use in the quantitative measurement of albumin in human serum or plasma on Atellica™ CH system. Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver or kidneys.

The Atellica™ IM Thyroid Stimulating Hormone (TSH) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum, and plasma (EDTA and lithium heparin) using the Atellica™ IM system. Measurements of the thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The Atellica™ CH Vancomycin (Vanc) assay is for in vitro diagnostic use in the quantitative measurement of vancomycin in human serum or plasma on the Atellica™ CH System. Vanc test results may be used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   Atellica™ Solution

I. Device Description:

The Atellica™ Solution is a configurable test system comprising combinations of the following modules: Atellica™ Sample Handler, Atellica™ Magline Transport system, Atellica™ IM system, and Atellica™ CH system. The basic system comprises one each of these modules. The Atellica™ Solution is customizable, based on the needs of the clinical laboratory, by configuring the system with single or up to three each of the sample handler and/or analyzers modules.

The Atellica™ Sample Handler is the main operator interface with the system. Patient samples, STAT samples, Calibrators, and QC materials are loaded, stored, and unloaded.

The Atellica™ Magline transports samples, controls, and calibrators between the sample handler and the analyzer modules using carriers.

The Atellica™ IM system and Atellica™ CH system were previously cleared as the Trinidad IM system and Trinidad CH system in k151792 and k151767 respectively.

The Atellica™ A-LYTE Integrated Multisensor (Na, K, Cl) are ion specific electrodes previously cleared for use on the Trinidad CH system instrument in k151767.

The Atellica™ CH Albumin BCP Reagent (Alb_P) is a photometric assay previously cleared as the Trinidad CH Albumin BCP Reagent (Alb_P) for use on the Trinidad CH system instrument in k151767.

The Atellica™ CH Vancomycin (Vanc) is a turbidimetric assay previously cleared for use as the Trinidad CH Vancomycin (Vanc) Assay on the Trinidad CH system instrument in k160202.

The Atellica™ IM Thyroid Stimulating Hormone (TSH) is a chemiluminescent immunoassay previously cleared as the Trinidad IM Thyroid Stimulating Hormone (TSH) Assay for use on the Trinidad CH system in k151792.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Trinidad TD-LYTE Integrated Multisensor (Na, K, Cl)
   Trinidad IM Thyroid Stimulating Hormone (TSH) Assay
   Trinidad CH Vancomycin (Vanc) Assay
   Trinidad CH Albumin BCP Reagent (Alb_P)

2. Predicate 510(k) number(s):

   k151767 (Na, K, Cl, Albumin)
   k151792 (TSH)
   k160202 (Vancomycin)

3. Comparison with predicate:

Similarities and Differences		
Item	**Candidate device Atellica Solution configured with Atellica CH system and Atellica IM system k161954**	**Predicate device Trinidad CH system (k151767) Trinidad IM system (k151792)**
Intended Use	For in vitro diagnostic use in the quantitative determination of sodium, potassium and chloride (Na, K, Cl) in human serum, plasma and urine, the quantitative measurement of Vancomycin (Vanc) and Albumin (Alb_P) in human serum or plasma, and thyroid-stimulating hormone (TSH, thyrotropin) in serum, heparinized plasma, and EDTA plasma	Same
Representative Assays	Sodium, Potassium, Chloride, Albumin Vancomycin, and thyroid-stimulating hormone	Same
Type of System	Random continuous access, batch, STAT, discrete processing	Same

Similarities and Differences		
Item	**Candidate device Atellica Solution configured with Atellica CH system and Atellica IM system k161954**	**Predicate device Trinidad CH system (k151767) Trinidad IM system (k151792)**
Types of Measurements	Atellica CH module - Electrolyte, Photometric, Turbidimetric Atellica IM module - Chemiluminescence using magnetic- particle solid phase and chemiluminescent label	Same
Sample Containers	Tubes - 5 mL, 7 mL, 10 mL Cups - 2 mL sample cups	Same
Sample handling	Samples loaded/unload to the Atellica Sample Handler	Samples loaded/unloaded directly to analyzer
Sample transport	Samples are transported by Atellica Magline Transport system to analyzer	None
External connectivity to LIS	Yes	Same
Auto-dilution	Automatic dilution from retained pre- diluted sample	Same
Customizable	Yes, configurable with one to three sample handlers and/or analyzer modules.	No, each module is standalone
Sample identification	Bar code and handheld barcode scanner	Same

Similarities and Differences		
Item	**Candidate device Atellica TD-LYTE Integrated Multisensor (Na, K, Cl) k161954**	**Predicate device TD-LYTE Integrated Multisensor (Na, K, Cl) k151767**
Intended Use	For in vitro diagnostic use in the quantitative determination of sodium, potassium and chloride (Na, K, Cl) in human serum, plasma and urine.	Same
Device Technology	Indirect potentiometric measurements with Integrated Multisensor Technology (IMT)	Same
Sample Type	Serum, lithium heparin plasma, urine	Same
Traceability	Na: Flame photometric method with NIST reference standards K: Flame photometric method with NIST reference serum Cl: Coulometric method with NIST standards	Same

Similarities and Differences		
Item	**Candidate device Atellica TD-LYTE Integrated Multisensor (Na, K, Cl) k161954**	**Predicate device TD-LYTE Integrated Multisensor (Na, K, Cl) k151767**
Calibrators	TD-LYTE IMT Standard A and TD-LYTE IMT Standard B + Salt Bridge	Same
Calibration Frequency	Every 4 hours	Same
Number of Calibrator Levels	Two levels, Target Value (mmol/L): Levelsodium potassium chloride 1 14.0 0.4 10.4 2 7.0 6.0 16.0	Same
Analyzer	Atellica Solution and Atellica CH system	Trinidad CH system

Similarities and Differences		
Item	**Candidate device Atellica CH Albumin BCP Reagent (Alb_P) k161954**	**Predicate device Trinidad CH Albumin BCP Reagent (Alb_P) k151767**
Intended Use	For in vitro diagnostic use in the quantitative measurement of albumin in human serum or plasma.	Same
Device Technology	bromocresol purple (BCP) dye-binding method	Same
Sample Type	Serum, lithium heparin plasma and potassium EDTA plasma	Same
Analytical Measuring Interval	0.5–8.0 g/dL	Same
Traceability	ERM-DA470k Reference Material	Same
Calibrators	Albumin BCP Calibrator	Same
Calibration Frequency	Every 30 days	Same
Number of Calibrator Levels	One level, Target value: 4.3 g/dL	Same
Analyzer	Atellica Solution and Atellica CH system	Trinidad CH system

Similarities and Differences		
Item	**Candidate device Atellica IM Thyroid Stimulating Hormone (TSH) assay k161954**	**Predicate device Trinidad IM Thyroid Stimulating Hormone (TSH) Assay k160202**
Intended Use	For in vitro diagnostic use in the quantitative determination of thyroid- stimulating hormone (TSH, thyrotropin) in serum, heparinized plasma, and EDTA plasma.	Same
Assay Principle	Chemiluminescence sandwich immunoassay	Same
Sample Type	serum, heparinized plasma, and EDTA plasma	Same
Detection Antibody	Monoclonal mouse anti-TSH antibody BSA conjugate labeled with acridinium ester (AE)	Same
Capture Antibody	Anti-fluorescein labeled (FITC) monoclonal mouse anti-TSH antibody covalently bound to paramagnetic particles	Same
Assay Range	0.008 – 150 µIU/mL	Same
Traceability	Traceable to the World Health Organization (WHO) 3rd International standard for human TSH (IRP 81/565)	Same
Calibrators	Atellica TSH Calibrators	Same
Number of Calibrators	Two levels, Target values (µIU/mL) : 0.032 and 97.5	Same
Analyzer	Atellica Solution and Atellica IM system	Trinidad IM system

Similarities and Differences		
Item	**Candidate device Atellica CH Vancomycin (Vanc) k161954**	**Predicate device Trinidad CH Vancomycin (Vanc) Assay k160202**
Intended Use	For in vitro diagnostic use in the quantitative measurement of vancomycin in human serum or plasma.	Same
Device Technology	Homogeneous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique	Same
Sample Type	Serum, Lithium heparin plasma	Same
Analytical Measuring Interval	3.0–50.0 µg/mL	Same
Traceability	Traceable to United States Pharmacopeia (USP) standards.	Same
Calibrators	Drug 3 Calibrator	Same

Similarities and Differences		
Item	**Candidate device Atellica CH Vancomycin (Vanc) k161954**	**Predicate device Trinidad CH Vancomycin (Vanc) Assay k160202**
Calibration Frequency	30 days	Same
Number of Calibrator Levels	Five levels, Target values (µg/mL): 0.0, 6.6, 12.5, 25.0, and 52.5	Same
Analyzer	Atellica Solution and Atellica CH system	Trinidad CH system

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP15-A3: User Verification of Precision and Estimation of Bias.

CLSI - EP09-A3: Method comparison and bias estimation using patient samples.

IEC 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General Requirements.

EN 61326-1:2012, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.

EN 61326-1:2012, Electrical equipment for measurement, control and laboratory use – Part 2-6: Particular Requirements – In vitro diagnostic (IVD) medical equipment.

IEC 61010-1:2010, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General Requirements.

IEC 61010-1:2010, Safety requirements for electrical equipment for measurement, control, and laboratory use - Parts 2- 6: Particular Requirements – In vitro diagnostic (IVD) medical equipment.

L. Test Principle:

The Atellica™ A-LYTE Integrated Multisensor (Na, K, Cl) uses indirect Integrated Multisensor Technology (IMT). There are four electrodes used to measure electrolytes. Three of these electrodes are ion selective for sodium, potassium and chloride. A reference electrode is also incorporated in the multisensor. A diluted sample (1:10 with IMT Diluent) is positioned in the sensor and Na^+, K^+ or Cl^- ions establish equilibrium with the electrode surface. A potential is generated proportional to the logarithm of the analyte activity in the sample. The electrical potential generated on a sample is compared to the electrical potential generated on a standard solution, and the concentration of the desired ions is calculated by use of the Nernst equation.

The Atellica™ CH Albumin BCP Reagent (Alb_P) is an adaptation of the bromocresol purple (BCP) dye-binding method. In the Atellica™ CH Albumin BCP Reagent (Alb_P) assay, serum or plasma albumin quantitatively binds to BCP to form an albumin-BCP complex that is measured as an endpoint reaction at 596/694 nm.

The Atellica™ CH Vancomycin (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. 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 nm and 694 nm.

The Atellica™ IM Thyroid Stimulating Hormone (TSH) assay employs anti-FITC monoclonal antibody covalently bound to paramagnetic particles, a FITC-labeled anti-TSH capture monoclonal antibody, and a tracer consisting of a proprietary acridinum ester and an anti-TSH monoclonal antibody conjugated to bovine serum albumin for chemiluminescent detection. A direct relationship exists between the amount of TSH present in the patient sample and the amount of relative light units detected by the system.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies for the Atellica™ A-LYTE Integrated Multisensor (Na, K, Cl) were previously reviewed under k151767 using the Trinidad A-LYTE Integrated Multisensor (Na, K, Cl) on the Trinidad CH system.

Precision studies for the Atellica™ CH Albumin BCP Reagent (Alb_P) were previously reviewed under k151767 using the Trinidad CH Albumin BCP Reagent (Alb_P) on the Trinidad CH system.

Precision studies for the Atellica™ CH Vancomycin (Vanc) assay were previously reviewed under k160202 using the Trinidad CH Vancomycin (Vanc) Assay on the Trinidad CH system.

Precision studies for the Atellica™ IM Thyroid Stimulating Hormone (TSH) assay were previously reviewed under k151792 using the Trinidad IM Thyroid Stimulating Hormone (TSH) Assay on the Trinidad IM system.

The measurement precision of the sodium, potassium, chloride, albumin, vancomycin, and TSH assays on the Atellica™ Solution was evaluated. Precision was tested in 5 sample replicates per run, one run per day for 5 days using QC

material and pooled serum with one reagent lot of each assay.

The Atellica™ Solution configuration used for precision testing comprised one Atellica™ Sample Handler, one Atellica™ Magline sample transport system, one Atellica™ CH system, and one Atellica™ IM system. Precision study results are summarized below:

Sodium:

Specimen	N	Mean (mmol/L)	Repeatability		Within Lab	
			SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum	25	72.7	0.23	0.3	0.45	0.6
Serum QC	25	114	0.62	0.5	0.62	0.5
Serum QC	25	141	0.4	0.3	0.6	0.4
Serum QC	25	155	0.82	0.5	0.82	0.5

Potassium:

Specimen	N	Mean (mmol/L)	Repeatability		Within Lab	
			SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum QC	25	2.72	0.01	0.4	0.01	0.4
Serum QC	25	4.04	0.01	0.2	0.05	1.2
Serum	25	5.86	0.02	0.4	0.03	0.4
Serum QC	25	7.34	0.04	0.6	0.04	0.6

Chloride:

Specimen	N	Mean (mmol/L)	Repeatability		Within Lab	
			SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum QC	25	77.2	0.14	0.2	0.31	0.4
Serum QC	25	100	0.42	0.4	0.57	0.6
Serum QC	25	114	0.55	0.5	0.58	0.5
Serum	25	188	0.68	0.4	0.81	0.4

Albumin:

Specimen	N	Mean (mmol/L)	Repeatability		Within Lab	
			SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum QC	25	2.3	0.02	0.9	0.02	0.9
Serum	25	2.9	0	0	0	0
Serum	25	4.0	0.05	1.2	0.05	1.3
Serum QC	25	4.9	0.03	0.6	0.03	0.6
Serum	25	6.4	0.06	0.9	0.06	0.9

Vancomycin:

Specimen	N	Mean (mmol/L)	Repeatability		Within Lab	
			SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum QC	25	6.9	0.08	1.1	0.1	1.5
Serum	25	11.7	0.12	1	0.14	1.2
Serum QC	25	18.4	0.13	0.7	0.24	1.3
Serum	25	34.0	0.32	0.9	0.38	1.1
Serum	25	43.1	0.38	0.9	0.46	1.1

TSH:

Specimen	N	Mean (μIU/mL)	Repeatability		Within Lab	
			SD (mmol/L)	CV (%)	SD (mmol/L)	CV (%)
Serum QC	25	0.067	0.001	2.1	0.001	2.1
Serum	25	1.12	0.027	2.4	0.037	3.3
Serum	25	6.28	0.155	2.5	0.189	3
Serum	25	11.1	0.15	1.3	0.353	3.2
Serum	25	31.7	0.497	1.6	1.36	4.3
Serum	25	59.3	0.974	1.6	3.758	6.3
Serum	25	103.0	1.706	1.7	5.772	5.6
Serum	25	122.4	2.225	1.8	6.914	5.6

b. Linearity/assay reportable range:

For linearity information for sodium, potassium, chloride and albumin, see k151767. For linearity information for vancomycin, see k160202. For linearity information for TSH, see k151792.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability

For traceability information for sodium, potassium, chloride and albumin, see k151767. For traceability information for vancomycin, see k160202. For traceability information for TSH, see k151792.

Stability

For stability information for sodium, potassium, chloride and albumin, see k151767. For stability information for vancomycin, see k160202. For stability information for TSH, see k151792.

Value assignment

For value assignment information for sodium, potassium, chloride and albumin, see k151767. For value assignment information for vancomycin, see k160202. For value assignment information for TSH, see k151792.

d. Detection limit:

For detection limit information for sodium, potassium, chloride and albumin, see k151767. For detection limit information for vancomycin, see k160202. For detection limit information for TSH, see k151792.

e. Analytical specificity:

For interference study information for sodium, potassium, chloride and albumin, see k151767. For interference study information for vancomycin, see k160202. For interference study information for TSH, see k151792.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were conducted with reference to CLSI EP09-A3.

The accuracy performance of the Atellica™ Solution for sodium, potassium, chloride, albumin, vancomycin, and TSH was established by conducting a method comparison study. The Atellica™ Solution was configured with one Atellica™ Sample Handler, one Atellica™ Magline sample transport system, one Atellica™ CH system, and one Atellica™ IM system. The comparators were an Atellica IM system with direct sample loading for TSH and Atellica CH system with direct sample loading for sodium, potassium, chloride, albumin, and vancomycin.

The study tested native serum samples and a small number of contrived samples to cover the analytical range of the assays.

Using one reagent lot for each assay, two replicates were run for each sample on both the Atellica™ Solution and comparators; the first replicate of each sample was used in the data analysis. The study was conducted internally. The personnel conducting the study were laboratory technicians with training similar to personnel who would conduct the tests in a hospital laboratory setting.

The Passing-Bablok regression analysis for sodium, potassium, chloride, the Ordinary Least Square regression analysis for albumin, the Deming regression analysis for vancomycin, and the Weighted Deming regression analysis for the TSH results are summarized below:

Analyte	Specimen Type	N	Slope	Intercept	Correlation Coefficient	Concentration range
Sodium	Serum	121	1.00	0.00 mmol/L	0.999	58.7 to 197
Potassium	Serum	125	1.00	0.00 mmol/L	0.999	1.30 to 9.66
Chloride	Serum	122	0.990	1.030 mmol/L	0.999	61.0 to 189
Albumin	Serum	105	0.994	-0.006 g/dL	0.999	0.9 to 5.8
Vancomycin	Serum	112	0.988	-0.063 µg/mL	0.997	6.1 to 48.8
TSH	Serum	116	1.02	0.069 µIU/mL	0.992	0.008 to 143

b. Matrix comparison:

For matrix comparison information for sodium, potassium, chloride, and albumin (between serum lithium heparin, and EDTA plasma), see k151767.

For matrix comparison information for vancomycin (between serum and lithium-heparin plasma), see k160202.

For matrix comparison information for TSH (between serum, lithium heparin, and EDTA plasma), see k151792.

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable.

b. Clinical specificity:

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable.

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

	Sodium	Potassium	Chloride
Serum (mmol/L)	136 -145	3.5 - 5.1	98 -107
Plasma (mmol/L)	136 -145	3.4 - 4.5	98 -107
Urine (mmol/24 hr)	40 - 220	25 -125	110 -250

The reported reference ranges for sodium, potassium, and chloride are from: Tietz Fundamentals of Clinical Chemistry, 5th ed, Philadelphia, PA; WB Saunders Company (2001), ISBN 0-7216-8634-6.

	Albumin, adult
Serum (g/dL)	3.4 - 5.0
Plasma (g/dL)	3.4 - 5.0

The reported reference ranges for albumin are from: Willey DA, Savory J, Lasky F. An Evaluation of a Revised Albumin Method for the aca® discrete clinical analyzer, Du Pont Company, Wilmington, DE, August 1982.

For expected values/reference range information for sodium, potassium, chloride and albumin, see also k151767.

	TSH
Infants (1 – 23 months)	0.87 – 6.15 µIU/mL
Children (2 – 12 years)	0.67 – 4.16 µIU/mL
Adolescents (13-20 years)	0.48 – 4.17 µIU/mL
Adults (≥ 21 years)	0.55 – 4.78 µIU/mL

The reference intervals for TSH were previously established on the Advia Centaur System in k150403. To verify the reference range, a transferability and verification study was conducted in k151792 per CLSI EP28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory. The study results support the original reference range.

For expected values/reference range information for TSH, see also k151792.

		Vancomycin
Peak Intervals after 60 minute infusion:	two hours:	18 - 26 µg/mL
	one hour:	25 - 40 µg /mL
	30 mins:	30 - 40 µg/mL
Trough Intervals:		5 - 10 µg/mL

The therapeutic intervals for vancomycin are from:

Burtis CA, Ashwood ER, Bruns DE. Tietz Textbook of Clinical Chemistry and Molecular Biology, Fourth Edition, Elsevier Saunders, St. Louis, MO

Finn AL, Taylor WJ. Individualizing Drug Therapy, Practical Applications of Drug Monitoring. New York: Gross, Townsend, Frank, Inc., 1981: 87-108.

For expected values/reference range information for vancomycin, see also k160202.

N. Instrument Name:

Atellica™ Solution

O. System Descriptions:

1. Modes of Operation:

   Random continuous access, batch, or discrete processing

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X___ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ___X___ or No _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X___ or No _____

3. Specimen Identification:

   Routine or STAT patient sample tube ID's may be manually entered through the user interface workstation or scanned by hand held barcode scanner. The system is optionally supplied with a barcode printer.

4. Specimen Sampling and Handling:

   Samples are stored and identified by the Atellica™ Sample Handler. Samples are transported to the analytical modules by the Atellica™ Magline sample transport system.

5. Calibration:

   Calibration of the analytical modules was established in k151767 for Atellica™ Clinical Chemistry (CH) sodium, potassium, chloride and albumin; in k160202 for Atellica™ Clinical Chemistry (CH) vancomycin; and in k151792 for Atellica™ Immunoassay (IM) TSH.

6. Quality Control:

   The labeling recommends that laboratories "follow government regulations or accreditation requirements for quality control frequency. At least once each day of use, analyze two levels (low and high) of commercially available quality control (QC) material with known Na, K, Cl, Albumin, TSH, and Vancomycin concentrations."

P. Other Supportive Instrument Performance Characteristics Data Not Covered In the "Performance Characteristics" Section above:

1. EMC

   The Atellica™ Solution comprising one Atellica™ Sample Handler, one Atellica™ Magline sample transport system, and one Atellica™ CH system was tested and passed for compliance to the following EMC and Electrical safety standards:

   IEC 61010-1 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General Requirements.

   EN 61326-1:2012, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.

   EN 61326-1:2012, Electrical equipment for measurement, control and laboratory use – Part 2-6: Particular Requirements – In vitro diagnostic (IVD) medical equipment.

   IEC 61010-1:2010, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General Requirements.

   IEC 61010-1:2010, Safety requirements for electrical equipment for measurement, control, and laboratory use - Parts 2- 6: Particular Requirements – In vitro diagnostic (IVD) medical equipment.

2. Software

The software documentation was reviewed and found to be acceptable. Documentation was provided to support that the device was designed, developed and is under good software lifecycle processes.

3. Barcode reader

The Atellica™ Solution includes a handle held 1D barcode scanner connected to the operator workstation to enter patient sample tube ID's. The system supports both alphanumeric and numeric codes for Code 128, Code 39, Industrial 2 of 5, and Codabar (NW7) bar codes and can read up to a maximum of 20 characters. The functional performance of the barcode reader was verified under a software validation protocol. The verification test demonstrated that the bar code reader operates as intended to the design specifications.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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