

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

A. 510(k) Number:

k070704

B. Purpose for Submission:

New submission for the TRILOGY Analyzer for the determination Glucose, Creatinine, Urea nitrogen, Chloride, Potassium, and Sodium using previously cleared reagents and ISE test systems from the following submissions:

- JAS Diagnostics, Inc. Glucose Hexokinase (Liquid) Reagent (k011900)
- JAS Diagnostics, Inc. Creatinine (Single Vial) Reagent (k003247)
- JAS Diagnostics, Inc. Urea Nitrogen (BUN) Liquid Reagent (k011596)
- Medica Corp. EasyElectrolytes Analyzer (k000926)

C. Measurand:

Glucose, Creatinine, Urea nitrogen, Chloride, Potassium, and Sodium

D. Type of Test:

Quantitative photometric and Ion Selective Electrode methods.

E. Applicant:

Drew Scientific, Inc.

F. Proprietary and Established Names:

TRILOGY Analyzer

G. Regulatory Information:

1. Regulation section:

21CFR - Sec 862.1345 - Glucose test system.

21CFR - Sec 862.1225 - Creatinine test system.

21CFR - Sec 862.1770 - Urea nitrogen test system.

21CFR - Sec 862.1170 - Chloride test system.

21CFR - Sec 862.1600 - Potassium test system.

21CFR - Sec 862.1665 - Sodium test system.

21CFR - Sec 862.2160 - Discrete Photometric Chemistry Analyzer for Clinical Use

2. Classification:

Class II for all except for Sec 862.2160 which is Class I

3. Product code:

CGA - Glucose Oxidase, Glucose

CGX - Alkaline Picrate, Colorimetry, Creatinine

CDQ - Urease And Glutamic Dehydrogenase, Urea Nitrogen

CGZ - Electrode, Ion-Specific, Chloride

CEM - Electrode, Ion Specific, Potassium

JGS - Electrode, Ion Specific, Sodium

JJE - Analyzer, Chemistry (Photometric, Discrete), For Clinical Use

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

TRILOGY is a fully automated, discrete, software-driven, multi-purpose analyzer for spectrophotometric and potentiometric in vitro determination of analytes in body fluids. It is an open system intended for clinical use in a professional setting for use with various chemistry assays that may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.

TRILOGY is intended for the quantitative determination of glucose, creatinine and urea nitrogen in serum. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. Creatinine measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis. Urea nitrogen measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

TRILOGY includes an optional Ion Selective Electrodes (ISE) module for the measurement of sodium, potassium, and chloride in serum and urine. These measurements are used to monitor electrolyte balance and in the diagnosis and treatment of diseases involving electrolyte imbalance.

3. Special conditions for use statement(s):

Prescription use

4. Special instrument requirements:

TRILOGY Analyzer

I. Device Description:

The TRILOGY Analyzer is composed of a carousel system for reagent bottles/tubes and sample tubes, a carousel compartment with refrigeration unit, barcode reader, a liquid distribution module, microplate platform, wash station and an optical module. Reagent bottles/tubes and sample tubes are loaded onto a specific reagent or sample carousel and are placed into the refrigeration unit of the TRILOGY Analyzer. Located within the refrigeration unit is a barcode scanner, which scans barcode-labeled reagents and specimens for identification. Reagents and specimens are acquired from the carousels via the liquid distribution module. The liquid distribution module is composed of two probes, the Sample (Small) probe and the Reagent (Large) probe. The Sample (Small) probe is used to aspirate and dispense volumes between 1 and 75 μL . It is primarily used for samples but can also be used for delivering small volumes of reagent. The Reagent (Large) probe is used to aspirate and dispense volumes between 40 and 250 μL and is primarily used for reagents. Reagents and samples are pipetted by the Reagent or Sample probes into the 96-well microplate located on the analyzer deck. In between each aspiration, both probes are rinsed internally and externally at the washing station to insure proper decontamination. Once the reagents and samples have been added to the 96-well plate, the optical module scans the plate and conducts light through each reaction well. The light received from each reaction well is measured by the spectrophotometer and the data sent to the computer for analysis.

Serum or urine samples are pipetted from the sample carousel into the ISE module through the ion selective electrode injection well. The specimen is then introduced into the ISE module and pumped through each ion selective electrode. When the sample passes each individual electrode, the electrical potential of the individual electrode is measured and the data are sent to the computer for analysis.

See k011900, k003247, k011596, and k000926 for descriptive details for the reagents.

J. Substantial Equivalence Information:

1. Predicate device name(s):
 - Roche Diagnostic Systems, Inc. Roche COBAS MIRA Chemistry System
 - JAS Diagnostics, Inc. Glucose Hexokinase (Liquid) Reagent
 - JAS Diagnostics, Inc. Creatinine (Single Vial) Reagent
 - JAS Diagnostics, Inc. Urea Nitrogen (BUN) Liquid Reagent
 - Medica Corp. EasyElectrolytes Analyzer
2. Predicate 510(k) number(s):
k851172, k011900, k003247, k011596, and k000926
3. Comparison with predicate:

**Comparison of TRILOGY Analyzer and Predicate Device –
Roche COBAS MIRA®**

Characteristics	Drew Scientific, Inc. TRILOGY Analyzer	Roche Diagnostics, Inc. Roche COBAS MIRA®
Intended Use	TRILOGY is a fully automated, discrete, software-driven, multi-purpose analyzer for spectrophotometric and potentiometric in vitro determination of analytes in body fluids. It is intended for clinical use in a professional setting for a variety of general chemistries. It includes an optional Ion Selective Electrodes (ISE) module for the measurement of sodium, potassium and chloride.	The COBAS MIRA® is a benchtop random access analyzer used for analysis in clinical chemistry with optional ion selective electrode module.
System Principle	Clinical chemistry analyses including end point, kinetic and fixed time assays in either a Routine or STAT mode	Selective analysis of chemistries in either a Routine or STAT mode

Characteristics	Drew Scientific, Inc. TRILOGY Analyzer	Roche Diagnostics, Inc. Roche COBAS MIRA®
Open/Closed Reagent System	Open	Open
Principles of Measurement	Spectrophotometric – parallel bi-chromatic measurement of light absorbance (Tungsten halogen lamp) Potentiometric – Direct (Serum) Indirect (Urine)	Monochromatic measurement of light absorbance Potentiometric – Direct (Serum) Indirect (Urine)
Light Source	Tungsten Halogen	Xenon Flash Tube
Reaction Vessel	96-well Microplate	Six 12-Cuvette Segments
Throughput Without ISE With ISE	170 tests/hour 280 tests/hour	140 tests/hour
Specimen Type (Chemistry Methods)	Serum	Serum and Plasma
Specimen Capacity	40 Tubes	150 Tubes
Barcode Reader	Integrated	None
Barcode Formats	Code 39, Code 128, Code 93, Interleaved 2 of 5, Code 2 of 5, EAN, UPC A	<i>Not applicable</i>
Probe Movement	XYZ	XYZ
Primary Tubes	1.5, 5, 7 and 10 mL	Sample Cup, 4, 10, 15 and 35 mL
Specimen Volume	1 to 75 µL	2 to 95 µL
Dilution of Specimens	Yes	Yes
Cross Contamination Prevention	Teflon® – coated, Washable Probes	Washable Probe
Reagent Type	Liquid	Liquid
Reagent Volume	1 to 250 µL	100 to 600 µL
Reagent Positions Onboard	Maximum 40 Tubes (10 mL) Varies with Carousel Set	Varies with Reagent Rack Set
Reaction Volume	80 to 450 µL	150 to 600 µL
Host Interface	Bidirectional RS-232C	Bidirectional RS-232C
Calibration Curve	Linear and Non-linear	Linear and Non-linear
User Setting	Clinical Laboratory	Clinical Laboratory

**Comparison of TRILOGY Analyzer and Predicate Device –
Medica Corp. EasyElectrolytes**

Characteristics	Drew Scientific, Inc. TRILOGY Analyzer	Medica Corp. EasyElectrolytes
Intended Use	TRILOGY is a fully automated, discrete, software-driven, multi-purpose analyzer for spectrophotometric and potentiometric in vitro determination of analytes in body fluids. It is intended for clinical use in a professional setting for a variety of general chemistries. It includes an optional Ion Selective Electrodes (ISE) module for the	The EasyElectrolytes Analyzer is designed for clinical laboratory use, for quantitative measurements of sodium, potassium, and chloride or lithium.

Characteristics	Drew Scientific, Inc. TRILOGY Analyzer	Medica Corp. EasyElectrolytes
	measurement of sodium, potassium and chloride.	
System Principle	Measurement of electrolytes in a biological matrix	Measurement of electrolytes in a biological matrix
Specimen Type	Serum and Urine	Serum, Plasma, Whole Blood and Urine
Principles of Measurement	Potentiometric – Direct (Serum) Indirect (Urine)	Potentiometric – Direct (Serum) Indirect (Urine)
Specimen Volume	65 µL (Serum) 165 µL (Diluted Urine)	55 µL (Specimen Container) 50 µL (Capillary) 300 µL (Diluted Urine)
Primary Tubes	1.5, 5, 7 and 10 mL	Vacuum collection tube, syringe sample or capillary
Cross Contamination Prevention	Washable Probe	Washable Probe
Throughput Serum Urine	180 tests/hour 111 tests/hour	70 tests/hour 60 tests/hour
Host Interface	Bidirectional RS-232C	Bidirectional RS-232C
User Setting	Clinical Laboratory	Clinical Laboratory

**Comparison of TRILOGY Analyzer with Predicate Device –
JAS Diagnostics, Inc. Glucose Hexokinase (Liquid) Reagent**

Characteristics	Drew Scientific, Inc. TRILOGY Analyzer with JAS Diagnostics, Inc. Glucose Hexokinase (Liquid) Reagent	JAS Diagnostics, Inc. Glucose Hexokinase (Liquid) Reagent
Instrument	TRILOGY Analyzer	Various Instruments
Method	Enzymatic method using hexokinase coupled with glucose-6-phosphate dehydrogenase	Enzymatic method using hexokinase coupled with glucose-6-phosphate dehydrogenase
Specimen	Serum	Serum
Component Reagent Packaging	Single, reagent bottle, ready to use	Single, reagent bottle, ready to use
Format	Liquid	Liquid
Reagent	ATP, NAD, hexokinase, glucose-6-phosphate-dehydrogenase, sodium azide, stabilizers and fillers	ATP, NAD, hexokinase, glucose-6-phosphate-dehydrogenase, sodium azide, stabilizers and fillers

**Comparison of TRILOGY Analyzer and Predicate Device –
JAS Diagnostics, Inc. Creatinine (Single Vial) Reagent**

Characteristics	Drew Scientific, Inc. TRILOGY Analyzer with JAS Diagnostics, Inc. Creatinine (Single Vial) Reagent	JAS Diagnostics, Inc. Creatinine (Single Vial) Reagent
Instrument	TRILOGY Analyzer	Various Instruments
Method	Kinetic modification of the Jaffe method using picric acid and sodium hydroxide	Kinetic modification of the Jaffe method using picric acid and sodium hydroxide
Specimen	Serum	Serum
Component Reagent Packaging	Single, reagent bottle, ready to use	Single, reagent bottle, ready to use
Format	Liquid	Liquid
Reagent	Picric acid, sodium hydroxide	Picric acid, sodium hydroxide

**Comparison of TRILOGY Analyzer and Predicate Device –
JAS Diagnostics, Inc. Urea Nitrogen (BUN) Liquid Reagent**

Characteristics	Drew Scientific, Inc. TRILOGY Analyzer with JAS Diagnostics, Inc. Urea Nitrogen (BUN) Liquid Reagent	JAS Diagnostics, Inc. Urea Nitrogen (BUN) Liquid Reagent
Instrument	TRILOGY Analyzer	Various Instruments
Method	Enzymatic method using urease	Enzymatic method using urease
Specimen	Serum	Serum
Component Reagent Packaging	Single, reagent bottle, ready to use	Single, reagent bottle, ready to use
Format	Liquid	Liquid
Reagent	α -Ketoglutarate, NADH, urease, GLDH, stabilizers and fillers	α -Ketoglutarate, NADH, urease, GLDH, stabilizers and fillers

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

- CLSI - Evaluation of Precision Performance of Clinical Chemistry Devices - EP05-A2
- CLSI - Method Comparison and Bias Estimation Using Patient Samples - EP09-A2
- CLSI - Evaluation of the Linearity of Quantitative Analytical Methods - EP06-A
- CLSI - Protocols for Determination of Limits of Detection and Limits of Quantitation - EP17-A
- Guidance for Industry In Vitro Diagnostic Chloride Test System; Final - 7/6/1998
- Guidance for Industry In Vitro Diagnostic Creatinine Test System; Final - 7/2/1998
- Guidance for Industry In Vitro Diagnostic Glucose Test System; Final - 7/6/1998

- Guidance for Industry In Vitro Diagnostic Potassium Test System; Final - 7/6/1998
- Guidance for Industry In Vitro Diagnostic Sodium Test System; Final - 7/6/1998
- Guidance for Industry In Vitro Diagnostic Urea Nitrogen Test System; Final - 7/6/1998
- Guidance for Off-the-Shelf Software Use in Medical Devices; Final - 9/9/1999
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - 5/11/2005
- IEC 61010-1:2001, Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements
- IEC 61326 (02), Electrical equipment for measurement, control and laboratory use – EMC requirements
- EN 61326 (97) + A1 (98) + A2 (01) + A3 (03), Electrical equipment for measurement, control and laboratory use – EMC requirements
- FCC Part 15 (06), Telecommunication, Chapter 1: Federal communications commission, Part 15: Radio frequency devices
- ISO 14971 Medical devices -- Application of risk management to medical devices

L. Test Principle:

Photometric methods and ISE see k011900, k003247, k011596, and k000926 for reagent principle details.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

Precision studies were performed following the CLSI standard, EP5A-2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline,

Within-run precision studies consisted of assaying each control in replicates of 20 for one (1) run. Total precision studies for the clinical chemistry methods consisted of assaying each control in replicates of two (2), twice a day for a total of 20 days.

Precision – Clinical Chemistry									
	Glucose Hexokinase			Creatinine			Urea Nitrogen (BUN)		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean (mg/dL)	72.3	102.7	291.2	1.26	7.17	11.57	8.42	12.25	50.49
Within-Run									
SD	1.90	1.60	2.70	0.04	0.14	0.27	0.41	0.42	0.86
%CV	2.6	1.5	0.9	3.2	1.9	2.3	4.9	3.4	1.7
Total									
SD	3.10	2.90	5.10	0.05	0.21	0.44	0.54	0.49	1.27
%CV	4.3	2.8	1.7	4.3	2.9	3.8	6.5	4.0	2.5

Precision – ISE Serum									
	SODIUM			POTASSIUM			CHLORIDE		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean (mmol/L)	118.4	142.7	160.53	2.22	3.98	7.77	79.00	100.21	117.96
Within-Run									
SD	0.70	0.70	0.78	0.02	0.01	0.02	0.37	0.26	0.26
%CV	0.6	0.5	0.5	0.7	0.2	0.3	0.5	0.3	0.2
Total									
SD	1.20	1.40	1.68	0.05	0.04	0.10	1.42	0.70	0.82
%CV	1.0	1.0	1.0	2.1	1.1	1.3	1.8	0.7	0.7

Only within run precision studies were performed for the ISE urine methods:

Precision – ISE Urine						
	Sodium		Potassium		Chloride	
	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2
Mean (mmol/L)	92.0	159.0	36.59	63.30	96.25	142.94
Within-Run						
SD	1.30	2.00	0.38	0.67	0.67	1.31
%CV	1.5	1.2	1.0	1.1	0.7	0.9

b. *Linearity/assay reportable range:*

The range of measurement (dynamic range) for the photometric assays are supported by Linearity and Detection limit studies:

Glucose – 12 to 500 mg/dl

Creatinine – 0.2 to 20 mg/dl

Urea Nitrogen – 4.7 to 115.0 mg/dl

Samples for the linearity studies were prepared following the CLSI standard, EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. The procedure used to evaluate linearity was to assay a series of samples with known analyte concentrations using commercially available reference standard materials.

Linearity – Clinical Chemistry			
Key Statistics	Glucose Hexokinase	Creatinine	Urea Nitrogen (BUN)
Linearity Panel Members (N)	11	11	9
Slope	0.9986	1.004	0.9911
Intercept (mg/dL)	2.2	0.38	-2.20
Maximum Deviation from 100%	2.7% at 210 mg/dL	13.4% at 2.4 mg/dL	14.8% at 14.5 mg/dL
Maximum Deviation from Linearity	4.7 mg/dL (1.8%) at 260 mg/dL	-0.49 mg/dL (-2.0%) at 23.8 mg/dL	3.32 mg/dL (2.6%) at 126.5 mg/dL
Range (mg/dL)	11.0 – 508.0	0.05 – 23.80	0.50 – 126.50

Linearity – ISE Serum			
Key Statistics	Sodium	Potassium	Chloride
Linearity Panel Members (N)	11	11	10
Slope	0.989	0.994	0.918
Intercept (mmol/L)	3.60	-0.04	14.69
Systematic Error (mmol/L):			
Observed	1.32	0.11	1.5%
Allowed	1.40	0.14	1.8%
Range (mmol/L)	104.30 – 209.00	0.94 – 11.79	52.47 – 172.07

Linearity – ISE Urine			
Key Statistics	Sodium	Potassium	Chloride
Linearity Panel Members (N)	9	9	8
Slope	0.969	0.951	0.968
Intercept (mmol/L)	1.80	-1.04	2.82
Systematic Error (mmol/L)			
Observed	0.60	1.01	1.7%
Allowed	0.83	1.05	1.8%
Range (mmol/L)	13.00 – 349.70	2.40 – 187.87	39.07 – 402.97

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

The cleared calibrators used for the performance studies were as follows:

- Chemistry Methods JAS Chemistry Calibrator
JAS Diagnostics, Inc.
k020454
- ISE Methods - Calibrant A and Calibrant B
Medica Corporation
k000926

d. Detection limit:

The photometric assays were evaluated using EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.

LOB/LOD/LOQ Data – Clinical Chemistry			
	Glucose Hexokinase	Creatinine	Urea Nitrogen (BUN)
LOB (mg/dL)	8.31	0.11	3.71
LOD (mg/dL)	12.0	0.17	4.7
LOQ			
(mg/dL)	16.6	0.23	5.5
% CV	13.66	16.88	11.47

Not Applicable for ISE methods

e. Analytical specificity:

Interference studies were performed following the CLSI standard, EP7-A: Interference Testing in Clinical Chemistry; Approved Guideline. The procedure used to evaluate interference was to assay a series of samples with known concentrations of interferent. Percent recoveries were calculated for each sample with interferent versus the matched sample without interferent. Interference was defined as the level at which less than a 10% difference was observed between a sample with and without interferent. Interferent concentrations above those stated in Table 3 would contribute to invalid patient results.

Interference – Clinical Chemistry			
Interferent	Glucose Hexokinase	Creatinine	Urea Nitrogen (BUN)
Hemoglobin (mg/dL)	200	No interference up to 1000	1000
Bilirubin (mg/dL)	23.4	6.7	No interference up to 39.3
Triglycerides (mg/dL)	370	1117.5	No interference up to 994

The below table reports the concentration of interferent where interference was not observed with a specific ISE serum method assayed by the TRILOGY Analyzer.

	Interfering substance: Bilirubin
Analyte concentration	
Sodium	
162 mmol/l	35.3 mg/dl
189 mmol/l	20.2 mg/dl
Potassium	
4.41 mmol/l	41.4 mg/dl
8.26 mmol/l	21.7 mg/dl
Chloride	
107 mmol/l	41.3 mg/dl
130 mmol/l	21.1 mg/dl

	Interfering substance: Hemoglobin
Sodium	
140 mmol/l	679 mg/dl
149 mmol/l	871 mg/dl
Potassium	
	Do not use hemolyzed samples
	Do not use hemolyzed samples
Chloride	
100 mmol/l	921 mg/dl
113 mmol/l	1000 mg/dl
	Interfering substance: Triglycerides
Sodium	
140 mmol/l	2296 mg/dl
148 mmol/l	2038 mg/dl
Potassium	
4.20 mmol/l	2296 mg/dl
6.85 mmol/l	2366 mg/dl
Chloride	
99.5 mmol/l	2296 mg/dl
110.4 mmol/l	2366 mg/dl

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Clinical Chemistry Methods

Serum specimens were assayed using the TRILOGY Analyzer and Roche COBAS MIRA® for each clinical chemistry method. Regression statistics were calculated as follows:

Method Comparison Studies – Clinical Chemistry Methods

Method Comparison – Clinical Chemistry			
Key Statistics	Glucose Hexokinase	Creatinine	Urea Nitrogen (BUN)
N	62	69	70
Corr. Coeff. (R)	0.9946	0.9945	0.9956
Slope* (95% CI)	0.9902 (0.9643 – 1.016)	0.9860 (0.9614 – 1.011)	1.088 (1.064 – 1.112)
Intercept* (mg/dL) (95% CI)	7.0 (2.8 – 11.2)	0.03 (-0.11 – 0.16)	-2.43 (-3.30 – -1.55)
Range (mg/dL)	42.0 – 463.0	0.7 – 14.7	4.8 – 80.0

* = Data presented are Deming linear regression statistics

ISE Serum Methods

Serum specimens were assayed using the TRILOGY Analyzer with ISE module and Medica EasyElectrolytes for each ISE serum method. Regression statistics were calculated as follows:

Method Comparison Studies – ISE Serum Methods

Method Comparison – ISE Serum			
Key Statistics	Sodium	Potassium	Chloride
N	101	101	94
Corr. Coeff. (R)	0.9869	0.9979	0.9972
Slope* (95% CI)	0.972 (0.941 – 1.004)	1.004 (0.991 – 1.017)	0.854 (0.840 – 0.867)
Intercept* (mmol/L) (95% CI)	6.2 (1.8 – 10.6)	0.11 (0.05 – 0.17)	14.8 (13.5 – 16.2)
Range (mmol/L)	107.0 – 183.0	2.1 – 9.6	56.0 – 149.0

*= Data presented are Deming linear regression statistics

ISE Urine Methods

Urine specimens were assayed using the TRILOGY Analyzer with ISE module and Medica EasyElectrolytes for each ISE urine method. Regression statistics were calculated as follows:

Method Comparison Studies – ISE Urine Methods

Method Comparison – ISE Urine			
Key Statistics	Sodium	Potassium	Chloride
N	76	77	76
Corr. Coeff. (R)	0.9972	0.9969	0.9967
Slope* (95% CI)	0.989 (0.971 – 1.006)	1.020 (1.002 – 1.039)	1.046 (1.026 – 1.065)
Intercept* (mmol/L) (95% CI)	0.69 (-2.33 – 3.71)	-0.521 (-1.789 – 0.747)	-3.36 (-7.12 – 0.39)
Range (mmol/L)	14.3 – 291.9	11.27 – 145.6	40.3 – 353.2

* = Data presented are Deming linear regression statistics

b. *Matrix comparison:*

See ISE urine method comparison above

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:
See k011900, k003247, k011596, and k000926

N. Instrument Name:
TRILOGY Analyzer

O. System Descriptions:

- 1. Modes of Operation:

Random access routine and stat modes
- 2. Software:

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

Yes or No
- 3. Specimen Identification:

Barcode
- 4. Specimen Sampling and Handling:

Sample tube carousel
- 5. Calibration:

End-point, enzymatic and quadratic curve-fitting can be chosen to analyze data. Calibration curve-fitting parameters such as Linear (linear regression, bi-logarithmic regression, weighted linear) and Non-linear (Logit-Log, Exponential and Polynomial) are available.
- 6. Quality Control:

The operational software of the TRILOGY Analyzer contains a database, which is capable of storing results from previous analyses. The operator can view raw data and graphs for each clinical chemistry and ISE method. QC options also allow displays for evaluating data using Westgard Rules, viewing Levey-Jennings plots, reviewing statistical performance and exporting the QC data in Text File (TXT)

format.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

None

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.