K131554

JAN - 9 2014

510(K) SUMMARY

1. SAFETY AND EFFECTIVENESS AS REQUIRED BY 21 CFR 807.92 STATEMENT

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

2. SUBMITTER NAME AND ADDRESS

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3. 510k NUMBER, DEVICE PROPRIETARY NAME, COMMON NAME, PURPOSE FOR SUBMISSION, REGULATORY CLASSIFCATION, PANEL, PRODUCT CODE AND 21 CFR NUMBER

Product Code	Regulation Name	Classification	Regulation Section	Panel
CIT	Aspartate amino transferase (AST/SGOT) Test system	II	21 CFR 862.1100	Chemistry (75)
JGS	Sodium Test System	II	21 CFR 862.1665	Chemistry (75)
CEM	Potassium Test System	II	21 CFR 862.1600	Chemistry (75)
CGZ	Chloride Test System	II	21 CFR 862.1170	Chemistry (75)
JJE	Discrete photometric chemistry analyzer for clinical use	I	21 CFR 862.2160	Chemistry (75)

Proprietary Names: RX Daytona Plus Chemistry Analyzer; RX Daytona Plus AST Reagent

4. PREDICATE DEVICE PROPRIETARY NAME AND 510 (k) NUMBER

Randox RX Imola Chemistry Analyzer with ISE Sodium, Potassium and Chloride electrodes K052914.

Randox AST assay K923505.

5. DEVICE DESCRIPTION

RX Daytona plus system

The RX Daytona Plus is a bench-top fully automated random access clinical analyser intended for use in clinical laboratories.

The RX Daytona Plus contains an ISE .module for the measurement of Potassium, Chloride and Sodium. The RX Daytona Plus has the capacity to perform up to 270 photometric tests or 450 tests per hour with ISE's and offers primary tube sampling, on-board sample dilution and a cooled reagent compartment.

- Cuvette wash system
- STAT facility
- Direct interface with host computer
- Automatic re-run and pre-dilution functions

The RX Daytona Plus uses dedicated software for easy access to all system facilities and functions. A color, graphic user interface guides through the operating functions and provides a comprehensive data management system.

Reagents

AST reagent is supplied in a kit containing:

- 4 x 20.0 mL Buffer/ enzyme
- 4 x 7.0 mL α-oxoglutarate/Coenzyme.

The primary reagent contains L-Aspartic acid, MDH, Tris Buffer and preservative. The secondary reagent contains α-oxoglutarate, NADH and preservatives.

ISE Electrodes, Sodium, Potassium and Chloride are comprised of ISE Calibrator H and L, ISE diluent, ISE reference solution and ISE etching solution.

6. TEST PRINCIPLE

RX Daytona plus system Operation

After a sample cup or patient tube is placed into the sample carousel, the analyser pipettes the sample into the cuvette, pipettes the reagent and mixes the sample and reagent together in the reaction cuvette. After the sample and reagent react the analyser measures the absorbance of the sample and based on the absorbance reactions for the analyte being measured, it calculates the concentration of the analyte in the sample. The test system can measure analytes from multiple matrices including serum and urine. The time to first result is approximately 13 minutes.

Test Principle for ISE Unit

Measuring procedure, sodium, potassium and chloride:

ISE unit measures ionic concentration in sample with ion-selective electrode (ISE). It converts the activity of a specific ion dissolved in a solution into an electrical potential, according to the Nernst equation (below)
Serum samples are measured by direct ISE method. Urine samples are pre-diluted with dedicated diluents and measured.

$$E=E0 + RT/nF \times \log a$$

E: Sample potential
E0 : Reference potential
R : Gas constant
T : Absolute temperature (K)
n : Ionic valance
F : Faraday constant (C)
a : Ion activity

Calculation of calibration slope

Slope is calculated according to the subtraction of H solution potential and L solution potential:

$$S = (EH - EL) / \log (CH / CL)$$

S : Slope (mV/decade)
EH : H solution potential
EL : L solution potential
CH : H solution concentration
CL : L solution concentration

Measurement

Sample concentration is obtained by measuring sample potential and L solution potential and calculated according to the slope which is obtained through the calibration.

$$C = CL \times 10^{\{(E - EL)/S\}}$$

C : Sample concentration
CL: L solution concentration
E : Sample potential
EL : L solution potential
S : Slope (mV/decade

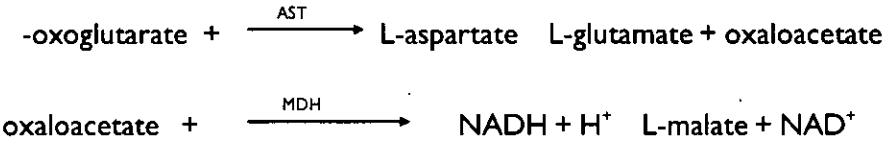
Process of analysis

1. Dispense sample into the sample port of the ISE module, with the sample probe (SPT).
2. Sample is delivered to electrodes.
3. Sample potential is measured.
4. Liquid in the flow path is wasted.
5. The flow path is cleaned with L solution.
6. L solution is delivered to electrodes.
7. L solution potential is measured.
8. Sample concentration is obtained by calculation according to sample potential and L solution potential.
9. Output the measurement result.

Test Principle for Chemistry Reactions

Randox AST Assay:

α-oxoglutarate reacts with L-aspartate in the presence of AST to form L-glutamate plus oxaloacetate. The indicator reaction utilizes the oxaloacetate for a kinetic determination of NADH consumption.



The ISE unit measures the concentration of Sodium (Na), Potassium (K) and Chloride (Cl) contained in serum and urine by using ion specific electrodes.

7. INTENDED USE

The RX Daytona Plus Chemistry analyzer is a bench top fully automated random access clinical chemistry analyzer intended for use in clinical laboratories. It is intended to be used for a variety of assay methods. The RX Daytona Plus includes an optional Ion Selective Electrode (ISE) module for the measurement of sodium, potassium and chloride in serum and urineThe RX Daytona Plus is not for Point-Of-Care testing.

Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance.

Potassium measurements 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.

The RX Daytona Plus AST reagent is for the quantitative in vitro diagnostic determination of the activity of the enzyme Aspartate aminotransferase (AST) in human serum. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart diseases.

8. COMPARISON WITH PREDICATE

The following table describes the similarities and differences between the two systems.

Table 1 **Technical Specification of the RX Daytona Plus and the RX Imola**

Parameter	RX Imola Automated Analyzer (K052914) Predicate	RX Daytona Plus Automated Analyser
Manufacturer	Furuno Electric Co. Ltd Japan on behalf of Randox Laboratories	Same
Device Classification	Chemistry Analyser (Photometric, Discrete) for	Same
Analyzer description:	High throughput, fully automated, random access bench top chemistry analyzer	Same
Dimensions	970mm (W) x 690mm (D) x 580mm (H	870mm (W) ×670mm (D) ×625mm (H)
Intended use:	An *In vitro* fully quantitative analyzer. The analyzer can be used to run tests including AST in serum samples. Various other assays are adaptable to the analyzer. The RX Imola analyzer and ISE unit must only be used by suitably qualified personnel, under appropriate laboratory conditions.	Same
Assay Tests	Endpoint, Kinetic, Bichromatic, turbidmetric, sample blanking, reagent blanking and ISE.	Monochromatic, bi-chromatic, endpoint, kinetic, sample and reagent blanking and ISE (via optional integrated ISE)
Calibration Principle	Factor, Linear, 2 point, point to point, spline, log-logit, exponential and ISE	Factor, Linear, Point to point, Log-logit, Exponential, Spline, Spline 2 and ISE
Cuvettes	90 reusable pyrex cuvettes (volume, 150ul min, 450ul max)	72 resin cuvettes (semi-disposable) (volume, 100ul min, 350ul max)
Cycle Time	9 seconds	13 seconds
Detection Principle	12 wavelengths generated via diffraction grating: 340, 380, 415, 450,510,546,570,600,660,700,750	Same
Detector Method	Direct absorbance in cuvette (bichromatic and monochromatic)	Same
Data Management	Storage of up to 10, 000 patient reports, search facility	Storage of up to 30, 000 reports, search facility

Table 1 **Technical Specification of the RX Daytona Plus and the RX Imola Cont..**

Parameter	RX Imola Automated Analyzer	RX Daytona Plus Automated Analyser
Light Source	Halogen Tungsten Lamp	Same
LIMS Connectivity	Bi-directional; ASTM Standard	Same
Maintenance	Daily maintenance-less than 5minutes. No rear access required. Simple twice yearly	Same
Analysis method:	Photometr ic	Same
Sample type:	Serum, urine	Same
Sample Addition	Sampling interruption for addition of samples	Same
Sample Volume	Normal Sample:2-35µl	Normal Sample:1.5-35µl
Sample Capacity	Removable tray with 72 positions for samples in outer ring, 20 positions for calibrators and controls in the inner ring.	Removable tray with 40 positions for samples in outer ring, 10 positions for calibrators and controls in the inner ring.
Sample Dilution	Pre-diluted and automatic re-assay with diluted, reduced and increased sample volume	Same
Sample Identification	Barcode sample identification	Same
Sample Pipette	Dedicated sample micropipette with liquid level sensor, crash protection and clot detection	Same
Sample Dead Volume	100ul in standard or primary tubes,	Same
Sample Tube Size	Multiple primary tube sizes(diameter 12 to 16mm, height 55 to	Same
Reagent Capacity	Removable tray with 60 cooled positions	Removable tray with 50 cooled positions
Reagent Cooling	8-	Same
Reagent Identification	Automatic barcode reagent	Same
Reagent Inventory	Calculation of remaining reagent volume and tests available. Alerts for shortage, expired reagent and expired	Same

Table 1 **Technical Specification of the RX Daytona Plus and the RX Imola Cont...**

Parameter	RX Imola Automated Analyzer (K052914) Predicate	RX Daytona Plus Automated Analyser
Reagent pipette	Two Dedicated reagent micropipette with liquid level sensor and crash detection. Rinsed inside and outside with purified	One Dedicated reagent micropipette with liquid level sensor and crash detection. Rinsed inside and outside with purified water
Reagent pipette Sampling Volume	R1:20-350ul (1ul increments) R2: 20-2501ul (1ul increments)	R1:20-250ul (1ul increments) R2: 20-180ul (1ul increments)
Minimum reaction volume	150u	100ul
Maximum Humidity	45-85% without condensation	45-85% without condensation
Incubation Temperature	37°C +/-0.3	37°C +/-0.1
Stirring System	Stick type rotating stirrer with variable speed to promote even mixing in all types of	Same
Stirring Speed	Dual 5 speed rotating stirrers	5 speed levels available
STAT sampling	STAT samples can be added immediately via emergency loading port	Same
Throughput	Capable of running 400 tests per hour, 560 tests per hour with	Capable of running 270 tests per hour, 450 tests per hour with ISE
Test Channels	60 photometric channels, 3 direct ISE (Total 63 channels)	50 photometric channels, 3 direct ISE (Total 53 channels)
Water Consumption	Maximum 18L per hour	Maximum 5L per hour

The RX Daytona Plus analyzer has the same intended use as the predicate device. Any differences in the technical characteristics of the RX Daytona Plus and the predicate device do not affect the safety or effectiveness. Therefore, the RX Daytona Plus analyzer demonstrates substantial equivalence to the predicate device

Table 2 **Technical Specifications of the RX Daytona Plus ISE Module and the RX Imola Analyzer ISE Module**

Parameter	RX Imola Automated Analyzer (K052914	RX Daytona Plus Automated Analyzer ISE Module
Sample	Serum, or Urine (Urine: automatic 10 fold dilution	Serum or Urine (Urine: automatic 7 times dilution)
Sample size	10ul Serum, (70ulx3) + 50ul Urine	50ul
Reproducibility **Na K** **Cl** **Na K** **Cl** **Na K** **Cl**	**Serum (Within Run)** CV <1.5% (100-160mmol/L) CV <2% (3.0-6.0mmol/L) CV <1.5% (80-120mmol/L) **Urine (Within Run)** CV <5% (20-500mmol/L) CV <5% (1-500 mm ol/L) CV <5% (20-500mmol/L) **Serum (Between days)** CV <2.0% (100-	**Serum (Within Run)** CV <1.0% (120-160mmol/L) CV <1.5% (2-6mmol/L) CV <1.2% (80-120mmol/L) **Urine (Within Run)** CV <3.8% (80-200mm ol/L) CV <3.8% (20-150mm ol/L) CV <3.8% (70-140mmol/L) **Serum (Between Days)** CV <2.0% (140mmol/L) CV <2.0% (5mmol/L) CV <2.0% (100mmol/L)
Analysis Time	Serum:30 seconds Urine 100 seconds	Serum 36 seconds Urine 54 seconds
Throughput	Serum 240 tests per hour, 80 samples per hour	Serum 300 tests per hour Urine 200 tests per hour
Max Temperature	37°C	Same
Calibration Frequency	24 hours (main calibration) After ISE cleaning,	Same
Reagents required	Calibrator A (Cal A bag) Calibrator B Cleaning solution	L Solution H solution ISE Cleaning solution Etching solution (Na cleaning) Urine Diluent
Power	12 VDC,	12V, 2A

The RX Daytona Plus analyzer ISE unit has the same intended use as the predicate device. Any differences in the technical characteristics of the RX Daytona Plus ISE unit and the predicate device do not affect the safety or effectiveness. Therefore, the RX Daytona Plus analyzer ISE unit demonstrates substantial equivalence to the predicate device.

Table 3 **Technical Specifications of the RX Daytona Plus ISE Calibrators and the RX Imola Analyzer ISE Calibrators**

Parameter	RX Imola Automated Analyzer (K052914)	RX Daytona Plus Automated Analyzer ISE Module
Intended use	CAL A and CAL B are used in the calibration of sodium, potassium and chloride on the RX Imola ISE module	ISE Calibrators are used for the calibration of sodium (Na+), potassium (K+) and chloride (Cl-) on the RX Daytona Plus analyzer equipped with ISE module.
Analyte	Sodium , Potassium, Chloride	Same: Sodium , Potassium, Chloride
Composition	Aqueous solution containing sodium, potassium and chloride at two different levels of concentration. **CAL A** Na+ = 140mmol/l K+ = 4mmol/l Cl- = 125 mmol/l **CAL B** Na+ = 70mmol/l K+ = 8mmol/l Cl- = 41 mmol/l	Aqueous solution containing sodium, potassium and chloride at two different levels of concentration. **L Solution** Na+ = 120mmol/l K+ = 4mmol/l Cl- = 100 mmol/l **H Solution** Na+ = 200mmol/l K+ = 7mmol/l Cl- = 150 mmol/l
Form	Liquid ready to use	Same
Storage (opened)	Once opened CAL A is stable for 2 months onboard the analyzer. CAL B is stable for 1 month when stored at +15 to +25°C	Once opened L Solution and H Solution are stable for 1 month at +15 to +25°C
Storage (Unopened)	Stable to the expiration date at +15 to +25°C	Stable to the expiration date at +15 to +25°C

The RX Daytona Plus analyzer ISE Calibrators have the same intended use as the predicate device. Any differences in the technical characteristics of the RX Daytona Plus ISE Calibrators and the predicate device do not affect the safety or effectiveness. Therefore, the RX Daytona Plus analyzer ISE Calibrators demonstrates substantial equivalence to the predicate device.

Table 4 **Technical Specifications of the AST predicate device with AST on the RX Daytona plus Analyzer ISE Module.**

CHARACTERISTICS	RANDOX AST REAGENT ON THE RX IMOLA ANALYZER K052914/A001	RX Daytona Plus AST REAGENT
Intended Use	The AST test system is a device intended for the quantitative in vitro determination of aspartate aminotransferase (AST) activity in serum and plasma. Measurements of AST are used in the diagnosis and treatment of certain types of liver and heart disease	Same
Assay Protocol	UV Method	Same
Format	Liquid which are ready to use	Same
Storage (unopened)	Reagents are stable up to the expiry date when stored unopened at +2 to +8°C	Same
Sample Type	Plasma and serum	Serum only
Control Frequency	Randox assayed human multisera Level 2 & 3 Two levels of control should be assayed at least once a day	Same
Calibration Frequency	Every 28 days, with a change of reagent lot or as indicated by quality control procedures.	Same
Materials required but not provided	Randox assayed human multisera Level 2 & 3. Randox Calibration Sera level 3. RX Series Saline.	Same

9. PERFORMANCE CHARACTERISTICS

Analytical performance:

a. Precision/Reproducibility:

Precision was evaluated consistent with C.L.S.I documents EP5
Precision studies were performed on one RX Daytona plus system using two levels of control material, calibration material, unaltered human serum samples and altered human serum samples for AST, Sodium, Potassium and Chloride. Urine precision studies were performed for Sodium, Potassium and Chloride using two levels of urine controls and two urine patient pools. Testing was conducted twice per day for 20 non consecutive days. Two replicates per run was performed for each sample.
The results are summarized in the tables below:

Table 2 **AST Precision Summary**

System: RX Daytona Plus			Within Run		Among Run		Among Day		Total	
Method	**Product**	**MEAN (U/L)**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
AST	Control 538UE	161.74	2.23	1.4	1.08	0.7	1.03	0.6	2.69	1.7
AST	Control 738UN	37.83	1.14	3.0	0.62	1.6	0.00	0.0	1.29	3.4
AST	Calibrator (532UE)	142.95	1.82	1.3	1.25	0.9	0.04	0.0	2.20	1.5
AST	HIGH Serum Pool	391.33	2.26	0.6	5.16	1.3	7.61	1.9	9.47	2.4
AST	NORMAL Serum Pool	18.83	0.43	2.3	0.70	3.7	0.71	3.8	1.08	5.8
AST	850 u/L Serum Pool	850.27	4.57	0.5	6.75	0.8	8.29	1.0	11.62	1.4
AST	LOW Serum Pool	6.68	0.53	8.0	0.49	7.3	0.37	5.6	0.81	12.2

Table 3 **Sodium Serum Precision Summary**

System: RX Daytona Plus			Within Run		Among Run		Among Day		Total	
Method	**Product**	**MEAN (mmol/l))**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
Sodium	Control 538UE	154.03	2.15	1.4	3.04	2.0	0.00	0.0	3.72	2.4
Sodium	Control 738UN	138.75	1.60	1.2	4.01	2.9	0.00	0.0	4.32	3.1
Sodium	Patient Pool 1	108.83	1.75	1.6	0.00	0.0	0.59	0.5	1.85	1.7
Sodium	Patient Pool 2	134.62	1.40	1.0	0.00	0.0	0.43	0.3	1.46	1.1
Sodium	Patient Pool 3	174.60	2.08	1.2	1.11	0.6	1.68	1.0	2.90	1.7

Table 4 **Sodium Urine Precision Summary**

System: RX Daytona Plus			Within Run		Among Run		Among Day		Total	
Method	**Product**	**MEAN (mmol/l))**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
Sodium	Control 575UC	61.84	2.59	4.2	2.12	3.4	0.80	1.3	3.44	5.6
Sodium	Control 580UC	192.25	6.21	3.2	3.77	2.0	5.87	3.1	9.34	4.9
Sodium	Patient Pool 1	135.65	4.05	3.0	2.65	2.0	5.75	4.2	7.51	5.5
Sodium	Patient Pool 2	281.59	5.37	1.9	6.58	2.3	8.50	3.0	12.02	4.3

Table 5 **Potassium Serum Precision Summary**

System: RX Daytona Plus			Within Run		Among Run		Among Day		Total	
Method	**Product**	**MEAN (mmol/l))**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
Potassium	Control 538UE	6.01	0.06	1.1	0.04	0.7	0.02	0.3	0.08	1.3
Potassium	Control 738UN	4.01	0.06	1.4	0.03	0.7	0.02	0.6	0.07	1.7
Potassium	Patient Pool 1	3.28	0.13	3.9	0.00	0.0	0.02	0.8	0.13	3.9
Potassium	Patient Pool 2	4.62	0.09	1.9	0.00	0.0	0.03	0.6	0.09	2.0
Potassium	Patient Pool 3	6.74	0.08	1.2	0.05	0.7	0.06	0.9	0.11	1.7

Table 6 **Potassium Urine Precision Summary**

System: RX Daytona Plus			Within Run		Among Run		Among Day		Total	
Method	**Product**	**MEAN (mmol/l))**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
Potassium	Control 575UC	32.69	0.55	1.7	0.34	1.0	0.72	2.2	0.97	3.0
Potassium	Control 580UC	103.23	2.08	2.0	2.45	2.4	3.17	3.1	4.52	4.4
Potassium	Patient Pool 1	31.86	0.57	1.8	0.46	1.4	0.47	1.5	0.87	2.7
Potassium	Patient Pool 2	84.26	2.04	2.4	0.77	0.9	2.04	2.4	2.98	3.5

Table 7 **Chloride Serum Precision Summary**

System: RX Daytona Plus			Within Run		Among Run		Among Day		Total	
Method	**Product**	**MEAN (mmol/l))**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
Chloride	Control 538UE	114.86	1.29	1.1	1.00	0.9	1.07	0.9	1.95	1.7
Chloride	Control 738UN	100.35	1.40	1.4	0.00	0.0	0.73	0.7	1.58	1.6
Chloride	Patient Pool 1	88.84	1.87	2.1	0.47	0.5	0.18	0.2	1.94	2.2
Chloride	Patient Pool 2	106.11	3.52	3.3	1.48	1.4	0.00	0.0	3.81	3.6
Chloride	Patient Pool 3	134.13	1.75	1.3	1.75	1.3	0.26	0.2	2.49	1.9

Table 8 **Chloride Urine Precision Summary**

System: RX Daytona Plus			Within Run		Among Run		Among Day		Total	
Method	**Product**	**MEAN (mmol/l))**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
Chloride	Control 575UC	86.44	3.15	3.6	2.70	3.1	2.12	2.5	4.66	5.4
Chloride	Control 580UC	240.25	5.23	2.2	4.38	1.8	13.41	5.6	15.04	6.3
Chloride	Patient Pool 1	171.06	4.98	2.9	5.34	3.1	0.00	0.0	7.30	4.3
Chloride	Patient Pool 2	260.24	3.74	1.4	5.61	2.2	3.82	1.5	7.75	3.0

b. Linearity/assay reportable range:

Linearity studies have been carried out in accordance with C.L.S.I. standard EP6-A. Linearity studies were performed at 11 levels to determine the analytical range of an assay - that is the range where the reported result is a linear function to the analyte concentration (or where deviation from linearity is less than 5%).

The results are summarized in the following tables:

Table 9 **Serum Linearity Summary**

Analyte	Linear regression	Reportable Range
AST	y=1.00x+0.65; R^2=1.000	5 – 1116U/L
Sodium	y=1.05x-5.45; R^2=0.999	90 – 226 mmol/l
Potassium	y=1.02x-0.13; R^2=0.999	0.5 – 11 mmol/l
Chloride	y=0.99x+1.14; R^2=0.998	72 – 210 mmol/l

Table 10 **Urine Linearity Summary**

Analyte	Linear regression	Reportable Range
Sodium	y=0.95x+7.26; R^2=0.998	45 – 318 mmol/l
Potassium	y=1.03x-1.20; R^2=1.000	1.5 – 168 mmol/l
Chloride	y=0.96x+3.41;R^2=0.999	61 – 319 mmol/l

Analyte	Serum Reportable Range	Urine Reportable Range
Sodium	90 – 226mmol/l	45 – 318 mmol/l
Potassium	0.5 – 11 mmol/l	1.5 – 168 mmol/l
Chloride	72 – 210 mmol/l	61 – 319 mmol/l

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

See K955489 Calibrator and K942458 Control for AST and K052914 for ISE

Table 11 **Traceability Table Randox AST Reagent and ISE's Sodium, Potassium and Chloride**

Analyte	Reference Material
AST	Standardized against primary calibrators traceable to AST reference material JSCC TS01
ISE: Sodium, Potassium and Chloride	Standardized against primary calibrators prepared gravimetrically from purified salts.

d. Detection limit:

Sensitivity studies have been carried out in accordance with C.L.S.I. guideline EP17-A 'Protocols for Determination of Limits of Detection and Limits of Quantification; Approved Guideline'. A Limit of Blank (L.o.B.), a Limit of Detection (L.o.D.) and a Limit of Quantification were performed on the RX Daytona Plus.

AST

The Limit of Detection (LoD) for AST on the RX Daytona Plus is 1.372 U/L based on 360 determinations, with 1 blank and 2 low level samples.

The Limit of Blank (LoB) is 0.50 U/L.

The Limit of Quantitation (LoQ) is 5 U/L as determined by the lowest concentration at which precision and accuracy are still met. Acceptable criteria ≤20% accuracy and ≤20% imprecision.

e. Analytical Specificity:

The effects of potential interferents were determined by calculating the mean value of the spiked interferent with the corresponding control solution.

Hemoglobin, Bilirubin, Triglycerides and Intralipid tested up to the following levels and were found not to interfere with the AST assay.

Table 12 **AST Interference Summary**

Interferent	AST @ 35 U/L
Hemoglobin	Interferes
Bilirubin (F)	60 mg/dl
Bilirubin (C)	60 mg/dl
Intralipid ®	500 mg/dl
Triglycerides	500 mg/dl

The analytes below were tested in serum up to the following levels and were found not to interfere with Sodium, Potassium and Chloride:

Table 13 **ISE Sodium, Potassium and Chloride Serum Interference Summary**

	Concentration		
Interferent	**Sodium @ 125 mmol/l**	**Potassium @ 2.95 mmol/l**	**Chloride @ 90 mmol/l**
Hemoglobin	500 mg/dl	* Interferes	750 mg/dl
Bilirubin (F)	60 mg/dl	60 mg/dl	30 mg/dl
Bilirubin (C)	60 mg/dl	60 mg/dl	60 mg/dl
Intralipid ®	2000 mg/dl	1500 mg/dl	2000 mg/dl
Triglycerides	2000 mg/dl	2000 mg/dl	2000 mg/dl

* Use non-hemolyzed samples as significant hemolysis will elevate AST and potassium levels.

A panel of drugs causes no significant interferences up to the indicated concentrations except Thyiocyanate and Salicylic acid which causes artificially elevated Chloride concentrations and Bromide which causes artificially elevated Chloride and Potassium concentrations.

Table 14 **ISE Sodium, Potassium and Chloride Serum Exogenous Interference Summary**

Interfering Substance	Concentration of interferent spiked into 140 mmol/l Sodium	Concentration of interferent spiked into 3.4 mmol/l Potassium	Concentration of interferent spiked into 108 mmol/l Chloride
Bromide	37.5mmol/L	Interference observed <9.38mmol/l	Interference observed <9.38mmol/l
Ascorbic Acid	342mmol/L	342mmol/L	342mmol/L
Thyiocyanate	6.88mmol/L	6.88mmol/L	Interference observed <1.72mmol/l
Lithium	3.2mmol/L	3.2mmol/L	3.2mmol/L
Salicylic Acid	4.34mmol/L	4.34mmol/L	Interference observed <1.085mmol/l

Urine Summary

The analytes below were tested in urine up to the following levels and were found not to interfere with Sodium, Potassium, and Chloride.

Table 15 **ISE Sodium, Potassium and Chloride Urine Interference Summary**

	Concentration		
Interferent	**Sodium @ 80 mmol/l**	**Potassium @ 21 mmol/l**	**Chloride @ 261 mmol/l**
Hemoglobin	500 mg/dl	500 mg/dl	750 mg/dl
Bilirubin (F)	60 mg/dl	60 mg/dl	30 mg/dl
Bilirubin (C)	30 mg/dl	60 mg/dl	45 mg/dl
Intralipid ®	2000 mg/dl	2000 mg/dl	1500 mg/dl
Triglycerides	2000 mg/dl	2000 mg/dl	2000 mg/dl

f. Method comparison with predicate device:

Correlation studies were carried out in accordance with C.L.S.I. guideline EP9-A2 'Method Comparison and Bias Estimation Using Patient Samples: Approved Guideline – Second Edition'.

AST:

92 serum patient samples spanning the range 5 to 817U/L were tested on the RX Daytona plus analyzer across 5 working days with each sample tested in singlicate. The test method was compared to the predicate device and the following linear regression equation was obtained:

$Y = 1.03x + 2.33$
Correlation coefficient of $r = 0.999$

Sodium: Serum

50 serum patient samples spanning the range 105 to 194mmol/l were tested on the RX Daytona plus analyzer across 5 working days with each sample tested in singlicate. The test method was compared to the predicate device and the following linear regression equation was obtained:

$Y = 1.04x - 9.57$
Correlation coefficient of $r = 0.990$

Sodium: Urine

42 urine patient samples spanning the range 54.9 to 288.5mmo/l were tested on the RX Daytona plus analyzer across 5 working days with each sample tested in singlicate. The test method was compared to the predicate device and the following linear regression equation was obtained:

$Y = 1.01x - 7.99$
Correlation coefficient of $r = 0.996$

Potassium: Serum

56 serum patient samples spanning the range 0.75 to 9.58mmol/l were tested on the RX Daytona plus analyzer across 5 working days with each sample tested in singlicate. The test method was compared to the predicate device and the following linear regression equation was obtained:

$Y = 1.02x - 0.13$

Correlation coefficient of $r = 0.997$

Potassium Urine

43 urine patient samples spanning the range 10.63 to 145.06mmo/l were tested on the RX Daytona plus analyzer across 5 working days with each sample tested in singlicate. The test method was compared to the predicate device and the following linear regression equation was obtained:

$Y = 1.04x - 1.48$

Correlation coefficient of $r = 0.999$

Chloride: Serum

61 serum patient samples spanning the range 81.3 to 189.3mmol/l were tested on the RX Daytona plus analyzer across 5 working days with each sample tested in singlicate. The test method was compared to the predicate device and the following linear regression equation was obtained:

$Y = 1.03x - 1.16$

Correlation coefficient of $r = 0.990$

Chloride: Urine

44 urine patient samples spanning the range 74.05 to 287.2mmo/l were tested on the RX Daytona plus analyzer across 5 working days with each sample tested in singlicate. The test method was compared to the predicate device and the following linear regression equation was obtained:

$Y = 0.97x + 5.08$

Correlation coefficient of $r = 0.997$

g. Expected values/Reference-range:

Referenced from literature

Reference intervals for the ISEs were verified using NCCLS C28-A2 guidelines. In a study, human serum from 30 normal donors were tested in singlicate on the RX daytona plus. The results obtained were ordered from lowest to highest before being examined for outliers using the Dixon test.
Upon confirmation there were no outliers, the values were compared to the quoted ranges for Sodium, Potassium and Chloride. Results of the study indicate that all values reported in the range for Healthy Individuals.

Analyte	Serum	Urine
AST[1]	Men-Up to 35 U/L; Women up to 31 U/L	N/A
Sodium (Na^+)[2]	136-145 mmol/l	40-220 mmol/24h
Potassium (K^+)[2]	3.5-5.1 mmol/l	25-125 mmol/24h
Chloride (Cl^-)[2]	98-107 mmol/l	110-250 mmol/24h

[1]Schumann G, Klauke R. New IFCC reference procedures for the determination of catalytic activity concentrations of five enzymes in serum; preliminary upper reference limits obtained in hospitalized subjects. Clin Chem Acta 2003; 327 (1-2) 69-79.

[2]Tietz NW, Pruden EL, Siggaard-Andersen O. Electrolytes. In: Burtis CA, Ashwood ER, eds. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia: WB Saunders 1994:1354-1374.

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

10. CONCLUSION

Testing results indicate that the proposed devices (RX Daytona Plus analyzer and Daytona Plus AST reagent) are safe and effective for the stated intended use and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 9, 2014

RANDOX LABORATORIES, LTD.
DR. PAULINE ARMSTRONG, QA/RA MANAGER
55 DIAMOND RD.
CRUMLIN, COUNTY ANTRIM BT29 4QY
UK

Re: K131554
Trade/Device Name: RX Daytona Plus Chemistry Analyzer, RX Daytona Plus Aspartate Aminotransferase (AST) Reagent
Regulation Number: 21 CFR 862.1100
Regulation Name: Aspartate amino transferase (AST/SGOT) test system
Regulatory Class: II
Product Code: CIT, JGS, CEM, CGZ, JJE
Dated: November 29, 2013
Received: November 30, 2013

Dear Ms. Armstrong:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

k131554

Device Name
RX Daytona Plus Chemistry analyzer
RX Daytona Plus Aspartate Aminotransferase (AST) reagent

Indications for Use *(Describe)*

The RX Daytona Plus Chemistry analyzer is a bench top fully automated random access clinical chemistry analyzer intended for use in clinical laboratories. It is intended to be used for a variety of assay methods. The RX Daytona Plus includes an optional Ion Selective Electrode (ISE) module for the measurement of sodium, potassium and chloride in serum and urine. The RX Daytona Plus is not for Point-Of-Care testing.

Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance.

Potassium measurements 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.

The RX Daytona Plus AST reagent is for the quantitative in vitro diagnostic determination of the activity of the enzyme Aspartate aminotransferase (AST) in human serum. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart diseases.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

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