

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

510(k) Number:

k024014

Analyte:

Glucose, Sodium, Potassium, and Chloride

Type of Test:

Quantitative / Enzymatic Photometric, ISE

Applicant:

RANDOX LABORATORIES, LTD.

Proprietary and Established Names:

RANDOX RX DAYTONA

Regulatory Information:

1. Regulation section:
21CFR§-862.2170 Micro chemistry analyzer for clinical use.
21CFR§-862.1345 Glucose test system.
21CFR§-862.1665 Sodium test system.
21CFR§-862.1600 Potassium test system.
21CFR§-862.1170 Chloride test system.
21CFR§-862.1150 Calibrator.
2. Classification:
1, II
3. Product Code:
JJF, CGA, JGS, CEM, CGZ, JIX
4. Panel:
Chemistry (75)

Intended Use:

5. Indication(s) for use:
The RX Daytona is an automated clinical chemistry analyzer complete with dedicated analyzer software. Software functions of the analyzer include the facility to interact with a host computer for direct download of test method selection details for individual samples. A barcode system is used for the rapid identification of patient samples, reagents and QC samples.

The analyzer can be used to run tests including glucose in serum samples. Various other assays are adaptable to the analyzer. Glucose measurements may be used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and pancreatic islet cell carcinoma.

An Ion Selective Electrode (ISE) unit is an optional addition, which may be used with the RX Daytona Analyzer for the measurement of the electrolytes sodium, potassium and chloride in serum, plasma or urine. The ISE unit consists of ion selective electrodes, supply and drain pump, preamplifier board and I/O board.

Sodium measurements may be used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases characterized by low or high levels of potassium. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

The RX Daytona analyzer and ISE unit must only be used by suitably qualified personnel, under appropriate laboratory conditions.

For in vitro diagnostic use only.

6. Special condition for use statement(s):
Not Applicable
7. Special instrument Requirements:
RX Daytona Analyzer

Device Description

The RX Daytona analyzer is an automated clinical chemistry analyzer capable of performing various in vitro photometric assays. The RANDOX GLUCOSE (GOD/PAP) was cleared under K003346 and is the chosen assay to demonstrate performance for the photometric unit. ISE unit measures sodium, potassium and chloride utilizing ion electrode technology.

Substantial Equivalence Information:

8. Predicate device name(s):
HITACHI 717 CHEMISTRY ANALYZER
RANDOX GLUCOSE (GOD/PAP)
Olympus AU600
9. Predicate K number(s):
K872494
K003346
K961274
3. Comparison with predicate:
Both the Rx Daytona and the predicate Hitachi 717 analyzer are random access photometric and ISE analyzers. The intended uses, assay types, calibration types, calibration system, sample types and automation technology of the devices are similar. Minor differences not affecting safety and effectiveness are throughput, sample input, reagent system capacity,

reagent range volume, number of wavelengths. The ISE unit and the predicate AU 600 ISE unit are both optional additions that may be used with the analyzer for the measurement of sodium, potassium and chloride utilizing the same technology. Minor differences not affecting safety and effectiveness are throughput, sample size, and range of measurement.

Standard/Guidance Document Referenced (if applicable):

None referenced

Test Principle:

For Glucose the RANDOX GLUCOSE (GOD/PAP) was cleared under K003346, details of this test principle can be found in that file. Ion Selective Electrodes are used to measure Sodium, Potassium and Chloride. The ISE module consists of a reference electrode, and three ion selective electrodes. The potential generated by the Sodium, Potassium and Chloride electrodes is compared to that of the reference electrode and used to calculate the concentration of Na⁺, K⁺ and Cl⁻ ions in the sample.

Performance Characteristics (if/when applicable):

4. Analytical performance:

a. *Precision/Reproducibility:*

| Intra Assay Precision | | | |
|-----------------------|------------------|------------------|------------------|
| Glucose | Level 1 (mmol/l) | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | 1.695 | 5.77 | 16.795 |
| SD | 0.076 | 0.113 | 0.375 |
| %CV | 4.48 | 1.96 | 2.23 |
| N | 20 | 20 | 20 |
| Inter Assay Precision | | | |
| Glucose | Level 1 (mmol/l) | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | 1.87 | 4.875 | 16.01 |
| SD | 0.066 | 0.286 | 0.588 |
| %CV | 3.51 | 5.87 | 3.67 |
| N | 20 | 20 | 20 |
| Intra Assay Precision | | | |
| Na ⁺ | | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | | 136.9 | 150.75 |
| SD | | 1.021 | 0.786 |
| %CV | | 0.75 | 0.52 |
| N | | 20 | 20 |
| Inter Assay Precision | | | |
| Na ⁺ | | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | | 140 | 154 |
| SD | | 1.792 | 1.386 |
| %CV | | 1.28 | 0.90 |
| N | | 20 | 20 |
| Intra Assay Precision | | | |

| | | | |
|-----------------------|------------------|------------------|------------------|
| K+ | | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | | 3.958 | 5.7775 |
| SD | | 0.021 | 0.022 |
| %CV | | 0.54 | 0.39 |
| N | | 20 | 20 |
| Inter Assay Precision | | | |
| K+ | | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | | 4.11 | 5.96 |
| SD | | 0.067 | 0.085 |
| %CV | | 1.63 | 1.43 |
| N | | 20 | 20 |
| Intra Assay Precision | | | |
| Cl- | | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | | 100.45 | 114.05 |
| SD | | 0.826 | 0.605 |
| %CV | | 0.82 | 0.53 |
| N | | 20 | 20 |
| Inter Assay Precision | | | |
| Cl- | | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | | 98.1 | 113 |
| SD | | 0.999 | 1.102 |
| %CV | | 1.02 | 0.97 |
| N | | 20 | 20 |
| Intra Assay Precision | | | |
| Urine Na+ | Level 1 (mmol/l) | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | 32.35 | 82.4 | 197.4 |
| SD | 0.813 | 0.821 | 1.635 |
| %CV | 2.51 | 1.00 | 0.83 |
| N | 20 | 20 | 20 |
| Inter Assay Precision | | | |
| Urine Na+ | | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | | 74.78571429 | 187.2571429 |
| SD | | 3.017 | 5.773 |
| %CV | | 4.03 | 3.08 |
| N | | 14 | 14 |
| Intra Assay Precision | | | |
| Urine K+ | Level 1 (mmol/l) | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | 18.263 | 55.445 | 107.3115 |
| SD | 0.251 | 0.562 | 1.024 |
| %CV | 1.37 | 1.01 | 0.95 |
| N | 20 | 20 | 20 |
| Inter Assay Precision | | | |
| Urine K+ | | Level 2 (mmol/l) | Level 3 (mmol/l) |

| | | | |
|-----------------------|------------------|------------------|------------------|
| Mean | | 54.29 | 107.0028571 |
| SD | | 0.935 | 1.843 |
| %CV | | 1.72 | 1.72 |
| N | | 14 | 14 |
| Intra Assay Precision | | | |
| Urine Cl- | Level 1 (mmol/l) | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | 54.55 | 124.5 | 275.05 |
| SD | 0.945 | 1.051 | 2.305 |
| %CV | 1.73 | 0.84 | 0.84 |
| N | 20 | 20 | 20 |
| Inter Assay Precision | | | |
| Urine Cl- | Level 1 (mmol/l) | Level 2 (mmol/l) | Level 3 (mmol/l) |
| Mean | | 114.4285714 | 264.3571429 |
| SD | | 3.228 | 4.517 |
| %CV | | 2.82 | 1.71 |
| N | | 14 | 14 |

b. Linearity/assay reportable range:

Glucose up to 450 mg/dl

| | Serum | Urine |
|-------|--------|---------|
| Na+ - | 20-200 | 20-1000 |
| K+ - | 0.2-20 | 1-50 |
| Cl- - | 25-200 | 20-500 |

c. Traceability (controls, calibrators, or method):

Not Applicable - previously cleared

d. Detection limit:

Glucose - 0.52 mg/dl

Na+K+Cl- see reportable range.

e. Analytical specificity:

Glucose - No interference up to

10 g/L Hgb

240 umol/L bili.

800 mg/dl Lipids

Na+K+ and Cl- No interference up to

10 g/L Hgb

25 mg/dl

800 mg/dl Lipids

f. Assay cut-off:

Not Applicable

5. Comparison studies:

a. Method comparison with predicate device:

Glucose $Y=1.0418X - 0.1507 / R^2= 0.9903 / N=40$

Na+ $Y=0.91X+8.60 / R^2=0.99 / N=91$

K+ $Y=0.97X+0.09 / R^2=0.99 / N=73$

Cl- $Y=0.98X-0.27 / R^2=0.99 / N=84$

b. Matrix comparison:

Glucose - Not Applicable

Urine Na+ $Y=1.00X+4.43 / R^2=1.00 / N=68$

Urine K+ $Y=1.02X-1.07 / R^2=1.00 / N=59$

Urine Cl- $Y=0.96X+6.09 / R^2=0.96 / N=60$

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:

Glucose = 75-115 mg/dl

Na+ =136-146

K+ =3.5-5.1

Cl- =97-107

from literature

Instrument Name:

RANDOX RX DAYTONA

System Descriptions:

1. Modes of Operation:

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. Sample Identification:

Bar Code, Normal Sample presentation

4. Specimen Sampling and Handling:

Random Access and Stat modes

5. Assay Types:

Rate, End Point (one or two read points)

6. Reaction Types:

Photometric, ISE

7. Calibration:

- Factor (Conc. = $K[\text{factor}]A[\text{absorbance}] + B[\text{initial concentration of corrected zero}]$)
- Single calibrator with auto dilution of highest calibrator or multi calibrator
 - Linear
 - Point to point
 - Log-Logit

- Spline
- Exponential
- ISE (reference electrode)

8. Quality Control:

Instrument contains a QC database that capable of storing up to 6 months of results. The user can view raw data and graphs for a period of 31 days for each test method. The software offers the facility to view up to three levels of QC data.

QC options also allow displays for 3 – month period and uses standard QC parameters and Westgard Rules.

Other Supportive Instrument Performance Characteristics Data Not Covered In The “L. Performance Characteristics” Section Of The SE Determination Decision Summary.

Conclusion:

The information and data provided by RANDOX LABORATORIES, LTD. supports a Substantial Equivalence (SE) determination to other 21CFR§-862.1345 Glucose test system, 21CFR§-862.1665 Sodium test system, 21CFR§-862.1600 Potassium test system, 21CFR§-862.1170 Chloride test system for use on ANALYZER, CHEMISTRY, MICRO, FOR CLINICAL USE regulated under 21 CFR §862.2170 - Micro chemistry analyzer for clinical use.