510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k043267

B. Purpose for Submission:

Notification of intent to manufacture and market the device: Potassium test kit and calibrator 1 and 2

C. Measurand:

Potassium

D. Type of Test:

Quantitative

E. Applicant:

Randox Laboratories

F. Proprietary and Established Names:

Proprietary – Randox Potassium; Established – Potassium

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1600 (Potassium) and 21 CFR 862.1150 (calibrator)

2. Classification:

   Class 2

3. Product code:

   CEJ (Potassium) and JIT (Calibrator)

4. Panel:

75 Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Randox Potassium Test Kit: The Randox Laboratories Ltd. Potassium Test Kit is an in vitro diagnostic quantitative determination of Potassium in serum. Potassium is determined enzymatically via Potassium dependant pyruvate kinase activity using phosphoenolpyruvate as substrate. The pyruvate formed reacts with NADH in the presence of LDH to form lactate and NAD. The corresponding decrease in absorbance at 340nm is proportional to the Potassium concentration.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

This application sheet has been developed for the Hitachi 704, 717, 902, and 911/912 Analyzers and must be used by suitable qualified laboratory personnel under appropriate laboratory conditions.

Randox Electrolyte Calibrator 1 and 2: Randox Electrolyte Calibrator 1 and 2 are liquid calibrators for in vitro diagnostic use in the calibration of NA^{+}, K^{+}, and Cl^{-} electrodes on the Hitachi systems ISE modules and Randox Enzymatic Potassium kit.

The Randox Electrolyte Calibrator 1 and 2 must only be used by suitable qualified laboratory personnel under appropriate laboratory conditions.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

The Randox Potassium Test kit and calibrators are developed for the Hitachi 704, 717, 902, and 911/912 Analyzers.

I. Device Description:

The Randox Laboratories Ltd. Potassium Test Kit is an in vitro diagnostic quantitative determination of Potassium in serum. The test kit comprises two reagent pack components: Reagent 1 is buffer and Enzyme substrate, Reagent 2 is diluent and Enzyme. Prior to loading the reagent onto the instrument, the reagent components are mixed according to directions. The test kit is also comprised of two calibrators labeled Calibrator 1 and Calibrator 2 which are composed of aqueous solutions containing electrolyte salts, sodium chloride, potassium chloride and preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Olympus ISE Potassium

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

k961274

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Matrix	Serum	Plasma, serum, urine
Calibration	2 point serum Calibration	2 point serum Calibration

Differences		
Item	Device	Predicate
Stability	Stable 2 weeks at 2^{o} to 8^{o}C or 5 days at 15^{o} to 25^{o}C	Once opened, stable 90 days at 15^{o} to 25^{o}C
Test Method	Enzymatic	Ion Selective Electrode

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

No Standard or Guidance Document was referenced in this submission.

L. Test Principle:

The Randox Laboratories Ltd. Potassium Test Kit is an enzymatic assay.

Potassium is determined enzymatically via Potassium dependant pyruvate kinase activity using phosphoenolpyruvate as substrate. The pyruvate formed reacts with NADH in the presence of LDH to form lactate and NAD. The corresponding decrease in absorbance at 340nm is proportional to the potassium concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Intra assay precision was determined on the Hitachi 717 by testing 20 of at least 2 different control sera or patient samples in one assay. Where possible, control sera or patient sample within normal range and at the decision making level were used. Acceptance criterion: %CV ≤ 7.5. The value may vary depending upon analyte concentration and analyzer used.

Intra Assay Precision

	Level 1	Level 2	Level 3
Mean (mmol/L)	3.4	4.5	7.1
SD	0.07	0.09	0.11
CV (%)	1.96	1.94	1.54
n	20	20	20

Inter assay precision was determined on the Hitachi 717 by testing 20 of at least 2 different control sera or patient samples in one assay. Where possible, control sera or patient sample within normal range and at the decision making level were used. Acceptance criteria: %CV ≤ 10. The value may vary depending upon analyte concentration and analyzer used.

Inter Assay Precision

	Level 1	Level 2	Level 3
Mean (mmol/L)	3.2	4.4	6.8
SD	0.08	0.15	0.23
CV (%)	2.4	3.4	3.4
n	20	20	20

b. Linearity/assay reportable range:

The reportable range of the test kit is based on the sensitivity (lower detection limit) and the linearity of the method.

To establish the range of an assay, where the reported result is a linear function of the analyte concentration, serial dilutions of a suitable control are tested and the observed value is compared to the known expected or

calculated expected result. Percentage deviations are calculated. The linearity claim is based on a percentage deviation of ≤5% at the 2 highest analyte concentrations.

This method is linear on the Hitachi 717 between potassium concentrations of 2 and 10 mmol/L (7.8 – 39.0 mg/dL)

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

Calibrator values are assigned from internal testing at Randox Laboratories Ltd and compared to a master lot stored at -80^{o}C.

Calibrator materials are stable until the expiration date when stored at 2 to 25°C.

d. *Detection limit:*

The minimum detectable concentration of potassium with an acceptable level of precision was 0.8 mmo/L. The acceptance criterion of ≤ 20% was met when assaying a sample on the Hitachi 717 ten times in one run. The observed %CV was 3.84%.

e. *Analytical specificity:*

The following analytes were tested up to the following levels and found not to interfere < 5% when using the Hitachi 717:

Bilirubin	665 µmol/L
Hemoglobin	1 g/L
Triglycerides	24.2 mmol/L

f. *Assay cut-off:* N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

A comparison of 40 samples, ranging in concentration from 3.9 to 6.6 mmol/L, is made using the Randox method on the Hitachi 717 and a comparable, commercially available test kit – the Predicate Device. The results obtained are correlated using least – squares regression analysis. The regression equation and correlation coefficient, r, are quoted along with the number and range of samples tested.

The resulting regression equation was: $Y= 0.96X + 0.229$, $R^2 = 0.9533$.

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

The labeling includes reference ranges that are cited from those quoted in the appropriate literature. A warning statement accompanies all reference ranges to indicate that they are provided for guidance only and that individual laboratories are advised to establish the own reference range to reflect the age, sex, diet, and geographical location of the specific population encountered in the daily course of laboratory operation. The values provided in the labeling are 3.5 – 5.1 mmol/L.

N. Proposed Labeling:

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

O. Conclusion:

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