

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

A. 510(k) Number:

k043268

B. Purpose for Submission:

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

C. Measurand:

Sodium

D. Type of Test:

Quantitative Enzymatic

E. Applicant:

Radox Laboratories Ltd.

F. Proprietary and Established Names:

Proprietary – Radox Sodium; Established – sodium

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1665 (Sodium) and 21 CFR 862.1150 (calibrator)

2. Classification:

Class 2

3. Product code:

CEI (Sodium) 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 Sodium Test Kit: The Randox Laboratories Ltd. Sodium Test Kit is an in vitro diagnostic reagent for the quantitative determination of Sodium in serum. Sodium is determined enzymatically via Sodium dependant β -galactosidase activity with ONPG (o-nitrophenyl- β -D-galactopyranose) as substrate. The absorbance at 405nm of the product O-nitrophenyl is proportional to the sodium concentration.

Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hyper-tension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

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 Sodium 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 only

4. Special instrument requirements:

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

I. Device Description:

The Randox Laboratories Ltd. Sodium Test Kit is an in vitro diagnostic reagent for the quantitative determination of Sodium 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 containing Sodium Chloride, Potassium Chloride and preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Olympus ISE Sodium

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° to 8°C or 5 days at 15° to 25°C	Once opened, stable 90 days at 15° to 25°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:

This is an enzymatic method via sodium dependant β -galactosidase activity with ONPG as substrate. Assay is calibrated via a two point calibration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

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

	Level 1	Level 2	Level 3
Mean (mmol/L)	125	142	159
SD	1.23	1.39	1.73
CV (%)	0.98	0.98	1.09
N	20	20	20

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

	Level 1	Level 2	Level 3
Mean (mmol/L)	130	149	166
SD	2.89	2.29	2.36
CV (%)	2.23	1.54	1.42
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. The method is linear for sodium values between 80 and 180 mmol/L.

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 were tested and the observed value is compared to the known expected or calculated expected result. Percentage deviations were calculated. The linearity claim is based on a percentage deviation of $\leq 5\%$ at the 2 highest analyte concentrations. The samples tested ranged in concentration from 52 to 199 mmol/L.

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°C .

The calibrator materials are stable until the printed expiration date when stored at 2 to 5 $^{\circ}\text{C}$.

d. Detection limit:

The minimum detectable concentration of sodium with an acceptable level of precision, $\leq 20\%$ was 58 mmol/L. This value was determined by testing 10 replicates of a sample targeted at 51 mmol/L.

e. Analytical specificity:

The following analytes were tested up to the following levels and found not to interfere more than 10% or less than 10% at a sodium concentration of 169 mmol/L.:

Bilirubin	665.125 $\mu\text{mol/L}$
Hemoglobin	10g/L
Triglycerides	13.185 mmol/L

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

A comparison of 70 samples, ranging in concentration from <80 to 157 mmol/L, was performed using the Randox method 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 results obtained yielded a linear regression equation of $Y = 0.94X + 5.75$, $r = 0.99$.

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 expected values stated in package insert are 136 to 146 mmol/L. These ranges are cited from those quoted in the appropriate literature. A warning statement accompanies the 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.

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.