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

A. 510(k) Number:

k110904

B. Purpose for Submission:

New device

C. Measurand:

Urine quality control materials containing the following: amylase, calcium, chloride, cortisol, creatinine, glucose, hCG, magnesium, microalbumin, osmolality, pH, inorganic phosphorus, potassium, total protein, sodium, specific gravity, urea, and uric acid.

D. Type of Test:

Not applicable

E. Applicant:

Randox Laboratories, Ltd.

F. Proprietary and Established Names:

Randox Liquid Urine Controls, Level 2 and Level 3

G. Regulatory Information:

1. Regulation section:

   21 § 862.1660

2. Classification:

   Class I, reserved

3. Product code:

   JJY

4. Panel:

   75, Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Randox Liquid Urine Controls Level 2 and Level 3 are liquid controls containing amylase, calcium, chloride, cortisol, creatinine, glucose, hCG pregnancy, magnesium, microalbumin, osmolality, pH, inorganic phosphate, potassium, total protein, sodium, specific gravity, urea, and uric acid. They have been developed for in vitro diagnostic use in the quality control of amylase, calcium, chloride, cortisol, creatinine, glucose, hCG pregnancy, magnesium, microalbumin, osmolality, pH, inorganic phosphate, potassium, total protein, sodium, specific gravity, urea, and uric acid assays on various clinical chemistry systems. This in vitro diagnostic device is intended for prescription use only.

3. Special conditions for use statement(s):

   The labeling contains a statement that all human source material was tested by FDA-approved methods and found to be non-reactive for the presence of HBsAg, HCV and antibody to HIV 1/2.

   In-vitro diagnostic use. Prescription use.

4. Special instrument requirements:

   Performance was evaluated on the following instrument systems: Abbott Architect c/ci systems, Beckman Coulter AU400/500/600/800, Beckman CX4/5/7/9/LX20/DxC600/800, Cobas Integra 400/800, Hitachi Series 717/7150/ 902/904/911/912/917, Johnson and Johnson Ortho Vitros 250/350/500/700/950/5.1FS, Roche Cobas 6000/c501/e601, Siemens Advia 1200/1650/2400, Siemens/Dade Dimension RxL/Max/Xpand, pH meter, freezing point depression osmometers.

I. Device Description:

The Randox Liquid Urine Controls Level 2 and Level 3 are ready-to-use, liquid controls derived from human urine. The source material has been tested by FDA approved methods and found non-reactive for Hepatitis B surface antigen, Hepatitis C and the antibody to HIV-1 and HIV-2. Each control level is purchased separately and

is packaged in 10x10 mL bottles intended to be stored at 2-8°C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   BioRad Liquichek Urine Chemistry Control, Levels 1 and Level 2

2. Predicate K number(s):

   k020817

3. Comparison with predicate:

Comparison Table		
Characteristics	Device	Predicate k020817
Intended use	Intended for in vitro diagnostic use in the quality control of diagnostic assays	Same
Matrix	Human urine	Same
Format	Liquid	Same
Vial size	10 mL	Same
Storage (unopened)	2-8°C	Same
Open vial stability	30 days at 2-8°C	Same
Shipping temperatures	2-8°C	Same
Analytes	amylase, calcium, chloride, cortisol, creatinine, glucose, hCG pregnancy, magnesium, microalbumin, osmolality, pH, inorganic phosphate, potassium, total protein, sodium, specific gravity, urea, and uric acid.	amylase, calcium, chloride, cortisol, creatinine, glucose, magnesium, microalbumin, osmolality, pH, inorganic phosphate, potassium, total protein, sodium, specific gravity, urea, urea nitrogen, and uric acid.

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

None were referenced

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Not applicable.

   b. Linearity/assay reportable range:

   Not applicable.

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

   Traceability and Value Assignment: Control solutions are derived from gravimetrically prepared stock solutions and analyzed in-house. Value assignment was determined through multiple analyses in- house on instrumentation calibrated with a master lot of calibrator. Control values were also confirmed in external studies with 9 different instrument families in 203 laboratories. Assigned control ranges are listed in the labeling by instrument family and analyte methods.

   Stability: Real time stability studies were conducted for closed and open vials. Shelf-Life and Open Vial Stability testing protocols and acceptance criteria were described and found to be adequate.
   Shelf-Life – The sponsor provided real time stability data demonstrating that the Randox Liquid Urine Controls, Levels 2 and 3, can be stored for 2 years at 2-8 °C.
   Open-vial – The sponsor provided data demonstrating that upon opening a vial, the material is stable for 30 days at 2-8 °C.

   d. Detection limit:

   Not applicable.

   e. Analytical specificity:

   Not applicable.

   f. Assay cut-off:

   Not applicable.

2. Comparison studies:

   a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

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:

Expected values are provided in the value assignment sheets provided with the package insert.

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.