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

A. 510(k) Number:

k110846

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for multiple constituents in urine: glucose, bilirubin, ketones, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes, hCG, microalbumin, creatinine, galactose, red blood cells, white blood cells, and crystals

D. Type of Test:

Qualitative and semi-quantitative urinalysis controls for urinalysis reagent test strips, tablet tests, and manual cell counts with hemocytometer

E. Applicant:

Randox Laboratories Limited

F. Proprietary and Established Names:

Randox Liquid Urinalysis Controls, Level 1 and Level 2

G. Regulatory Information:

1. Regulation section:

   862.1660, Quality control material, (assayed, and unassayed)

2. Classification:

   I, reserved

3. Product code:

   JJW

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

   See below

2. Indication(s) for use:

   The Randox Urinalysis Controls (URNAL Control 1 and URNAL Control 2) are urine controls containing Bilirubin, Blood, Creatinine, Crystals, Galactose, Glucose, hCG, Ketones, Leukocytes, Microalbumin, Nitrite, pH, Protein, Red Blood Cells, Specific Gravity, Urobilinogen and White Blood Cells. The Randox Urinalysis controls (URNAL Control 1 and URNAL Control 2) are intended for in vitro diagnostic use in the quality control of urine test strips for the analytes; Bilirubin, Blood, Creatinine, Glucose, Ketones, Leukocytes, Microalbumin, Nitrite, pH, Protein, Specific Gravity and Urobilinogen. This control is also intended for the evaluation of microscopic test procedures for Crystals, Red Blood Cells and White Blood Cells and also for the confirmatory tests hCG and Galactose. 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:

   For use with the urine analyzers listed in the labeling.

I. Device Description:

The Randox Urinalysis Controls URNAL Control 1 and URNAL Control 2 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 12x12 mL bottles intended to be stored at 2-8°C.

J. Substantial Equivalence Information:

1. Predicate Device Name	2. 510(k)
Quantimetrix Urine Dipstick Control	k874890
Quantimetrix Urinalysis Microscopics Control	k925256

3. Comparison with predicate:

COMPARISON OF RANDOX URINALYSIS CONTROLS WITH THE PREDICATE DEVICE

CHARACTERISTICS	RANDOX URINALYSIS CONTROLS LEVELS 1 & 2	QUANTIMETRIX URINALYSIS MICROSCOPICS CONTROL k925256	QUANTIMETRIX URINE DIPSTICK CONTROL k874890
INTENDED USE	The Randox Urinalysis Controls Level 1 and 2 are intended for in vitro diagnostic use in the quality control of the urinalysis test	Same	Same
TYPE OF TEST	Reagent strip, sediment examination, confirmatory tests	Sediment examination	Reagent strip, confirmatory tests
SIZE	12ml	120ml	120ml
FORMAT	Liquid	Liquid	Liquid
MATRIX	Human Urine	Human Urine	Human Urine
STORAGE (Unopened)	2 to 8^{o}C until expiration date	2 to 8^{o}C until expiration date	2 to 8^{o}C until expiration date
OPEN VIAL CLAIM	30 days at 2^{o}C to 25^{o}C	2 to 8^{o}C until expiration date	2 to 8^{o}C until expiration date
SHIPPING TEMPERATURE	2 to 8^{o}C	2 to 8^{o}C	2 to 8^{o}C
ANALYTES	Bilirubin, Blood, Creatinine, Crystals, Galactose, Glucose, hCG, Ketones, Leukocytes, Microalbumin, Nitrite, pH, Protein, Red Blood Cells,	Red Blood Cells, White Blood Cells, Casts, Crystals and Bacteria	Glucose, Bilirubin, Ketones, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes, Microalbumin, Creatinine, Total protein

	Specific Gravity, Urobilinogen and White Blood Cells		

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 for visual reading and on instrumentation. Urinalysis instrumentation calibration is factory preset. Control values are confirmed in external studies with 5 different instrument families in 113 laboratories. Assigned control ranges are listed in the labeling by manufacturer and method.

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 to demonstrate that the Randox Urinalysis Controls, Levels 1 and 2, can be stored for 18 months 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:

Not applicable

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.