

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

A. 510(k) Number:

k043266

B. Purpose for Submission:

Notification of intent to manufacture and market the device: Urine Control Level 2 and Level 3

C. Measurand:

Calcium, Chloride, Creatinine, Glucose, Magnesium, Osmolality, Phosphorus, Potassium, Sodium, Urinary Protein, Urea, Uric Acid.

D. Type of Test:

Quality Control Material

E. Applicant:

Randox Laboratories

F. Proprietary and Established Names:

Proprietary – Randox Urine Controls assayed and unassayed. Established – Urinalysis Controls assayed and unassayed.

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660

2. Classification:

Class I (reserved)

3. Product code:

JJW

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Randox Laboratories Ltd. Urine Controls are based on lyophilized human and have been developed for the control of both accuracy and precision in clinical chemistry applications, particularly urine analysis. These control materials are available at two constituent concentrations.

The Randox Assayed and Unassayed Urine Controls should only be used by suitably qualified personnel under appropriate laboratory conditions.

3. Special conditions for use statement(s):

The Randox Assayed and Unassayed Urine Controls should only be used by suitably qualified personnel under appropriate laboratory conditions.

4. Special instrument requirements:

Not Applicable

I. Device Description:

The Randox Laboratories Urine Controls are supplied at 2 levels, level 2 and level 3. Each bottle contains lyophilized human serum and urine and bovine hemoglobin and is reconstituted in 10ml of distilled water. Target ranges are supplied for the following analytes at both levels; calcium, copper, chloride, cortisol, Creatinine, dopamine, epinephrine, glucose, 5 hydroxy indole acetic acid, magnesium, metanephrine, microalbumin, norepinephrine, normetanephrine, Osmolality, oxalate, phosphorus inorganic, potassium, total protein, sodium, urea, uric acid and vanillylmandelic acid.

Human source material from which this product has been derived has been tested at the donor level for the Human Immunodeficient Virus (HIV1, HIV2) antibody, Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus (HCV) and found to be non-reactive. FDA approved methods have been used to conduct these tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Lyphochek Quantitative Urine Control Normal and Abnormal

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

Urine control 2 – k880495

Urine control 3 – k880496

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Matrix	Lyophilized human urine with spiked constituents	Lyophilized human urine with spiked constituents
Control values	Assayed and unassayed	Assayed and unassayed
Shelf life	Reconstituted urine is stable at +25°C and 5 days at +4°C if capped in original container and free from contamination or 14 days at -20°C.	Reconstituted urine is stable at +25°C and 5 days at +4°C if capped in original container and free from contamination or 14 days at -20°C.

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

Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material

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):

Concentrations of each analytes are spiked into the control solution to meet target range of each analyte.

Each control level is submitted to 400 laboratories and the controls are tested on a range of different clinical chemistry/immunoassay analyzers. After testing the data are returned to Randox Laboratories Ltd. A summary of the method means is prepared. From these data the target value is assigned and the range calculated (usually ± 2 S.D. from the target mean.)

Shelf life has been set on stressed data. Reconstituted and frozen stability data is supplied for both assayed and unassayed controls. Vials should be refrigerated at $2 - 8^{\circ}\text{C}$. Reconstituted urine is stable at $+25^{\circ}\text{C}$ and 5 days at $+4^{\circ}\text{C}$ if capped in original container and free from contamination or 14 days at -20°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.