

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

A. 510(k) Number:

k110534

B. Purpose for Submission:

New device

C. Measurand:

Multi-analyte quality control materials

D. Type of Test:

Not applicable.

E. Applicant:

Radox Laboratories Limited

F. Proprietary and Established Names:

Radox Liquid Cardiac Control Levels 1, 2, and 3

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

Class I, reserved

3. Product code:

JJY - Multi-Analyte Control

4. Panel:

75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

The Randox Liquid Cardiac Controls Level 1, Level 2, and Level 3 are liquid controls containing BNP, CK MB Mass, Digoxin, D-Dimer, Homocysteine, hsCRP, Myoglobin, NT-ProBNP, Troponin I, and Troponin T. They have been developed for use in the quality control of BNP, CK MB Mass, Digoxin, D-Dimer, Homocysteine, hsCRP, Myoglobin, NT-ProBNP, Troponin I, and Troponin T assays on various clinical chemistry and immunoassay systems. This *in vitro* diagnostic device is intended for prescription use only.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use. For prescription use only.

4. Special instrument requirements:

Values are listed in the package insert for several analyzers.

I. Device Description:

The Randox Liquid Cardiac Controls are prepared from human plasma, human serum, and human proteins. The controls contain the following analytes: BNP, CK MB Mass, Digoxin, D-Dimer, Homocysteine, hsCRP, Myoglobin, NT-ProBNP, Troponin I, and Troponin T. The product consists of three levels. Sodium azide is present as a preservative.

Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NONREACTIVE. FDA approved methods have been used to conduct these tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Liquicheck Cardiac Markers Plus Controls

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

k050537

3. Comparison with predicate:

Item	Device (k110534)	Predicate (k050537)
Indications for use	For use as a quality control material in clinical chemistry assays.	Same
Format	Liquid, ready for use	Same
Matrix	Human serum and plasma	Human serum
Analytes	BNP, CK MB Mass, Digoxin, D-Dimer, Homocysteine, hsCRP, Myoglobin, NT-ProBNP, Troponin I, and Troponin T	BNP, Creatine Kinase (Total), CRP, Homocysteine, Digitoxin, NT-proBNP, CKMB, Myoglobin, Troponin I, Troponin T
Stability	<u>Unopened</u> Store at 2-8°C until expiration date <u>Opened</u> 2-8°C for 30 days	<u>Unopened</u> Store at -20 to -70°C until expiration date <u>Opened</u> 2-8°C for 20 days
Levels	3	Same

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

None were referenced in the submission.

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):*

Expected values for the Randox Liquid Cardiac Controls are determined by repeat analyses at a minimum of three laboratory sites for each control level. Pre-determined acceptance criteria for analyte recovery must be met for each control lot. Control assigned values are lot dependent and are listed in the lot-specific Cardiac Control value sheet.

Stability

Stability testing protocols and acceptance criteria for the Randox Liquid Cardiac Controls were reviewed and found acceptable. The manufacturer claims an open vial stability of 30 days and a shelf life stability of 24 months at the recommended storage temperatures of 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:

The expected values are provided in the labeling for each specific lot.

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.