

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

A. 510(k) Number:

k121603

B. Purpose for Submission:

New device

C. Measurand:

Multi-analyte control materials (calcitonin, gastrin, procalcitonin)

D. Type of Test:

Not applicable

E. Applicant:

Radox Laboratories Limited

F. Proprietary and Established Names:

Radox Immunoassay Speciality Control (II) 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

4. Panel:

Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Randox Immunoassay Speciality Control (II), Level 1, Level 2, Level 3 are intended for in vitro diagnostic use as assayed quality control material for Calcitonin, Gastrin, and Procalcitonin to monitor the precision of the laboratory testing systems listed in the package insert. 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:

Randox Immunoassay Speciality Control (II) is manufactured at three levels, Level 1, Level 2 and Level 3. Each control is prepared from human serum with added constituents of human origin, chemicals, stabilizers and preservatives. They are supplied in lyophilized form in 5x1ml vials and require reconstitution with 1ml of distilled water.

Human source material from which this product has been derived and has been tested at the donor level for the Human Immunodeficiency Virus (HIV1 & HIV2) antibody, Hepatitis B surface antigen (HbsAg) and the Hepatitis C virus (HCV) antibody and were found to be non-reactive based on FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Biorad Lyphochek^R Immunoassay Plus Control Levels 1, 2 and 3

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

k981532

3. Comparison with predicate:

Similarities and Differences		
Item	Device	Predicate
	Randox Speciality Immunoassay Control (II) Levels 1, 2 and 3	BIO-RAD Lyphocheck ^R Immunoassay Plus Control Levels 1, 2 & 3 k981532
Intended Use/Indications for use	Same	For use as an assayed quality control serum to monitor the precision of laboratory testing procedures listed in the package insert
Format	Lyophilized	Same
Matrix	Human Serum	Same
Storage (Unopened)	+2 to +8 °C Until expiration date	Same
Open Vial Claim	Store refrigerated +2 to +8°C. In reconstituted serum Procalcitonin is stable for 1 day, Gastrin and Calcitonin are stable for 8 hours at +2 to +8°C if kept capped in original container and free from contamination. The control is stable if frozen once for 28 days at -20°C.	Calcitonin and Gastrin should be assayed immediately after reconstitution. After reconstituting and freezing the control, all analytes are stable for 20 days when stored tightly capped at -10°C to -20°C with the exception of Calcitonin as there is no frozen stability claim supplied.
Shipping Temperature	+2 to +8°C	+2 to +8°C
Analytes	Procalcitonin, Gastrin and Calcitonin.	92 analytes, including Gastrin and Calcitonin
Volume	1 mL	5 mL

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

None

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

The analytes contained in the Randox Speciality Immunoassay Control (II) Levels 1, 2 and 3 were obtained from commercially available sources (see table below).

ANALYTE	SUPPLIER	PRODUCT NUMBER	ORIGIN	SOURCE
Calcitonin	Sigma	T-3525	Synthetic Analytical Grade Chemical	Commercial source, added volumetrically
Gastrin	Sigma	G-9020	Human Gastrin	Commercial source, added volumetrically
Procalcitonin	Randox	RCP9522	Extracted and purified from <i>E.coli</i>	Commercial source, added volumetrically

Stability

Shelf-life and open-vial stability protocols and acceptance criteria were reviewed and found acceptable. Closed vial (shelf-life) stability at the recommended storage temperature of (2 to 8 °C) was demonstrated based on

accelerated stability. Closed vials are stable until the date printed on individual vials. Real-time closed vial stability studies are on-going. In reconstituted serum Procalcitonin is stable for 1 day, Gastrin and Calcitonin are stable for 8 hours at +2 to +8°C if kept capped in original container and free from contamination. The control is stable if frozen once for 28 days at -20°C. All storage recommendations are provided in the labeling.

Value Assignment

Value assignment was determined for each analyte contained in the Randox Speciality Immunoassay Control (II) Levels 1, 2 and 3 using multiple analyzer platforms.

Value assignment data were collated and an appropriate target value was assigned to each analyte based on the average of the observed values. Ranges were then assigned as +/- 25% of the target. The labeling states that obtained values should fall within the specified range provided on lot-specific value sheets and that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

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:

Target and range values for representative analyzers are found in the package insert 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.