510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k113720

B. Purpose for Submission:

New device

C. Measurand:

Multi-analyte control materials

D. Type of Test:

Not applicable

E. Applicant:

Randox Laboratories Limited

F. Proprietary and Established Names:

Randox Maternal Controls Level 1, Level 2 and Level 3

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY – Quality Control Material (Assayed and Unassayed)	Class I, reserved	862.1660	Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for use:

The Randox Maternal Controls Level 1, Level 2 and Level 3 are intended for in vitro diagnostic use in the quality control of Unconjugated Estriol and Total β-Human Chorionic Gonadotrophin methods on clinical chemistry systems.

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 Maternal Controls are manufactured at three levels, Level 1, Level 2 and Level 3. The analyte concentrations in each of the three levels have been chosen to span a range that includes the chemically significant or medical decision level(s) for each analyte (Free Estriol and Total β-Human Chorionic Gonadotrophin [Beta hCG]). The analyte concentrations are clinically relevant for use in routine hospital laboratories.

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):

   Bio-Rad Lyphochek Maternal Serum Controls

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

   k984594

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	Randox Maternal Controls	Bio-Rad Lyphochek Maternal Serum Control (k984594)
Intended Use	The Randox Maternal	Same

Similarities		
Item	Device	Predicate
	Controls Level 1, Level 2 and Level 3 are intended for in vitro diagnostic use in the quality control of Unconjugated Estriol and Total β-Human Chorionic Gonadotrophin	
Size	1 ml	5 ml
Format	Lyophilized	Same
Matrix	Human serum	Same
Storage (unopened)	+2 - +8 °C Until expiration date	Same
Open vial claim	7 days at +2 - +8 °C	10 days at +2 - +8 °C
Analytes	Unconjugated Estriol, and Total β-Human Chorionic Gonadotrophin	Same, but with Alphafoetoprotein
Number of Levels	3	Same

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

Not applicable

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 Maternal Controls were obtained from commercially available standards.

Stability

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. For open-vial stability, the sponsor demonstrated that reconstituted serum is stable for 7 days at the recommended storage temperature of 2 to 8°C. All storage recommendations are provided in the labeling.

Value Assignment

Value assignment was determined for each analyte contained in the Randox Maternal Controls using multiple analyzer platforms and replicate analysis of samples by external clinical laboratories and internal testing conducted at Randox Laboratories Ltd.

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 depending on the analyte. 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:

All 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.