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

A. 510(k) Number:

k112337

B. Purpose for Submission:

New Device

C. Measurand:

Serum quality control materials containing the following analytes: 17-OH-progesterone, Aldosterone, Alpha fetoprotein, Amikacin, Carbamazepine, Carcinoembrionic Antigen (CEA), Cortisol, DHEA-S, Digoxin, Ethosuximide, Ferritin, Folate, Free T3, Free T4, FSH, Gentamicin, Growth Hormone (GH), Immunoglobulin E, Insulin, Luteinizing Hormone (LH), Estradiol, Acetaminophen, Phenytoin, Primidone, Progesterone, Prolactin, PSA Free, PSA Total, Salicylic Acid, SHBG, T Uptake, Testosterone, Theophylline, Thyroid Stimulating Hormone, Tobramycin, Total Beta hCG, Total T3, Total T4, Valproic Acid, Vancomycin and Vitamin B12.

D. Type of Test:

Not Applicable.

E. Applicant:

Randox Laboratories LTD.

F. Proprietary and Established Names:

Randox Liquid Immunoassay Premium Controls, Level 1, level 2, Level 3 and Tri Level

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I, reserved	21 CFR § 862.1660, Quality control material	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Please see indications for use below.

2. Indication(s) for use:
   The Randox Liquid Immunoassay Premium Controls, Level 1, Level 2, Level 3 and Tri Level are liquid controls developed for use in the quality control of quantitative assays stated in the package insert.

3. Special conditions for use statement(s):

   For prescription use.

4. Special instrument requirements:
   Performance was evaluated on the following instrument systems: Abbott Architect, Abbott AXSYM, Roche Cobas 6000, Roche Modular E170, Roche Elecsys, Roche Cobas E411, Roche Integra, bioMerieux Vidas, Siemens Immulite 1000, Siemens Immulite 1000 1st generation, Siemens Immulite 2000/2500, Siemens Advia Centaur, Beckman Access, Beckman Dxl800, Beckman Access, Vitros ECi and Vitros, Tosoh (model A1A360), Diasorin Liaison.

I. Device Description:

The Randox Liquid Immunoassay Premium Controls are ready to use, liquid controls derived from human based serum. The Human based serum from which this product is derived has been tested by FDA approved methods 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 non-reactive. Each control level is purchased separately or as a kit (Tri Level) and is packaged in 12 x 5ml bottles.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bio-Rad Liquichek Immunoassay Plus Controls Level 1, 2 and 3.

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

   k001373

3. Comparison with predicate:

Characteristics	Randox Liquid Immunoassay Premium Controls, Level 1, level 2, Level 3 and Tri Level (Candidate Device)	Bio-Rad Liquichek Immunoassay Plus Controls Level 1, 2 and 3 (Predicate - k001373)
Indication for use / Intended for Use	The Randox Liquid Immunoassay Premium Controls, Level 1, Level 2, Level 3 and Tri Level are liquid controls developed for use in the quality control of quantitative assays stated in the package insert.	Same
Test System (Instrumentation /	Abbott Architect, Abbott AXSYM, Roche Cobas 6000, Roche Modular E170, Roche Elecsys, Roche Cobas E411, Roche	Same

technology)	Integra, bioMerieux Vidas, Siemens Immulite 1000, Siemens Immulite 1000 1st generation, Siemens Immulite 2000/2500, Siemens Advia Centaur, Beckman Access, Beckman Dxl800, Beckman Access, Vitros ECi and Vitros, Tosoh (model A1A360), Diasorin Liaison.	
Analyte	17-OH-progesterone, Aldosterone, Alpha fetoprotein, Amikacin, Carbamazepine, Carcinoembryonic Antigen (CEA), Cortisol, DHEA-S, Digoxin, Ethosuximide, Ferritin, Folate, Free T3, Free T4, FSH, Gentamicin, Growth Hormone (GH), Immunoglobulin E, Insulin, Luteinizing Hormone (LH), Estradiol, Acetaminophen, Phenytoin, Primidone, Progesterone, Prolactin, PSA Free, PSA Total, Salicylic Acid, SHBG, T Uptake, Testosterone, Theophylline, Thyroid Stimulating Hormone, Tobramycin, Total Beta hCG, Total T3, Total T4, Valproic Acid, Vancomycin and Vitamin B12.	Same
Stability claim / Storage Temperature Thaw	Opened: 7 days @ 2-8ºC Unopened: 30 days @ 2-8ºC	Opened: 14 days when stored at 2-8°C, with the exception of: Folate 4 days and Estradiol 5 days. Unopened: 30 days with exception of Folate 4 days, Estradiol 8 days, Free PSA, PSA and Prolactin 14 days.
Shelf life	12 months @ -20 to - 70	28 months @ -20

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

None 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. Each lot of Liquid Immunoassay Premium is submitted to a number of reference laboratories using multiple instruments and values are assigned

from a consensus of the results obtained by these laboratories. With each lot a control range is provided for each analyte and instrument. The control range is equivalent to the mean ±2 SD. Assigned control ranges are listed in the labeling by instrument and analyte.

Stability

Real time stability study protocols and acceptance criteria were described and found to be acceptable.

The stability claim for the controls is 12 months at -20 to -70 ºC for unopened vials. Thawed unopened vials stability claim is 30 days when stored at 2-8ºC. Thaw stability claim for opened vials is 7 days when stored at 2-8ºC.

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:
   Expected values and control ranges are provided in the package insert.

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.