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

A. 510(k) Number:

k140971

B. Purpose for Submission:

New device

C. Measurand:

Multi-analyte quality control materials

D. Type of Test:

Not applicable

E. Applicant:

Randox Laboratories Limited

F. Proprietary and Established Names:

Randox Liquid Assayed Chemistry Control Premium Plus 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 (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:
   The Liquid Assayed Chemistry Control Premium Plus Levels 1, 2 and 3 are assayed quality control materials intended for in vitro diagnostic use in the quality control of diagnostic assays. This material can be used to monitor the accuracy or reproducibility of analytes listed in the package insert. This device is for prescription use only.

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   Performance was evaluated on the following instrument systems: Beckman Coulter AU 400, Hitachi Modular P, Johnson and Johnson Vitros 5600, Siemens Advia 1200 /1650 /2400, Roche Cobas 8000, Randox RX Imola / RX Daytona, and Beckman capillary electrophoresis (Paragon CZE 2000), or Sebia capillary electrophoresis (Capillary 2).

I. Device Description:

Randox Liquid Assayed Chemistry Control Premium Plus is manufactured at three levels, Levels 1, 2 and 3, for each analyte indicated in the package insert. Individual analyte values are listed in the package insert and are specific for the instrument system or method utilized.

Each control is prepared from human sera with added purified biochemical, chemicals, drugs, preservatives, and stabilizers. Each level of control is supplied in frozen liquid form in a 12 x 5ml vials and require thawing before use.

Human source material from which this product has been derived has been tested at the donor level for Human Immunodeficiency Virus (HIV-1 & HIV-2) antibody, Hepatitis B surface antigen (HbsAg) and Hepatitis C virus (HCV) antibody and were found to be no-reactive based on the FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bio-Rad Laboratories, Liquid Assayed Multiqual Premium

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

k130162

3. Comparison with predicate:

Similarities / Differences		
Item	Randox Liquid Assayed Chemistry Control Premium Plus k140971 (Candidate Device)	Bio-Rad Laboratories Liquid Assayed Multiqual Premium k130162 (Predicate Device)
Intended Use	Intended for in vitro diagnostic use in the quality control of diagnostic assays.	Same
Format	Liquid	Same
Matrix	Human Serum	Same
Analytes	**Total: 98 Analytes** Alpha-1-Acid Glycoprotein, Alpha-1-Antitrypsin, Total Acid Phosphatase, Albumin, Alkaline Phosphatase, alpha-HBDH, ALT, Amikacin, Amylase Pancreatic, Amylase Total, APO A-1, APO B, AST, Beta-2-microglobulin, Bicarbonate, Bile Acids, Bilirubin Direct, Bilirubin Total, C3, C4, Caffeine, Calcium, Carbamazepine, Ceruloplasmin, Chloride, Cholesterol, Cholinesterase, CK Total, Copper, Cortisol, Creatinine, CRP, DHEA-S, D-3-Hydroxybutyate, Digoxin, Electrophoresis (albumin, alpha-1-globulin, alpha-2-globulin, beta-globulin, gamma-globulin), Ethanol, Ferritin, Folate, Free T3, Free T4, FSH, Gamma-GT, Gentamicin, GLDH, Glucose, Haptoglobin, HDL, Immunoglobulin A, Immunoglobulin E, Immunoglobulin G, Immunoglobulin M, Iron, Lactate, LAP, LDH, LDL, LH, Lipase, Lp(a), Lithium, Magnesium, Myoglobin, Osmolality, Paracetamol, Phenobarbital, Phenytoin, Phosphate Inorganic, Potassium, Prealbumin, Progesterone, Prolactin, Protein Total, PSA Total, Salicylate, Sodium, Testosterone, Theophylline, Total beta	**Total: 78 Analytes** Alpha-1-Acid Glycoprotein, Alpha-1-Antitrypsin, Albumin, Alkaline Phosphatase, alpha-HBDH, ALT, Amikacin, Amylase Pancreatic, Amylase Total, ASO, AST, Beta-2-microglobulin, Bicarbonate, Bilirubin Direct, Bilirubin Total, C3, C4, Caffeine, Calcium, Carbamazepine, Ceruloplasmin, Chloride, Cholesterol, Cholinesterase, CK Total, Copper, Cortisol, Creatinine, CRP, Cystatin C, Ethanol, Ferritin, , Free T3,Free T4, Gamma GT, Gentamicin, Glucose, Haptoglobin, HDL, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, Iron, Lactate, LDH, LDL, Lipase, Lithium, Lidocaine, Magnesium, Methotrexate, NAPA, Osmolality, Paracetamol, Phenobarbital, Phenytoin, Phosphate Inorganic, Potassium, Prealbumin, Procainamide, Protein Total, Quinidine, Salicylate, Sodium, Theophylline, Tobramycin, Total T3, Total T4, TSH, TIBC, Transferrin, Triglycerides, T uptake, Urea, Uric Acid, Valproic acid, Vancomycin, Vitamin B12.

Similarities / Differences		
Item	Randox Liquid Assayed Chemistry Control Premium Plus k140971 (Candidate Device)	Bio-Rad Laboratories Liquid Assayed Multiqual Premium k130162 (Predicate Device)
	hCG Total T3, Total T4, TSH, TIBC, Transferrin, Triglycerides, Troponin T, T uptake, Urea, Uric Acid, Valproic acid, Vancomycin, Vitamin B12, Zinc	
Storage	Until expiration date at -20 to -70°C	Same
Open vial Claim	Store refrigerated at +2 to +8°C. Thawed serum is stable for 7 days with the following exceptions: Troponin T is stable for 3 days at +2 to +8°C.	Once the control material is thawed and opened, all analytes will be stable for 14 days when stored tightly capped at 2 to 8°C, with the following exceptions: Direct Bilirubin will be stable for 11 days, Triglycerides, HDL, Cholinesterase and Phosphorous will be stable for 7 days. LAP Arylamidase will be stable for 3 days.
Size	12 x 5ml	6 x 5ml

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

None was 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:

The analytes contained in the Randox Liquid Assayed Chemistry Controls Premium Plus Levels 1, 2, and 3 were obtained from commercially available sources. Control solutions are derived from gravimetrically prepared stock solutions and analyzed in-house.

Value Assignment:

Values are assigned through multiple analyses in-house on instrumentation calibrated with a master lot of calibrator. The mean and the CV ranges printed in the package insert were derived from replicate analyses and are specific for the lot. Assigned values of each batch of Liquid Assayed Chemistry Control Premium Plus are confirmed using several external laboratories with several different instrument families. Assigned control ranges are listed in the labeling by instrument family and analyte methods.

Stability Studies:

Real Time stability studies were conducted for closed and open vials. The shelf life of the Liquid Chemistry Assayed Control Premium Plus Levels 1, 2, and 3 is 18 months from the date of manufacture when stored at –20ºC to –70ºC. Open vial stability when stored refrigerated (+2ºC to + 8ºC): Thawed control is stable for 7 days at +2ºC to +8ºC, with the following exceptions: Troponin T is stable for 3 days at +2ºC to +8ºC.

Real time studies are ongoing. Shelf life and open-vial stability studies protocols and acceptance criteria were reviewed and found to be acceptable.

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 for the representative analyzers are provided in the labeling for each specific lot. The labeling indicates each laboratory should establish its own acceptable ranges and use those provided only as a guide.

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.