DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 8, 2014

RANDOX LABORATORIES LIMITED
PAULINE ARMSTRONG, QA/REGULATORY AFFAIRS MANAGER
55 DIAMOND RD. CRUMLIN,
COUNTY ANTRIM BT29 4QY
UNITED KINGDOM

Re: K140971
Trade/Device Name: Liquid Assayed Chemistry Control Premium Plus Level 1,2 and 3
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class 1, Reserved
Product Code: JJY
Dated: October 31, 2014
Received: October 31, 2014

Dear Dr. Pauline Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140971

Device Name
Liquid Assayed Chemistry Control Premium Plus Level 1, Level 2 and Level 3

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY, LIQUID ASSAYED CHEMISTRY CONTROL PREMIUM PLUS LEVELS 1, 2 AND 3

1. SAFETY AND EFFECTIVENESS AS REQUIRED BY 21 CFR 807.92 STATEMENT

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement 21 CFR 807.92.

2. SUBMITTER NAME AND ADDRESS

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E-mail: Pauline.Armstrong@randox.com

Date of Summary Preparation: December 5, 2014

3. 510k NUMBER, DEVICE PROPRIETARY NAME, COMMON NAME, PURPOSE FOR SUBMISSION, REGULATORY CLASSIFCATION, PANEL, PRODUCT CODE AND 21 CFR NUMBER

510k No: k140971

Device Proprietary Name: Liquid Assayed Chemistry Control Premium Plus Levels 1, 2 & 3

Common Name: Liquid Assayed Chemistry Control Premium Plus Levels 1, 2 & 3

Purpose for Submission: New Device

Regulatory Classification: Multi-analyte Controls, All kinds (Assayed and Unassayed)

Panel: Clinical Chemistry

Product Code: JJY
21 CFR Number: 21 CFR 862.1660

4. PREDICATE DEVICE PROPRIETARY NAMES AND 510 (k) NUMBERS

Predicate Device Proprietary Name:
Bio-rad Laboratories, Liquid Assayed Multiqual Premium

510 (k) Number: K130162

5. INTENDED 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.

6. DEVICE DESCRIPTION

The Liquid Assayed Chemistry Control Premium Plus is human liquid sera to which purified biochemical material, chemicals, drugs, preservatives and stabilizers have been added. The material is supplied at levels 1, 2 and 3. Each 5 ml vial of liquid serum is stored at -20°C to -70°C.

Each level is supplied in a 12 by 5ml vials.

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.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

7. PREDICATE DEVICE COMPARISON TABLE

COMPARISON OF LIQUID ASSAYED CHEMISTRY CONTROL PREMIUM PLUS LEVELS 1, 2 AND 3 WITH THE PREDICATE DEVICE

CHARACTERISTICS	LIQUID ASSAYED CHEMISTRY CONTROLPREMIUM PLUS LEVELS 1, 2 AND 3 *(New Device)*	*BIO-RAD LABORATORIES LIQUID ASSAYED MULTIQUAL PREMIUM K130162 (Predicate Device)*
Differences		
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 hCG Total T3, Total T4, TSH, TIBC, Transferrin, Triglycerides, Troponin T, T uptake, Urea, Uric Acid, Valproic acid, Vancomycin, Vitamin B12, Zinc.	**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.
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.
SIZE	12 x 5ml	6 x 5ml

Similarities		
INTENDED 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.	Liquid assayed Multiqual Premium is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
FORMAT	Liquid	Liquid
MATRIX	Human Serum	Human Serum
STORAGE (Unopened)	Until expiration date at -20 to -70°C	Until expiration date at -20 to -70°C

8. SUMMARY OF STABILITY STUDIES

Thawed Open vial stability

Thawed Open vial stability of the Liquid Assayed Chemistry Control Premium Plus levels 1, 2 & 3 was assessed by removing the product from the routine storage temperature of -18 to -24°C, thawed at +15 to 25°C and stored at +2 to 8°C for 3 and 8 days.

All acceptance criteria were met for all the analytes

The data demonstrates that the Liquid Assayed Chemistry Control Premium Plus Control levels 1, 2 & 3 are stable for 7 days when thawed and stored + 2 to 8°C. Troponin T is stable for 3 days when thawed and stored at +2°C to +8°C.

Shelf-life Study

Real Time Testing

The Liquid Assayed Chemistry Control Premium Plus levels 1, 2 & 3 were stored at ultra frozen conditions -75 to -90°C. Following storage at the ultra frozen temperature, the controls were then tested alongside control material stored unopened at the routine storage temperature of -18°C to -24°C at various time points and the percentage deviation is calculated.

All acceptance criteria were met for all the analytes

Current Real Time studies support an 18 month shelf life.

9. SUMMARY OF VALUE ASSIGNMENT

Each batch of Liquid Assayed Chemistry Control Premium Plus is submitted to a number of external laboratories and values are assigned from results obtained by these laboratories and/or by in-house testing. Statistical analysis including the mean, SD and % CV were calculated. With each batch, an assigned value is calculated from the target mean specific value and an analyte specific fixed percentage range is applied. Average values should normally fall within the listed range. However, variations may be caused by instrument, reagent, and laboratory technique. Therefore the range provided should only be considered as a reference and it is recommended that each laboratory establish its own ranges. All the assigned values for all the specific analyzers tested are printed in the package insert.

10. TRACEABILITY

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

11. CONCLUSION

Testing results indicate that the proposed device is substantially equivalent to the predicate device.