MAY 2 2 2014

RANDOX

510 (k) Summary
Randox Immunoassay Premium Plus Controls Levels 1, 2 and 3, Immunoassay Premium Plus Tri-Level Control

K140522

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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Date of Summary Preparation: May 15, 2014

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

510k No: K140522

Device Proprietary Name: Randox Immunoassay Premium Plus Controls Levels 1, 2 & 3, Immunoassay Premium Plus Tri-Level Control.

Common Name: Randox Immunoassay Premium Plus Controls Levels 1, 2 & 3, Immunoassay Premium Plus Tri-Level Control.

Purpose for Submission: New Device

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

Classification: Class 1, Reserved

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:
Randox Immunoassay Controls Levels 1, 2 and 3

510 (k) Numbers: K040379

5. INTENDED USE

This product is intended for in vitro diagnostic use as assayed quality control material to monitor the accuracy and reproducibility of analytes listed in the package insert.

6. DEVICE DESCRIPTION

Randox Immunoassay Premium Plus Controls are manufactured at three levels, Level 1, Level 2 and Level 3. The materials are supplied as Level 1, Level 2 , Level 3 and a Tri-Level configuration. Each 5 ml vial of lyophilized serum is reconstituted with exactly 5 ml of distilled water at +20 to 25° C.

The base matrix used for the manufacture of Randox Immunoassay Premium Plus Controls is Human Serum with added chemicals.

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

TABLE 1: COMPARISON OF RANDOX IMMUNOASSAY PREMIUM PLUS CONTROLS LEVELS 1, 2 AND 3 WITH THE PREDICATE DEVICE

CHARACTERISTICS	RANDOX IMMUNOASSAY PREMIUM PLUS CONTROLS LEVELS 1, 2 AND 3 *(New Device)*	RANDOX IMMUNOASSAY CONTROLS LEVELS 1, 2 AND 3 *K040379* *(Predicate Device)*
INTENDED USE	This product is intended for in vitro diagnostic use as assayed quality control material to monitor the accuracy and reproducibility of analytes listed in the package insert.	The Randox Immunoassay Controls Levels 1, 2 and 3 are intended for *in vitro* diagnostic use in the quality control of Immunoassays on clinical chemistry and Immunoassay systems.
FORMAT	Lyophilised	Lyophilised
MATRIX	Human Serum	Human Serum
ANALYTES	49 Analytes 25-OH Vitamin D, ACTH, AFP, Aldosterone(Levels 2 & 3 only), Amikacin, Androstenedione, Beta-2 Microglobulin, C-Peptide, CA15-3, CA19-9, CA125, Carbamazepine, CEA, Cortisol, DHEA-S, Digoxin, Ferritin, Folate, Free T3, Free T4, FSH, Gentamicin, GH, IgE, Insulin, LH, Oestradiol, Paracetamol, PTH, Phenytoin, Primodone, Progesterone, Prolactin, PSA Free, PSA Total, Salicylic Acid, SHBG, T-Uptake, Testosterone, Theophylline, Thyroglobulin, TSH, Tobramycin, Total Beta hCG, Total T3, Total T4, Valproic Acid, Vancomycin, Vitamin B12.	33 Analytes AFP, Beta-2 Microglobulin, CA15-3, CA19-9, CA125, Carbamazepine, CEA, Cortisol, DHEA-S, Digoxin, Ferritin, Folate, Free T3, Free T4 FSH, GH, IgE, LH, Oestradiol, 17-OH-Progesterone, Phenytoin, Progesterone, Prolactin, PSA Free, PSA Total, Testosterone, Theophylline, TSH, Tobramycin, Total Beta hCG, Total T3, Total T4, Valproic Acid, Vitamin B12.
STORAGE (Unopened)	2 to 8 ^{0}C Until expiration date	2 to 8 ^{0}C Until expiration date
OPEN VIAL CLAIM	Reconstituted serum is stable for 7 days at +2°C to +8°C if kept capped in original container and free from contamination or 4 weeks frozen once at -20°C. C-Peptide is stable for 1 day at +2°C to +8°C. Parathyroid hormone (PTH) and Thyroglobulin should be tested within 4 hours of reconstitution, when stored at +2°C to +8°C or within 2 weeks when stored at -20°C. ACTH should be assayed within 4 hours of reconstitution, when stored at +2°C to +8°C.	Reconstituted serum is stable for 7 days at +2°C to +8°C if kept capped in original container and free from contamination or 4 weeks frozen once at -20°C. The PSA in this sera will be stable for 2 days at +2°C to +8°C.
SIZE	12 x 5ml	10 x 5ml
SHELF LIFE	36 months	36 months

8. SUMMARY OF STABILITY STUDIES

Open vial stabiltiy

Open vial stability of the Randox Immunoassay Premium Plus Controls levels 1, 2 & 3 was assessed by opening a set of Immunoassay Premium Plus Controls levels 1, 2 & 3 and reconstituting them according to the package insert. Samples were reconstituted and stored at +2 to +8°C for 7 days and tested for the quoted analytes except C-Peptide stable for 1 day, Thyroglobulin, ACTH and Parathyroid hormone (PTH) should be tested within 4 hours of reconstitution.

The acceptance criteria state the percentage deviation of reconstituted to fresh should be ≤10%.

The tables below show the summary of the open vial stability.

Results

Reconstituted Stability Day 7

Control	Lot number	Reconstituted Stability at Day 7
Randox Immunoassay Premium Plus Control levels 1	972EC	All analytes pass
Randox Immunoassay Premium Plus Control levels 2	974EC	All analytes pass
Randox Immunoassay Premium Plus Control levels 3	977EC	All analytes pass
Randox Immunoassay Premium Plus Tri-Level Control	972EC, 974EC, 977EC	All analytes pass

Reconstituted Stability Day 1 for C-Peptide

Control	Lot number	Reconstituted Stability at Day 1
Randox Immunoassay Premium Plus Control levels 1	972EC	Pass
Randox Immunoassay Premium Plus Control levels 2	974EC	Pass
Randox Immunoassay Premium Plus Control levels 3	977EC	Pass
Randox Immunoassay Premium Plus Tri-Level Control	972EC, 974EC, 977EC	Pass

Reconstituted Stability 4 Hours for ACTH, Thyroglobulin & Parathyroid Hormone.

Control	Lot number	Reconstituted Stability at 4 Hours
Randox Immunoassay Premium Plus Control levels 1	972EC	All analytes pass
Randox Immunoassay Premium Plus Control levels 2	974EC	All analytes pass
Randox Immunoassay Premium Plus Control levels 3	977EC	All analytes pass
Randox Immunoassay Premium Plus Tri-Level Control	972EC, 974EC, 977EC	All analytes pass

The data demonstrates that the Randox Immunoassay Premium Plus Controls levels 1, 2 & 3 are stable for 7 days reconstituted and stored at + 2 - 8°C. C-Peptide is stable for 1 day at +2°C to +8°C. Parathyroid hormone (PTH) Thyroglobulin and ACTH should be tested within 4 hours of reconstitution, when stored at +2°C to +8°C

Frozen stabiltiy

Frozen stability of the Randox Immunoassay Premium Plus Controls levels 1, 2 & 3 was assessed by opening a set of Immunoassay Premium Plus Controls levels 1, 2 & 3 and reconstituting them according to the package insert. Samples were reconstituted and stored at -18 to -24°C for 28 days. After this period, the controls were thawed and a fresh vial was tested alongside the stability vials.

The acceptance criteria state the percentage deviation of reconstituted to fresh should be ≤10%. No frozen stability claim is made for ACTH, Aldosterone and C-Peptide.

The table below shows the summary of the Frozen stability

Frozen stability after 4 weeks at -20°C

Control	Lot number	Reconstituted Stability at Day 7
Randox Immunoassay Premium Plus Control levels 1	972EC	All analytes pass
Randox Immunoassay Premium Plus Control levels 2	974EC	All analytes pass
Randox Immunoassay Premium Plus Control levels 3	977EC	All analytes pass
Randox Immunoassay Premium Plus Tri-Level Control	972EC, 974EC, 977EC	All analytes pass

The data demonstrates that the Randox Immunoassay Premium Plus Controls levels 1, 2 & 3 are stable for 28 days reconstituted and stored frozen at -18 to -24°C. No frozen stability claim is made for ACTH, Aldosterone and C-Peptide.

Real Time Testing & Accelerated Stability Testing

Accelerated stability was used to predict the shelf life of control materials. The Randox Immunoassay Premium Plus Controls levels 1, 2 & 3 were stored at elevated temperature for a period of four weeks. Following storage at the elevated temperature (28-32 °C, 35-39 °C and 43-47 °C), the accelerated stability control is then tested alongside a fresh control and the percentage deviation is calculated

The acceptance criteria state the percentage deviation to fresh should be ≤10%.

The shelf life of these products was set at 3 years from the date of manufacture, based on the performance of the accelerated stability testing.

The real time stability of the controls was monitored to verify and validate the predicted or desirable shelf life.

The Randox Immunoassay Premium Plus Controls 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 +2 to +8°C at various timepoints and the percentage deviation is calculated.

The acceptance criteria state the percentage deviation to controls stored at the routine temperature should be ≤10%.

Current Real Time studies support a 3 year shelf life.

The table below shows the summary of the accelerated stability and real time testing.

Accelerated stability and Real time testing

Control	Lot number	Accelerated Stability	Real time testing
Randox Immunoassay Premium Plus Control levels 1	852EC/ 941EC	All analytes pass at Week 4	36 Months
Randox Immunoassay Premium Plus Control levels 2	854EC/ 943EC	All analytes pass at Week 4	36 Months
Randox Immunoassay Premium Plus Control levels 3	857EC/ 946EC	All analytes pass at Week 4	36 Months
Randox Immunoassay Premium Plus Tri-Level Control	852/941EC, 854/943EC, 857/946EC	All analytes pass at Week 4	36 Months

9. SUMMARY OF VALUE ASSIGNMENT

Each batch of Immunoassay Premium Plus is submitted to a number of external laboratories and values are assigned from a consensus of 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 mean specific value and an analyte specific 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.

10. CONCLUSION

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

RANDOX LABORATORIES LIMITED
PAULINE ARMSTRONG
QA/RA MANAGER
'55 DIAMOND RD.
CRUMLIN, CO. ANTRIM BT29 4QY, UK

Re: K140522
Trade/Device Name: Randox Immunoassay Premium Plus Control Levels 1, 2 & 3
Immunoassay Premium Plus Tri-level Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJY
Dated: April 01, 2014
Received: April 4, 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" (21CFR 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,

Courtney H. Lias -S

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)*

K140522

Device Name
Immunoassay Premium Plus Controls Levels 1, 2 & 3, Immunoassay Premium Plus Tri-Level Control.

Indications for Use *(Describe)*

This product is intended for in vitro diagnostic use as assayed quality control materials to monitor the accuracy and reproducibility of the analytes listed in the package insert.

This in vitro diagnostic device is intended 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)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

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

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