

K132156

**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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OCT 23 2013

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

**510k No:** K132156

**Device Proprietary Name:** Radox CSF Controls Levels 2 and 3

**Common Name:** Radox CSF Controls Levels 2 and 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:**

Roche PreciControl PUC (Proteins in Urine/CSF) norm and PreciControl PUC path

**510 (k) Number:** k040280

#### **5. INTENDED USE**

The Randox CSF Controls Levels 2 and Level 3 are intended for *in vitro* diagnostic use as assayed quality control material to monitor the precision of laboratory testing procedures for Clinical Chemistry systems. This device is intended for prescription use only.

#### **6. DEVICE DESCRIPTION**

The Randox CSF controls consist of a buffered aqueous solution with biological materials; they are supplied at 2 levels, level 2 and 3.

Target values and ranges are supplied for the following analytes at both levels: Chloride, Glucose, IgG, Lactic Acid, Sodium, Total Protein (Pyrogallol Red), and % Total Protein quoted for Electrophoresis regions at both levels: Albumin, Alpha-1-Globulin, Alpha-2-Globulin, Beta Globulin and Gamma Globulin.

## 7. PREDICATE DEVICE COMPARISON TABLE

### COMPARISON OF RANDOX CSF CONTROLS LEVELS 2 AND 3 WITH THE PREDICATE DEVICE

<b>Similarities</b>		
<b>CHARACTERISTICS</b>	<b>RANDEX CSF CONTROLS LEVELS 2 and 3</b>	<b>Roche Precinorm PUC Precipath PUC K040280</b>
<b>INTENDED USE</b>	Intended for in vitro diagnostic use as assayed quality control material for diagnostic methods using CSF sample on clinical chemistry systems.	Precinorm/path PUC (Proteins in Urine/CSF) is used for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet
<b>STORAGE (Unopened)</b>	Stable until expiry date unopened and stored at 2-8°C.	Same
<b>MATRIX</b>	Buffered Aqueous Base with Biological Materials added as required to obtain desired component levels in either the normal or pathological range	Same
<b>SIZE</b>	3ml	Same

<b>Differences</b>		
<b>CHARACTERISTICS</b>	<b>RANDEX CSF CONTROLS LEVELS 2 and 3</b>	<b>Roche Precinorm PUC Precipath PUC K040280</b>
<b>FORMAT</b>	Lyophilised	Liquid
<b>OPEN VIAL CLAIM</b>	Stable for 14 days after opening capped and stored at 2-8°C	Stable for 4 weeks after opening capped and stored at 2-8°C
<b>Constituent Analytes</b>	Albumin Alpha-1-globulin Alpha-2-globulin Beta-globulin Gamma-globulin Chloride Glucose Immunoglobulin G Lactate Protein Total Sodium	Albumin Creatinine Total Protein Urine/CSF Protein

## 8. SUMMARY OF STABILITY STUDIES

Open vial stability of the Randox CSF controls levels 2 and 3 was assessed by opening a set of CSF Controls levels 2 and 3 and reconstituting them according to the package insert. The current open vial stability is 14 days. Once reconstituted the material was stored at + 2 - 8°C for 14 days. On day 14 a fresh sample was reconstituted and compared to the reconstituted vial stored at + 2 - 8°C for 14 days. The mean of the replicates and the percentage deviation of the 14 day reconstituted vial to the fresh vial are calculated.

The acceptance criteria state the percentage deviation of reconstituted to fresh should be  $\pm 3\%$ .

The table below shows the summary of the open vial stability. Open vial stability is assessed for Chloride, Glucose, Lactate, Sodium and Protein Total only as albumin, alpha-1, alpha-2, beta and gamma globulin and immunoglobulin G are all calculated as a percentage of the total protein.

### Results

Control	Lot number	Reconstituted Stability
Randox CSF Control Level 2	059CF	14 days
Randox CSF Control Level 3	060CF	14 days

The data demonstrates that the Randox CSF controls levels 2 and 3 are stable for 14 days reconstituted and stored at + 2 - 8°C for 14 days.

Shelf life for the Randox CSF controls levels 2 and 3 was assessed by real-time stability studies. Once a new batch of Randox CSF controls levels 2 and 3 are manufactured 10 sets of each control are stored unopened at ultra frozen conditions -75 to 90°C and another 10 are stored unopened at the routinely stored temperature of + 2 - 8°C. The results of the routinely stored are compared to the ultra frozen.

The acceptance criteria states the control recovery for routinely stored compared to ultra-frozen should be within  $\pm 15\%$  deviation.

The following table shows the summary of real time stabilities.

In some cases the real time stability is assessed for protein total only as albumin, alpha-1, alpha-2, beta and gamma globulin and immunoglobulin G are all calculated as a percentage of the total protein.

## Results

Randox CSF Controls CF1500-CF1501	
Randox CSF Control Level 2	
Lot number	Real-time tested and passed
038CF	37 months
Randox CSF Control Level 3	
Lot number	Real-time tested and passed
035CF	37 months

The data demonstrates that the Randox CSF controls levels 2 and 3 are stable for 37 months from the date of manufacture. This meets the current shelf life stability claim of 3 years and exceeds this by 1 month.

## 9. SUMMARY OF VALUE ASSIGNMENT

Value assignment is used to calculate a target value for the Randox CSF Controls levels 2 and 3. The Randox CSF controls are used to measure various analytes including albumin, alpha-1-globulin, alpha-2-globulin, beta globulin, gamma globulin, chloride, glucose, immunoglobulin G, lactate, total protein and sodium. There are two methods of value assignment applied depending on the analyte being measured.

### Value assignment method 1:

Electrophoresis is the method used to assign a target value for albumin, alpha-1-globulin, alpha-2 globulin, beta-globulin and gamma globulin. Once a new lot of CSF controls are manufactured vials are analyzed at an external site. The mean of several replicates is taken, the total protein value is set at 100% and the fraction of each of the individual proteins calculated as a percentage of the total protein. The calculated % of the total protein is used as the target value for the labeling and a range applied dependent on the protein being measured. Please refer to the following tables.

### Value assignment method 2:

The remaining analytes (chloride, glucose, immunoglobulin G, lactate, and sodium) are assigned a target value and assessed against the master lot. Several replicates of the test controls are assessed and the mean and CV calculated. The recovery of the master lot is also measured.

The acceptance criteria is dependent upon the analyte being assigned. Typically the precision is measured by the CV for the master and test lots and the recovery of the master lot is measured. A target value is assigned and a range applied that is dependent on the analyte being measured. Please refer to the following tables.

### **RANDEX CSF CONTROL LEVEL 2 VALUE ASSIGNMENT CRITERIA**

Analyte	Unit	Target Value	Percentage Range Applied (%)	Acceptable range	%CV	% Recovery error
Albumin (electrophoresis)	N/A	59.9	10	53.9 – 65.9	N/A	N/A
Alpha-1-globulin (electrophoresis)	N/A	2.0	25	1.5 – 2.5	N/A	N/A
Alpha-2-globulin (electrophoresis)	N/A	4.6	25	3.5 – 5.8	N/A	N/A
Beta-globulin (electrophoresis)	N/A	5.3	25	4.0 – 6.6	N/A	N/A
Gamma-globulin	N/A	28.3	25	21.2 – 35.4	N/A	N/A
Chloride	mmol/l	86.8	10	78.1 – 95.5	3	5
Glucose Oxidase	mmol/l	3.11	15	2.64 – 3.58	3	5
Glucose Hexokinase	mmol/l	2.85	15	2.42 – 3.28	3	5
Immunoglobulin G	mg/l	25.3	25	19.0 - 31.6	10	10
Lactate	mmol/l	0.38	15	0.32 – 0.44	3	5
Protein Total	g/l	0.235	20	0.188 – 0.282	5	5
Sodium	mmol/l	127	5	121 - 133	3	5

## RANDOX CSF CONTROL LEVEL 3 VALUE ASSIGNMENT CRITERIA

Analyte	Unit	Target Value	Percentage Range Applied (%)	Acceptable range	%CV	% Recovery error
Albumin (electrophoresis)	N/A	59.0	10	53.1 – 64.9	N/A	N/A
Alpha-1-globulin (electrophoresis)	N/A	2.4	25	1.8 – 3.0	N/A	N/A
Alpha-2-globulin (electrophoresis)	N/A	7.4	25	5.5 – 9.3	N/A	N/A
Beta-globulin (electrophoresis)	N/A	6.9	25	5.2 – 8.6	N/A	N/A
Gamma-globulin	N/A	24.3	25	18.23 – 30.4	N/A	N/A
Chloride	mmol/l	110	10	99 - 121	3	5
Glucose Oxidase	mmol/l	5.81	15	4.94 – 6.68	3	5
Glucose Hexokinase	mmol/l	5.53	15	4.70 – 6.64	3	5
Immunoglobulin G	mg/l	70.3	25	52.7 – 87.9	10	10
Lactate	mmol/l	3.93	15	3.34 – 4.64	3	5
Protein Total	g/l	0.489	20	0.391 – 0.587	5	5
Sodium	mmol/l	169	5	161 - 177	3	5

## 10. TRACEABILITY

ANALYTE	SUPPLIER	PRODUCT NUMBER	ORIGIN	SOURCE
Glucose	SIGMA	G8270	Synthetic Analytical Grade chemical	Commercial source, added volumetrically
Lactic Acid	EUROPA	UBL7016	Synthetic Analytical Grade chemical	Commercial source, added volumetrically
Chloride	SIGMA	59888	Synthetic Analytical Grade chemical	Commercial source, added volumetrically
Sodium	SIGMA	59888/56014	Synthetic Analytical Grade chemical	Commercial source, added volumetrically
Albumin, alpha-1-globulin, alpha-2-globulin, beta-globulin, immunoglobulin G, total protein-proteins all derived from Human serum	Intergen	Received under a lot number	Human	Human source

## 11. CONCLUSION

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



October 23, 2013

RANDOX LABORATORIES, LTD.  
c/o Dr. Pauline Armstrong  
55 Diamond Rd.  
CRUMLIN, COUNTY ANTRIM BT29 4QY  
UK

Re: K132156  
Trade/Device Name: Radox CSF Controls Levels 2 and 3  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material (assayed and unassayed)  
Regulatory Class: I, reserved  
Product Code: JJY  
Dated: September 6, 2013  
Received: September 9, 2013

Dear Dr. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Carol  Benson -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

## Indications for Use

510(k) Number (if known): k132156

Device Name: Randox CSF Controls Levels 2 and 3

Indication for Use:

The Randox CSF Controls Levels 2 and 3 are intended for *in vitro* diagnostic use as assayed quality control material to monitor the precision of diagnostic methods using CSF as a sample on clinical chemistry systems.

This *in vitro* diagnostic device is intended for prescription use only.

Prescription Use           ✓           And/Or  
(21 CFR Part 801 Subpart D)

Over the Counter Use         
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

**Yung W. Chan -S**

Division Sign-Off  
Office of In Vitro Diagnostics and Radiological Health

510(k) k132156