K 132227

510(k) Summary

Liquichek Immunoassay Premium Control

1.0 **Submitter**

Bio-Rad Laboratories
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Contact Person

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OCT 25 2013

Date of Summary Preparation

October 17, 2013

2.0 **Device Identification**

Product Trade Name:	Liquichek Immunoassay Premium Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Immunoassay Plus Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K001373

4.0 **Description of Device**

Liquichek Immunoassay Premium Control is prepared from human serum with added constituents of human and animal origin, chemicals, therapeutic drugs, stabilizers and preservatives. The control is provided in liquid form for convenience.

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source material for which there are no approved tests.

5.0 Value Assignment

The mean values and the corresponding ±3SD ranges printed in this insert were derived from replicate analyses and are specific for this lot of product. Data from Unity™ Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

6.0 Intended Use

Liquichek Immunoassay Premium Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

7.0 Comparison of the new device with the Predicate Device

Liquichek Immunoassay Premium Control claims substantial equivalence to the Liquichek Immunoassay Plus Control currently in commercial distribution (K001373). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Liquichek Immunoassay Premium Control *(New Device)*		Liquichek Immunoassay Plus Control *(Predicate Device,* K001373*)*	
Similarities				
Intended Use	Liquichek Immunoassay Premium Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.		Liquichek Immunoassay Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	
Matrix	Human Serum		Human Serum	
Form	Liquid		Liquid	
Storage unopened (Shelf life)	-20°C to -70°C until expiration date		-20°C to -70°C until expiration date	
Differences				
Fill Volume	Trilevel, Level 1, 2 and 3 – 6 x 5 mL		Level 1, 2 and 3– 12 x 5 mL	
	Trilevel MiniPak - 3 x 5 mL		Trilevel MiniPak - 3 x 5 mL	
Thawed Opened Stability	14 days at 2 to 8°C		14 days at 2°C to 8 °C	
	Except	Folate: 4 days at 2 to 8°C	*Except*	Folate: 4 days at 2 to 8°C
		Estradiol: 5 days at 2 to 8°C		Estradiol: 5 days at 2 to 8°C
		Free PSA: 7 days at 2 to 8°C		
		Vitamin D: 9 days at 2 to 8°C		
		Total PSA: 13 days at 2 to 8°C		

<table>
<tr><td>Thawed Unopened Stability</td><td colspan="2">28 days at 2 to 8°C</td><td colspan="2">30 days at 2 to 8°C</td></tr>
<tr><td></td><td rowspan="3">Except</td><td>Folate: 4 days at 2 to 8°C</td><td rowspan="3">Except</td><td>Folate: 4 days at 2 to 8°C</td></tr>
<tr><td></td><td>Estradiol: 8 days at 2 to 8°C</td></tr>
<tr><td></td><td>Free PSA & Prolactin: 16 days at 2 to 8°C</td><td>Free PSA, PSA, Prolactin: 14 days at 2 to 8°C</td></tr>
<tr><td></td><td></td><td>Total PSA: 17 days at 2 to 8°C</td><td></td><td></td></tr>
<tr><td>Frozen aliquot</td><td colspan="2">28 days at -20 to -70 °C
Analytes Include: Folate, Estradiol, Free PSA, Total PSA and Total Vitamin D</td><td colspan="2">No Claim</td></tr>
<tr><td>Analytes</td><td colspan="2">Contains:
• 25-Hydroxy Vitamin D
• Acetaminophen
• Acid Phosphatase, Prostatic (PAP)
• Alpha Fetoprotein
• Amikacin
• Caffeine
• Carbamazepine
• Carcinoembryonic Antigen
• Cortisol
• Digoxin
• Disopyramide
• DHEA-Sulfate
• Estradiol
• Estriol, Free
• Ethosuximide
• Ferritin
• Folate
• Follicle Stimulating Hormone (FSH)
• Gentamicin
• hCG, Total beta
• Human Growth Hormone
• Immunoglobulin A
• Immunoglobulin G
• Immunoglobulin E
• Immunoglobulin M
• Insulin
• Luteinizing Hormone
• Lidocaine
• Lithium
• N-Acetylprocainamide
• Phenobarbital
• Phenytoin
• Phenytoin, Free
• Primidone
• Procainamide
• Progesterone
• Prolactin
• Prostatic Specific Antigen, Free
• Prostate Specific Antigen, Total
• Quinidine
• Salicylate
• T3 Uptake / T Uptake
• T3, Free
• T3, Total
• T4, Free
• T4, Total
• Tricyclic Antidepressants Screen
• Testosterone
• Theophylline
• Tobramycin
• Thyroid Stimulating Hormone
• Thyroxine Binding Globulin
• Valproic Acid
• Valproic Acid, Free
• Vancomycin
• Vitamin B12
• Sex Hormone Binding Globulin
• Beta-2-Microglobulin
• CA 125
• CA 15-3
• CA 19-9
Does not Contain:
• 17-Alpha Hydroxyprogesterone
• 11-Deoxycortisol
• Aldosterone
• Amiodarone
• Amitriptyline
• Androstenedione
• Angiotensin I
• Antithyroid Peroxidase Antibodies
• Antithyroglobulin antibody
• Carbamazepine, Free
• Chloramphenicol
• CK-MB Isoenzyme
• Cyclosporine
• Desipramine
• Dehydroepiandrosterone
• Estrogen, Total
• Estriol, Total
• Flecainide
• Fructosamine
• Human Chorionic Gonadotropin- Beta Subunit
• Ibuprofen
• Iron
• Imipramine
• Netilmicin
• Nortriptyline
• Propanolol
• Parathyroid Hormone - MM
• Somatomedin-C
• Testosterone, Free
• Total Iron Binding Capacity
• Thyroglobulin</td><td colspan="2">Contains:
• 26-Hydroxy Vitamin D
• Acetaminophen
• Acid Phosphatase, Prostatic (PAP)
• Alpha Fetoprotein
• Amikacin
• Caffeine
• Carbamazepine
• Carbamazepine, Free
• Carcinoembryonic Antigen
• Cortisol
• Cyclosporine
• Digoxin
• Disopyramide
• DHEA-Sulfate
• Estradiol
• Estriol, Free
• Ethosuximide
• Ferritin
• Folate
• Follicle Stimulating Hormone (FSH)
• Gentamicin
• hCG, Total beta
• Human Growth Hormone
• Immunoglobulin A
• Immunoglobulin G
• Immunoglobulin E
• Immunoglobulin M
• Insulin
• Luteinizing Hormone
• Lidocaine
• Lithium
• N-Acetylprocainamide
• Nortriptyline
• Phenobarbital
• Phenytoin
• Phenytoin, Free
• Primidone
• Procainamide
• Progesterone
• Prolactin
• Prostatic Specific Antigen, Free
• Prostate Specific Antigen, Total
• Quinidine
• Salicylate
• T3 Uptake / T Uptake
• T3, Free
• T3, Total
• T4, Free
• T4, Total
• Tricyclic Antidepressants Screen
• Testosterone
• Theophylline
• Tobramycin
• Thyroid Stimulating Hormone
• Thyroglobulin
• Thyroxine Binding Globulin
• Valproic Acid
• Valproic Acid, Free
• Vancomycin
• Vitamin B12
• Sex Hormone Binding Globulin
• 17-Alpha Hydroxyprogesterone
• 11-Deoxycortisol
• Aldosterone
• Amiodarone
• Amitriptyline
• Androstenedione
• Angiotensin I
• Antithyroid Peroxidase Antibodies
• Antithyroglobulin antibody
• Chloramphenicol
• CK-MB Isoenzyme
• Desipramine
• Dehydroepiandrosterone
• Estrogen, Total
• Estriol, Total
• Flecainide
• Fructosamine
• Human Chorionic Gonadotropin- Beta Subunit
• Ibuprofen
• Iron
• Imipramine
• Netilmicin
• Propanolol
• Parathyroid Hormone - MM
• Somatomedin-C
• Testosterone, Free
• Total Iron Binding Capacity
Does not Contain:
• Beta-2-Microglobulin
• CA 125
• CA 15-3
• CA 19-9</td></tr>
</table>

8.0 Statement of Supporting Data

Accelerated Stability studies have been performed to predict the Shelf life stability and real time studies were conducted to establish Thawed (opened and unopened) & Frozen aliquot claims for Liquichek Immunoassay Premium Control. Product claims are as follows:

Thawed Opened Stability:	14 days at 2 to 8°C *(for most analytes)*
Thawed Unopened Stability:	28 days at 2 to 8°C *(for most analytes)*
Frozen Aliquot	28 days at -20°C to -70°C
Shelf Life Stability:	28 Months at -20°C to -70°C *(for most analytes)*

The acceptance criteria for above studies is defined as the recovery result on final day (T_{Final}) being $\pm$ 10% of the recovery result of time zero vial (T_{Zero}).

Real-time stability studies are ongoing to support the shelf life of this product.

9.0 Conclusion

Based on the performance characteristics indicated above, Liquichek Immunoassay Premium Control is substantially equivalent to the predicate device (K001373).

All supporting data is retained on file at Bio-Rad Laboratories.

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

October 25, 2013

BIO-RAD LABORATORIES
c/o Ms. Suzanne Parsons
9500 Jeronimo Rd.
IRVINE CA 92618-2017

Re: K132227
Trade/Device Name: Liquichek Immunoassay Premium Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, reserved
Product Code: JJY
Dated: September 25, 2013
Received: September 26, 2013

Dear Ms. Parsons:

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 C. 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): k132227

Device Name: Liquichek Immunoassay premium Control

Indication for Use:

Liquichek Immunoassay premium Control 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.

Prescription Use _____✓_____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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[redacted]an -S

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

510(k) k132227