Summary of Safety and Effectiveness

Liquichek Immunoassay Plus Control

OCT 17 2012

1.0 Submitter

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Date of Summary Preparation

October 16, 2012

2.0 Device Identification

Product Trade Name:	Liquichek Immunoassay Plus Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I
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 Plus 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. 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 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.

7.0 Comparison of the new device with the Predicate Device

Liquichek Immunoassay Plus 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 Plus Control *(New Device)*	Liquichek Immunoassay Plus Control (*Predicate Device,* K001373*)*	
Similarities			
Intended Use	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.	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	
Differences			
Fill Volume	Level 1, 2 and 3 – 12 x 2.5 mL	Level 1, 2 and 3– 12 x 5 mL	
	Trilevel MiniPak - 3 x 2.5 mL	Trilevel MiniPak - 3 x 10 mL	
Thawed Opened Stability	4 days at 2 to 8°C	14 days at 2°C to 8 °C	
		Except	Folate: 4 days at 2 to 8°C
			Estradiol: 5 days at 2 to 8°C
Thawed Unopened Stability	4 days at 2 to 8°C	30 days at 2 to 8°C	
		Except	Folate: 4 days at 2 to 8°C
			Estradiol: 8 days at 2 to 8°C
			Free PSA, PSA, Prolactin: 14 days at 2 to 8°C
Storage unopened (Shelf life)	-20°C to -50°C until expiration date	-20°C to -70°C until expiration date	

Analytes	Contains:		Contains:	
	• Acetaminophen • Alpha Fetoprotein • Amikacin • Caffeine • Carbamazepine • Carcinoembryonic Antigen • CK-MB Isoenzyme • Digoxin • Estradiol • Ferritin • Folate • Follicle Stimulating Hormone • Gentamicin • Human Chorionic Gonadotropin -Beta Subunit • Immunoglobulin A • Immunoglobulin E • Immunoglobulin G • Immunoglobulin M • Iron • Luteinizing Hormone • Lidocaine	• Lithium • N-Acetylprocainamide • Phenobarbital • Phenytoin • Procainamide • Prolactin • Prostate Specific Antigen • Prostate Specific Antigen, Free • Salicylate • T_3, Free • T_3, Total • T_3 Uptake/T Uptake • T_4, Free • T_4, Total • Theophylline • Tobramycin • Thyroid Stimulating Hormone • Valproic Acid • Vancomycin • Vitamin B_{12}	• 17-Alpha Hydroxyprogesterone • 11-Deoxycortisol • 25-Hydroxy Vitamin D • Acetaminophen • Alpha Fetoprotein • Aldosterone • Amikacin • Amiodarone • Amitriptyline • Androstenedione • Angiotensin I • Antithyroid Peroxidase Antibodies • Antithyroglobulin antibody • Caffeine • Carbamazepine • Carbamazepine, Free • Carcinoembryonic Antigen • Chloramphenicol • CK-MB Isoenzyme • Cortisol • Cyclosporine • Desipramine • Dehydroepiandrosterone • Dehydroepiandrosterone Sulfate • Digoxin • Disopyramide • Estradiol • Estriol, Free • Estrogen, Total • Ethosuximide • Estriol, Total • Ferritin • Flecainide • Folate • Follicle Stimulating Hormone • Fructosamine • Gentamicin • Human Chorionic Gonadotropin • Human Chorionic Gonadotropin -Beta Subunit • Human Growth Hormone • Ibuprofen • Immunoglobulin A • Immunoglobulin E • Immunoglobulin G • Immunoglobulin M	• Imipramine • Insulin • Iron • Luteinizing Hormone • Lidocaine • Lithium • N-Acetylprocainamide • Netilmicin • Nortriptyline • Prostatic Acid Phosphatase • Phenobarbital • Phenytoin • Phenytoin, Free • Primidone • Procainamide • Progesterone • Prolactin • Propanolol • Prostate Specific Antigen • Prostatic Specific Antigen, Free • Parathyroid Hormone - MM • Quinidine • Salicylate • Sex Hormone Binding Globulin • Somatomedin-C • T_3, Free • T_3, Total • T_3 Uptake/T Uptake • T_4, Free • T_4, Total • Thyroxine Binding Globulin • Testosterone • Testosterone, Free • Theophylline • Tobramycin • Total Iron Binding Capacity • Thyroid Stimulating Hormone • Tricyclic Antidepressants Screen • Thyroglobulin • Valproic Acid • Valproic Acid, Free • Vancomycin • Vitamin B_{12}
	Does not Contain:			
	• 17-Alpha Hydroxyprogesterone • 11-Deoxycortisol • 25-Hydroxy Vitamin D • Aldosterone • Amiodarone • Amitriptyline • Androstenedione • Angiotensin I • Antithyroid Peroxidase Antibodies • Antithyroglobulin antibody • Carbamazepine, Free • Chloramphenicol • Cortisol • Cyclosporine • Desipramine • Dehydroepiandrosterone • Dehydroepiandrosterone Sulfate • Disopyramide • Estriol, Free • Estriol, Total • Estrogen, Total • Ethosuximide • Flecainide • Fructosamine • Human Chorionic Gonadotropin	• Human Growth Hormone • Ibuprofen • Imipramine • Insulin • Netilmicin • Nortriptyline • Prostatic Acid Phosphatase • Phenytoin, Free • Primidone • Progesterone • Propanolol • Parathyroid Hormone - MM • Quinidine • Sex Hormone Binding Globulin • Somatomedin-C • Thyroxine Binding Globulin • Testosterone • Testosterone, Free • Total Iron Binding Capacity • Tricyclic Antidepressants Screen • Thyroglobulin • Valproic Acid, Free		

8.0 Statement of Supporting Data

Stability studies have been performed for Liquichek Immunoassay Plus Control to determine following claims:

Thawed Opened Stability: 4 days at 2 to 8°C
Thawed Unopened Stability: 4 days at 2 to 8°C.
Shelf Life Stability: 28 Months at -20°C to -50°C

The acceptance criteria for above studies is defined as the recovery result on final day (T_{Final}) being ± 10% of the recovery result of freshly opened vial (T_{Zero}).

9.0 Conclusion

Liquichek Immunoassay Plus Control is intended to be used for the same purpose as the predicate device. It has human serum matrix and performs similarly as the predicate device.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bio-Rad Laboratories
c/o Suzanne Parsons
9500 Jeronimo Road
Irvine, CA 92618-2017

OCT 17 2012

Re: k122838
Trade Name: Liquichek Immunoassay Plus Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: September 13, 2012
Received: September 17, 2012

Dear Suzanne 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Devices and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH'S Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-576-. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/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) 796-5680 or at its Internet address http://www.fda/gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

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

Enclosure

Indications for Use Form

510(k) Number (if known): **k122838**

Device Name: **Liquichek Immunoassay Plus control**

Indications for Use:

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 the package insert.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(K) k122838