K043208

Summary of Safety and Effectiveness
Liquid Assayed Multiqual

JAN - 7 2005

1.0 **Submitter**

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Contact Person

Maria Zeballos
Regulatory Affairs Specialist
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Date of Summary Preparation

November 16, 2004

2.0 **Device Identification**

Product Trade Name:	Liquid Assayed Multiqual
Common Name:	Multi-Analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

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

Liquid Assayed Multiqual
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K011867

4.0 **Description of Device**

Liquid Assayed Multiqual is prepared from human serum to which purified biochemical material (tissue extracts of human and animal origin), chemicals, drugs, preservatives, and stabilizers have been added.

5.0 **Intended Use**

Liquid Assayed Multiqual 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.

6.0 Comparison of the new device with the Predicate Device

Liquid Assayed Multiqual claims substantial equivalence to the Liquid Assayed Multiqual currently in commercial distribution (K011867). Both of these are liquid, human serum based controls. The new Liquid Assayed Multiqual contains the same analytes as the predicate device with the addition of Lactic Acid.

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

Characteristics	**Bio-Rad Laboratories** Liquid Assayed Multiqual Control (New Device)	**Bio-Rad Laboratories** Liquid Assayed Multiqual Control (Predicate Device K011867)
Similarities		
Intended Use	Liquid Assayed Multiqual 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.	Liquid Assayed Multiqual 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.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Storage (Unopened)	-20°C or colder Until expiration date	-20°C or colder Until expiration date
Open Vial Claim	14 days at 2 to 8°C, with the following exception: LAP Arylamidase will be stable for 3 days.	14 days at 2 to 8°C, with the following exception: LAP Arylamidase will be stable for 3 days.
Differences		
Analytes	Contains: Acetaminophen Alpha-1-Antitripsin αHBDH Apolipoprotein A-1 Apolipoprotein B Alkaline Phosphatase (ALP) ALT/SGPT Amikacin Amylase Amylase, Pancreatic AST/SGOT Acid Phosphatase Albumin Bilirubin, Direct Bilirubin, Neonatal Bilirubin, Total C3 Complement C4 Complement Ceruloplasmin Cholinesterase Calcium, Ionized Copper Calcium, Total Carbamazepine Carbon Dioxide (CO2) Chloride HDL LDL Cholesterol, Total CK-MB Isoenzyme Cortisol Creatinine Creatine Kinase (CK) Ferritin Ethanol Digoxin GGT Gentamicin Globulin Glucose Haptoglobin Iron Immunoglobulin A (IgA) Immunoglobulin G (IgG) Immunoglobulin M (IgM) TIBC UIBC Lactate (Lactic Acid) LDH LAP Arylamidase Lipase Lithium Magnesium Osmolality Phenobarbital Phenytoin Phospholipids Phosphorus Potassium Prealbumin PAP Protein Electrophoresis Protein, Total Salicylate Sodium T3 Free T3 Total T3 Uptake/T-Uptake T4 Total T4 Free Theophylline TSH Tobramycin Transferrin Triglycerides Urea Urea Nitrogen (BUN) Uric Acid Valproic Acid Vitamin B12 Zinc	Contains: Same analytes as the new device with the exception of Lactic Acid.

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquid Assayed Multiqual. Product claims are as follows:

7.1	**Open vial**	14 days at 2 to 8°C, with the following exception: LAP Arylamidase will be stable for 3 days.
7.2	**Thawed and Unopened**:	30 days at 2 to 8°C, with the following exceptions: Total Bilirubin values may decrease, Alkaline Phosphatase activity may rise. The control must be stored frozen when using AST methods without pyridoxal-5-phosphate.
7.3	**Shelf Life Stability**	3 Years at -20°C or colder

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 7 2005

Ms. Maria Zeballos
Regulatory Affairs Specialist
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k043208
Trade/Device Name: Liquid Assayed Multiqual
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: November 16, 2004
Received: November 19, 2004

Dear Ms. Zeballos:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043208

Device Name: **Liquid Assayed Multiqual**

Indications For Use: **Liquid Assayed Multiqual 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.**

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

acting
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043208