Summary of Safety and Effectiveness
Liquid Assayed Multiqual

K100727

1.0 **Submitter**

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SEP 14 2010

Contact Person

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Date of Summary Preparation

September 10, 2010

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: K043208

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 this 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 (K043208). Both of these controls are liquid human serum base with identical formulation. 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	Bio-Rad Laboratories Liquid Assayed Multiqual (New Device)	Bio-Rad Laboratories Liquid Assayed Multiqual (Predicate Device K043208)
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
Differences		
Storage (Unopened)	Until expiration date at -20°C to -50°C	Until expiration date at -20°C to -70°C
Thawed and Unopened Claim	30 days at 2 to 8°C, with the following exceptions: Direct Bilirubin 11 days, Triglycerides, HDL, Cholinesterase, Phosphorus 7 days. Total Bilirubin and Direct Bilirubin values may decrease, Alkaline Phosphatase activity may rise.	30 days at 2 to 8°C, with the following exceptions: Direct Bilirubin 11 days, Triglycerides, HDL, Phosphorus 7 days, Total Bilirubin and Direct Bilirubin values may decrease, Alkaline Phosphatase activity may rise. The control must be stored frozen when using AST methods without pyridoxal-5-phosphate.
Thawed and Opened Claim	5 days at 2 to 8°C. Note: CO_2 values may gradually decrease on-board the Siemens Dimension Vista, following product sampling into the aliquot plate if allowed to stand for an extended time period.	14 days at 2 to 8°C, with the following exception: Direct Bilirubin, Triglycerides, HDL, Phosphorus will be stable for 7 days, LAP Arylamidase will be stable for 3 days.
Frozen Aliquot	None	AST/SGOT, Direct Bilirubin, HDL, Phosphorus, LDL, Triglycerides, LAP Arylamidase: 14 days in amber vials at –20 to –70°C
Fill Volume	2.5 mL	3 mL
Analytes	Contains: Acetaminophen Alpha-1-Antitripsin Apolipoprotein A-1 Apolipoprotein B Albumin Alkaline Phosphatase (ALP) ALT/SGPT Amylase AST/SGOT Bilirubin, Direct Bilirubin, Total C3 Complement C4 Complement Ceruloplasmin Calcium, Total Carbamazepine Carbon Dioxide (CO2) Chloride HDL LDL Cholesterol, Total Pseudocholinesterase Creatinine Creatine Kinase (CK) Digoxin Ethanol Ferritin GGT Gentamicin Glucose Haptoglobin Iron Immunoglobulin A (IgA) Immunoglobulin G (IgG) Immunoglobulin M (IgM) TIBC Lactate (Lactic Acid) LDH Lipase Lithium Magnesium Phenobarbital Phenytoin Phosphorus Potassium Prealbumin Protein, Total Salicylate Sodium T3 Total T3 Uptake/T-Uptake T4 Total T4 Free Theophylline TSH Tobramycin Transferrin Triglycerides Urea Nitrogen (BUN) Uric Acid Valproic Acid Vitamin B12 **Does Not Contain:** αHBDH Amikacin Amylase, Pancreatic Acid Phosphatase Bilirubin, Neonatal Calcium, Ionized Copper CK-MB Isoenzyme Cortisol Globulin UIBC LAP Arylamidase Osmolality Phospholipids PAP Protein Electrophoresis Urea Zinc	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

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**	5 days at 2 to 8°C
7.2	**Thawed and Unopened**:	30 days at 2 to 8°C, with the following exceptions: Direct Bilirubin 11 days, Triglycerides, HDL, Cholinesterase, Phosphorus 7 days. Total Bilirubin and Direct Bilirubin values may decrease, Alkaline Phosphatase activity may rise.
7.3	**Shelf Life Stability**	3 Years at -20°C to -50°C
7.4	**Assignment of Values**	The assigned values were derived from replicate analyses and are specific for each lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of the product lot. Assigned values are presented as means and ±3SD ranges.

8.0 Conclusion

Liquid Assayed Multiqual (new device) is intended to be used for the same purposes as the predicate device, it has the same 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
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Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Bio-Rad Diagnostics Group
c/o Suzanne Parsons
Regulatory Affairs/QA/QC Manager
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Irvine, CA 92618-2017, USA

SEP 1 4 2010

Re: k100727
Trade/Device Name: Liquid Assayed Multiqual
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: August 27, 2010
Received: September 3, 2010

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.

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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
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 Form

510(k) Number (if known): **K100727**

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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) K100727