510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k100727

B. Purpose for Submission:

Formulation change

C. Measurand:

Multi-analyte quality control material. See list of analytes in Section I: Device Description of this 510(k) Decision Summary.

D. Type of Test:

Quality Control Material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquid Assayed Multiqual 1
Liquid Assayed Multiqual 2
Liquid Assayed Multiqual 3
Liquid Assayed Multiqual MiniPak

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

   Class I, reserved

3. Product code:

   JJY - Multi-Analyte Controls, All Kinds (Assayed)

4. Panel:

   75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below.

2. Indication(s) 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 the package insert.

3. Special conditions for use statement(s):

   For *in vitro* diagnostic use. For prescription use only.

4. Special instrument requirements:

   For use with the Siemens Dimension Vista test system.

I. Device Description:

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. The product consists of three different levels for each of the analytes listed below and it is provided as a liquid.

List of Analytes	
Acetaminophen	Iron
Alpha-1-Antitripsin	Immunoglobulin A (IgA)
Apolipoprotein A-1	Immunoglobulin G (IgG)
Apolipoprotein B	Immunoglobulin M (IgM)
Albumin	TIBC
Alkaline Phosphatase (ALP)	Lactate (Lactic Acid)
ALT/SGPT	LDH
Amylase	Lipase
AST/SGOT	Lithium
Bilirubin, Direct	Magnesium
Bilirubin, Total	Phenobarbital
C3 Complement	Phenytoin
C4 Complement	Phosphorus

Ceruloplasmin	Potassium
Calcium, Total	Prealbumin
Carbamazepine	Protein, Total
Carbon Dioxide (CO2)	Salicylate
Chloride	Sodium
HDL	T3 Total
LDL	T3 Uptake/T-Uptake
Cholesterol, Total	T4 Total
Pseudocholinesterase	T4 Free
Creatinine	Theophylline
Creatine Kinase (CK)	TSH
Digoxin	Tobramycin
Ethanol	Transferrin
Ferritin	Triglycerides
GGT	Urea Nitrogen (BUN)
Gentamicin	Uric Acid
Glucose	Valproic Acid
Haptoglobin	Vitamin B12

The manufacturer included the following statement in the product package insert: "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. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens."

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Liquid Assayed Multiqual

2. Predicate 510(k) number(s):

   k043208

3. Comparison with predicate:

Similarities		
Item	Device (k100727)	Predicate (k043208)
Indications for use	For use as an assayed quality control serum to monitor the precision of laboratory testing procedures	Same

Similarities		
Item	Device (k100727)	Predicate (k043208)
	for the analytes listed in the package insert.	
Format	Liquid	Same
Matrix	Human serum	Same
Levels	3	Same

Differences		
Item	Device (k100594)	Predicate (k092168)
Analytes	See device description, section I of this 510(k) Decision Summary	Also contains: 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
Fill Volume	2.5 mL	3 mL
Instrument	Siemens Dimension Vista	Various
Stability	Unopened -20 to -50°C until expiration date. Unopened-Thawed 30 days at 2-8°C, with 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. Opened 5 days at 2-8°C.	Unopened -20 to -70°C until expiration date. Unopened-Thawed 30 days at 2-8°C, with 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. Opened 14 days at 2-8°C, with the following exceptions: Direct Bilirubin, Triglycerides, HDL, Phosphorus-7 days; LAP Arylamidase-3 days

K. Standard/Guidance Document Referenced (if applicable):

None were referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

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.

Expected Values and Value Ranges

Expected values for the Liquid Assayed Multiqual are determined by duplicate analyses of levels 1 to 3 using Siemens Dimension Vista analyzers by the analyzer manufacturer. Pre-determined acceptance criteria for analyte recovery must be met for each control lot. The target value for each CalCheck is the mean of the observed values. Assigned values and value ranges are lot dependent and are listed in the lot-specific value sheet. Test results should fall within the corresponding ±3SD range printed on the lot-specific value sheet. The labeling states that laboratories should establish their own means and acceptable ranges.

Stability

Stability testing data support the manufacturer claims that the Liquid Assayed Multiqual is stable until the expiration date printed on the vial when stored unopened at -20 to -50°C. Accelerated stability testing supports the target shelf life claim of three years. The manufacturer has an on-going real-time stability study design to support the recommended storage conditions for the life of the product. The unopened-thawed vials are stable for thirty days at 2-8°C with the following exceptions: Direct Bilirubin-11 days; Triglycerides, HDL, Cholinesterase, Phosphorus-7 days. The following statement has been

added to the label: Total Bilirubin and Direct Bilirubin values may decrease; Alkaline Phosphatase activity may rise under these storage conditions. The opened vials (on-board) are stable for five days at 2-8°C.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values are provided in the labeling for each specific lot.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.