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

A. 510(k) Number:

k093492

B. Purpose for Submission:

New devices

C. Measurand:

Quality control and calibrator material for multiple constituents listed in the indications for use H. 2. below.

D. Type of Test:

Not applicable

E. Applicant:

Diamond Diagnostics Inc.

F. Proprietary and Established Names:

Mission CliniCheck Assayed Chemistry Control I and II

Mission CliniCAL Calibrator

G. Regulatory Information:

1. Regulation Section:

21 CFR 862.1660

21 CFR 862.1150

2. Classification:

Class II, Class I, reserved

3. Product Code:

JJY, JIT

4. Panel:

75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

   Mission ClinCheck Controls is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the following analytes Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Amylase, Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total) Calcium, Carbon Dioxide (CO_2), Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatinine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Iron, Iron Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, sodium, Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid which are listed in the expected values chart.

   Mission CliniCAL Calibrator is an *in vitro* diagnostic product intended for use as a calibration serum in clinical chemistry assays. Mission CliniCAL is a single level calibratoe based on lypholized human serum which contains the following analytes Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Amylase, Aspartate Aminotransferase (AST/GOT), Bicarbonate (CO2) Bilirubin (Direct) Bilirubin (Total), Calcium, Chloride, Cholesterol (Total), Cholinesterase, Creatinine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Iron, Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Sodium, Triglycerides, Urea, Urea Nitrogen and Uric Acid. The concentrations and activities are suitable for calibration of clinical chemistry assays both manually and on various automatic analyzers.

3. Special conditions for use statement(s):

   For Prescription Use Only

4. Special instrument requirements:

   Abbott chemistry analyzers, ROCHE Hitachi and Cobas Mira analyzers, Beckman chemistry analyzers, and Olympus chemistry analyzers. The package insert lists the

specific analyzers for each analyte.

I. Device Description:

Mission CliniCheck Assayed Chemistry Control is a human serum based product containing constituents of purified biochemicals (tissue extracts of human and animal origin), chemicals, therapeutic drugs, preservatives and stabilizers. Two levels of Control are provided in a lyophilized form. It is packaged into a glass amber bottle, each containing 5ml of product. The product is packaged in single level boxes (10 x 5mL) or multiple level boxes (5 x 2 x 5mL).

Mission ClinCAL Calibrator is a single level calibrator based on lyophilized human serum containing constituents of purified biochemicals (tissue extracts of human and animal origin), chemicals, therapeutic drugs, preservatives and stabilizers. It is packaged in a glass amber bottle, each containing 3mL of product. The product is packaged in multiple level boxes (5 x 2 x 3mL).

All human source material was tested and found negative by FDA approved methods for HBsAG, HCV, and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   BioRad Lyphochek Assayed Chemistry Control (Level 1, 2)

   Randox Level 3 Calibrator

2. Predicate 510(k) numbers:

   k040273

   k053153

3. Comparison with Predicate

Similarities		
Characteristics	**Mission CliniCheck Assayed Chemistry Control**	**Predicate Device BioRad Lyphochek Assayed Chemistry Control k040273**
Intended Use	For *in vitro* diagnostic use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the following analytes Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Amylase, Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct),	Same

	Bilirubin (Total) Calcium, Carbon Dioxide (CO2), Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatinine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Iron, Iron Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, sodium, Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid which are listed in the expected values chart.	
Matrix	Serum	Same
Form	Lyophilized	Same
Levels	Two	Same
Storage	2-8˚C	Same
Shelf Life	24 months	Same

Differences		
Characteristics	**Mission CliniCheck Asssayed Chemistry Control**	**Predicate Device BioRad Lyphochek Assayed Chemistry Control k040273**
Constituents	Does not contain values for Acetominophen, Alpha Hydroxybytryate Dehydrogenase (α-HBDH), Alpha-1-Antitrypsin, Alpha-Fetoprotein, Amylase (Alpha), Amylase (Pancreatic), Apolipoprotein B, Bilirubin (Indirect), C3 Complement, C4 Complement, Calcium (ionized) Carbamazepine, Carcinoembryonic Antigen, Ceruloplasmin, Copper, Cortisol, Digoxin, Gentamicin, Globulin, Glutamate Dehydrogenase (GLDH), Haptoglobin, hCG-Beta Subunit, Immunoglbulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron Binding Capacity, Total (TIBC), LAP-Arylamidase, Osmolality, Phenobarbital, Phenytoin, Prostate Specific Antigen (PSA), Prostatic Acid Phosphatase (PAP), protein Electrophoresis, T3 Free, T3 Total, T3 Uptake/T Uptake, T4 Free, T4 Total, Theophylline, Thyroid Stimulating Hormone (TSH), Thyroxine Binding Globulin (TBG), Tobramycin, Valproic Acid, Vancomycin, Vitamin B12 and Zinc.	Does contain values for the analytes listed to the left.
Reconstituted Stability	20 days at -20˚C	30 days at -20˚C

Similarities		
Characteristics	**Mission CliniCAL Calibrator**	**Predicate Device Randox Level 3 Calibrator k053153**
Intended Use	For *in vitro* diagnostic use as a calibration serum in clinical chemistry assays. Mission CliniCAL is based on lypholized human serum which contains the following analytes Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline	Same

	Phosphatase (ALP), Amylase, Aspartate Aminotransferase (AST/GOT), Bicarbonate (CO2) Bilirubin (Direct) Bilirubin (Total), Calcium, Chloride, Cholesterol (Total), Cholinesterase, Creatinine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Iron, Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Sodium, Triglycerides, Urea, Urea Nitrogen and Uric Acid. The concentrations and activities are suitable for calibration of clinical chemistry assays both manually and on various automatic analyzers.	
Matrix	Serum	Same
Form	Lyophilized	Same
Storage	2-8˚C	Same

Differences		
Characteristics	**Mission ClinCAL Calibrator**	**Predicate Device Randox Level 3 Calibrator k053153**
Constituents	Does not contain values for Acid Phosphatase (non-prostatic), Acid Phosphatase (prostatic), Bile Acids, Copper, D-3 Hydroxybutyrate, Glutamate Dehydrogenase (GLDH), Alpha Hydroxybutyrate Dehydrogenase, (α-HBDH), Leucine Aminopeptidase (LAP), Osmolality, Iron Binding Capacity, Total (TIBC), and Zinc	**Does contain values for the analytes listed to the left.**
Volume	3 mL per bottle	5 mL per bottle
Reconstitution Diluent	Bicarbonate Buffer	DI Water
Shelf Life	24 months	36 months
Reconstituted Stability	3 days at 2-8˚C, 20 days at -20˚C	7 days at 4˚C, 30 days at -20˚C
Levels	One	Two

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

Guidance for Industry and FDA Staff-Assayed and Unassayed Quality Control Material

Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final Guidance for Industry

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):

Mission Clinicheck Assayed Chemistry Control and Mission Clinical Calibrator

Analyte	Traceability
Sodium Chloride, lithium acetate, sodium lactate, BUN (Urea), calcium acetate, creatinine, dextrose, magnesium chloride, NaHPO4, uric acid, potassium chloride, iron, sodium acetate, transferring, conjugated bilirubin, bilirubin	ACS or Reagent grade
LD, AST, ALT, CK, GGT, Amylase, Lipase, Alkaline Phosphatase, Cholinesterase, Acid Phosphatase	Animal or plant derived from commercial vendors
Triglyceride	In house preparation
Albumin, Cholesterol, HDL Cholesterol, LDL Cholesterol	Commercial vendors
Salicylate	ACS or Reagent Grade

Mission Clinicheck Assayed Chemistry Control

Target values for each analyte were obtained by analyzing multiple replicates of each analyte over several days. Multiple replicates of each analyte were tested daily. An average of the values obtained was used to establish the target concentration. Range is assigned based upon pre-determined intervals. Value assignment for the Mission Clinicheck controls is lot specific. Lot to lot variation is determined by testing new lot versus previous lot normalized to either a serum standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or predetermined intervals.

Shelf-Life, Open Vial and Accelerated Stability testing protocols and acceptance criteria were described and found to be adequate. The Mission Clinicheck Assayed Chemistry controls have an estimated shelf life of 24 months when stored at 2-8˚C. The Mission Clinicheck Assayed Chemistry controls are stable for 7 days when stored at 2-8˚C with the following exception: Acid Phosphatase will be stable for 3 days when stored tightly capped at 2-8˚C. The labeling states that the Mission

Clinicheck Assayed Chemistry controls are stable up to 20 days after reconstitution when stored tightly capped at -10 to -20˚C. The labeling states that the control material should not be refrozen. Once thawed the remaining material should be discarded. Real time stability testing is ongoing.

Mission CliniCAL Calibrator

The mean values listed in the package insert were derived from multiple determinations performed on randomly selected samples from that particular lot. Multiple replicates of test samples and a master calibrator lot were measured for the analytes on consecutive days. The mean analyte values were calculated using the master lot of calibrator and target values assigned. To substantiate the new values created, the new lots of Mission CliniCAL calibrator were tested against predetermined intervals on selected chemistry analyzers using 2 levels of commercially available quality control material.

Shelf-Life, Open Vial, and Accelerated Stability testing protocols and acceptance criteria were described and found to be adequate. The Mission CliniCAL calibrator has an estimated shelf life of 24 months when stored at 2-8˚C. Once reconstituted, with the diluent provided, the Mission CliniCAL is stable for 72 hours at 2-8˚C with the following exception: Total Alkaline Phosphatase is stable for at least one day when stored tightly capped at 2-8˚C. The labeling states that the Mission ClinCAL calibrator is stable for at least 20 days after reconstitution when stored tightly capped at -20˚C. The labeling also states that the control material should not be refrozen. Once thawed the remaining material should be discarded. Real time stability testing is ongoing.

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 values for each analyte are provided in the package insert.

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.