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

A. 510(k) Number:

k124009

B. Purpose for Submission:

Addition of the following 7 analytes to a previously cleared quality control material (k103364): Acetaminophen, Alpha-1 Anti-Trypsin, Alpha Fetoprotein, Carcinoembryonic Antigen, Ceruloplasmin, Digoxin, and Haptoglobin.

C. Measurand:

Quality control materials for Acetaminophen, Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Alpha-1 Anti-Trypsin, Alpha Fetoprotein, Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Amylase, Apolipoprotein A-1 (APO-A1), Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO_2), Carcinoembryonic Antigen (CEA), Ceruloplasmin, Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Digoxin, Gamma Glutamyltransferase (GGT), Glucose, Haptoglobin, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron-Binding Capacity, Total (TIBC), Iron-Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, Sodium, T_3 Free, T_3 Total, T_4 Free, T_4 Total, Thyroid Stimulating Hormone (TSH), Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid.

D. Type of Test:

Not applicable

E. Applicant:

Diamond Diagnostics, Inc.

F. Proprietary and Established Names:

Mission CliniCheck Assayed Chemical Control

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1660

2. Classification:

   Class I, reserved

3. Product code:

   JJY

4. Panel:

   Clinical chemistry (75)

H. Intended Use:

1. Intended use(s):

   See section H.2 "Indication(s) for use" below

2. Indication(s) for use:

   Mission CliniCheck Controls is intended to use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the following analytes: Acetaminophen, Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Alpha-1 Anti-Trypsin, Alpha Fetoprotein, Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Amylase, Apolipoprotein A-1(APO-A1), Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO_2), Carcinoembryonic Antigen (CEA), Ceruloplasmin, Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Digoxin, Gamma Glutamyltransferase (GGT), Glucose, Haptoglobin, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron-Binding Capacity, Total (TIBC), Iron-Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, Sodium, T_3 Free, T_3 Total, T_4 Free, T_4 Total, Thyroid Stimulating Hormone (TSH), Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid on instruments listed in the expected values chart.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   The package insert lists the following instruments for which the quality control material is intended: Abbott Chemistry Analyzers, Abbot AxSYM Analyzer, Roche Hitachi Chemistry Analyzers, Beckman Chemistry Analyzers, Beckman Olympus Chemistry Analyzers, Siemens Advia Series, and Siemens Dimension Series.

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 per analyte are provided in a lyophilized form. Each level is packaged into a glass amber bottle containing 5 mL of product. The product is packaged in single level boxes (12 x 5 mL) or multiple level boxes (6 x 2 x 5mL) and stored at 2 – 8 °C.

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):
   Mission CliniCheck Assayed Chemistry Control
2. Predicate 510(k) number(s):
   k103364
3. Comparison with predicate:

Similarities		
Characteristics	New Device (k124009)	Predicate (k103364)
Name	Mission CliniCheck Assayed Chemistry Control	Same
Intended use	For in vitro diagnostics use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.	Same
Matrix	Serum	Same
Form	Lyophilized	Same
Levels	Two	Same
Storage	2-8° C	Same
Reconstituted stability	20 days at -20°C	Same
Shelf Life	24 months	Same

Differences		
Characteristics	New Device (k124009)	Predicate (k103364)
Constituents	Acetaminophen, Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Alpha-1 Anti-Trypsin, Alpha Fetoprotein, Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Amylase, Apolipoprotein A-1(APO-A1), Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO_2), Carcinoembryonic Antigen (CEA), Ceruloplasmin, Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Digoxin, Gamma Glutamyltransferase (GGT), Glucose, Haptoglobin, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron-Binding Capacity, Total (TIBC), Iron-Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, Sodium, T_3 Free, T_3 Total, T_4 Free, T_4 Total, Thyroid Stimulating Hormone (TSH), Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid.	Not assayed for Acetaminophen, Alpha-1 Anti-Trypsin, Alpha Fetoprotein, Carcinoembryonic Antigen, Ceruloplasmin, Digoxin, and Haptoglobin

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):

Traceability:

Acetaminophen and Digoxin are manufactured gravimetrically using US Pharmacopeia (USP) grade reference material. Alpha Fetoprotein, and Carcinoembryonic Antigen are manufactured and referenced to WHO standards. Ceruloplasmin is manufactured and referenced to IFCC standard. Alpha-1 Anti-Trypsin and Haptoglobin are endogenously sourced from the base matrix comprised of human serum.

Stability:

Shelf-Life and Reconstitution Stability testing protocols and acceptance criteria were described and found to be adequate.

Shelf-Life Stability – Accelerated stability testing supports a shelf-life stability claim of 2 years at 2-8ºC for Mission CliniCheck Assayed Chemistry Controls. Real-Time stability study is on-going.

Reconstitution Stability – Real time testing was performed and supports the following claims: reconstituted Mission CliniCheck Assayed Chemistry Controls are stable for up to 7 days at 2-8°C and 20 days at -20°C.

Value Assignment:

Olympus AU 600 and Abbott AxSYM were used for value assignment. Sixteen replicates of each analyte were tested over 4 days with 4 replicates tested each day. The 16 data points were compiled and the mean was used as the target concentration. Value assignment ranges were established at ±20% around the target concentration. The target mean and range for each analyte are provided in tabular form in the value assignment sheets.

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:

Expected values are provided in the value assignment sheets provided with the package insert.

N. Proposed Labeling:

The labeling is sufficient and 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.