

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

A. 510(k) Number:

k103364

B. Purpose for Submission:

Addition of the following analytes to a previously cleared quality control material (k093492): Alpha Hydroxybutyrate dehydrogenase (α -HBDH), Apolipoprotein A-1, C3 Complement, C4 Complement, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron Binding Capacity, Total (TIBC), T3 Free, T3 Total, T4 Free, T4 Total, Thyroid Stimulating Hormone (TSH)

C. Measurand:

Quality control materials for Alpha Hydroxybutyrate dehydrogenase (α -HBDH), Apolipoprotein A-1, C3 Complement, C4 Complement, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron Binding Capacity, Total (TIBC), T3 Free, T3 Total, T4 Free, T4 Total, Thyroid Stimulating Hormone (TSH)

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 1, reserved

3. Product code:

JJY

4. Panel:

Clinical chemistry

H. Intended Use:

1. Intended use(s):

See section H.2 “Indication(s) for use”

2. Indication(s) for use:

Mission CliniCheck Controls is intended or 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), Alubmin, Alkaline Phosphatase (ALP), Alpha Hydroxybutyrate Dehydrogenase (α -HBDH), Amylase, apolipoprotein A-1, Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO₂), Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron Binding Capacity, Total (TIBC), Unsaturated (UIBC), Lactate (Lactic Acid), Lactate Dehydrogenase (LDH), Lipase, Lithioum, Magnesi, Phophorus, Potassium, Protein-Total, Salicylate, Sodium, T₃ Free, T₃ Total, T₄ Free, T₄ 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, Olympus Chemistry Analyzers, Roche Diagnostics Cobas Mira Analyzers, 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Mission CliniCheck Assayed Chemistry Control, Levels 1 and 2
2. Predicate 510(k) number(s):
k093492
3. Comparison with predicate:

Similarities		
Characteristics	Device: Mission CliniCheck Assayed Chemistry Control	Predicate: Mission CliniCheck Assayed Chemistry Control, k093492
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	Device: Mission CliniCheck Assayed Chemistry Control	Predicate: Mission CliniCheck Assayed Chemistry Control, k093492
Constituents	Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Alubmin, Alkaline Phosphatase (ALP),	Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Amylase,

Differences		
Characteristics	Device: Mission CliniCheck Assayed Chemistry Control	Predicate: Mission CliniCheck Assayed Chemistry Control, k093492
	Alpha Hydroxybutyrate Dehydrogenase (α -HBDH), Amylase, apolipoprotein A-1, Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO ₂), Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Gamma Glutamyltransferase (GGT), Glucose, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron Binding Capacity, Total (TIBC), 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	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
Packaging	12 x 5 mL	10 x 5 mL

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:

Values assigned to the T3, T4 and TSH assays are traceable to the reference standards used by the commercial vendor as referenced in their Certificate of Analysis to establish instrument response in their assays. Alpha Hydroxybutyrate dehydrogenase, Apolipoprotein A-1, C3 Complement, C4 Complement, IgA, IgG and IgM are endogenously sourced from the base matrix comprised of human serum.

Stability:

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

Shelf-Life – The sponsor provided accelerated stability data to support data demonstrating that the Mission CliniCheck Assayed Chemistry Controls can be stored for 2 years. Real-Time stability study is on-going.

Open-vial – The sponsor provided data demonstrating that upon opening a vial Mission CliniCheck Assayed Chemistry Controls, the material is stable for 7 days at 2-8 °C and 20 days -20°C.

Value Assignment:

Instruments used for the value assignment included Hitachi 911, Roche Cobas Mira, Olympus AU 600, Beckman CX7, Abbott AxSYM, and Siemens Dimension RxL. Sixteen replicates of each analyte were collected over a period of 4 days; 4 replicates of each analyte were tested. The 16 data points were compiled and the average used as the target concentration. The range represents ± 3 SD (95% CI) around the mean value. The mean and range 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.