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

A. 510(k) Number:

k102700

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for Cholesterol (TC), Triglyceride (TRG), High-Density Lipoprotein (HDL), Glucose (Glu), Alanine Transaminase (ALT) and Aspartate Transaminase (AST)

D. Type of Test:

Quality Control Materials

E. Applicant:

Alere San Diego, Inc.

F. Proprietary and Established Names:

The Alere Cholestech LDX Lipid Controls

The Alere Cholestech LDX Multianalyte Controls

The Alere Cholestech LDX Calibration Verification

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I, reserved	21 CFR 862.1660 Quality Control Material	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

Refer to indication for use below

2. Indication(s) for use:

   The Alere Cholestech LDX Lipid Controls, Level 1 and Level 2, are designed to be used only for monitoring the performance of test procedures on the Alere Cholestech LDX System.

   The Alere Cholestech LDX Multianalyte Controls, Level 1 and Level 2, are designed to be used only for monitoring the performance of test procedures on the Alere Cholestech LDX System.

   The Alere Cholestech LDX Calibration Verification, Levels 1-4, are designed to be used for verifying the reportable range tests on the Alere Cholestech LDX System. This material is intended for use with any Alere Cholestech LDX cassette type that includes total cholesterol, triglycerides and glucose.

3. Special conditions for use statement(s):

   For prescription use

4. Special instrument requirements:

   Alere Cholestech LDX System

I. Device Description:

The Alere Cholestech LDX Lipid Controls, the Alere Cholestech LDX Multianalyte Controls, and the Alere Cholestech LDX Calibration Verification are prepared from human and animal constituents in a BSA-based buffered medium containing antimicrobial and antifungal agents. The ranges of the analyte concentrations are summarized in the below tables:

Alere Cholestech LDX Lipid Controls

Control Range	TC (mg/dL)	HDL (mg/dL)	TRG (mg/dL)	Glu (mg/dL)
Level 1	155-185	30-40	120-150	110-140
Level 2	235-285	60-80	250-300	250-300

Alere Cholestech LDX Multianalyte Controls

Control Range	TC (mg/dL)	HDL (mg/dL)	TRG (mg/dL)	Glu (mg/dL)	ALT (U/L)	AST (U/L)
Level 1	155-185	30-40	120-150	110-140	50-65	38-52
Level 2	235-285	60-80	250-300	250-300	175-250	125-175

Alere Cholestech LDX Calibration Verification

Control Range	TC (mg/dL)	HDL (mg/dL)	TRG (mg/dL)	Glu (mg/dL)
Level 1	130-150	25-30	130-150	75-95
Level 2	185-215	35-45	185-215	185-215
Level 3	285-315	50-60	285-315	280-320
Level 4	360-400	70-80	430-470	375-425

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Cholestech LDX Lipid Controls, Cholestech LDX Multianalyte Controls, Cholestech LDX Calibration Verification Materials

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

   k913687

3. Comparison with predicate:

   Other than the manufacturing site change, the new device is produced using the same raw materials and manufacturing processes with the same intended use as the predicate device.

Characteristic	Alere Cholestech LDX Lipid Controls **(New Device)**	Cholestech LDX Lipid Controls **(Predicate Device)**
Intended Use	Same	Assayed quality control material for the use with the Cholestech LDX system
Format	Same	Liquid
Analyte(s) Reported	Same	TC HDL TRG GLU
Levels	Same	2
Matrix	Same	BSA-based buffer
Packaging	Same	Chipboard box with chipboard cut-out insert

Characteristic	Alere Cholestech LDX Multianalyte Controls **(New Device)**	Cholestech LDX Multianalyte Lipid Controls **(Predicate Device)**
Intended Use	Same	Assayed quality control material for the use with the Cholestech LDX system
Format	Same	Liquid
Analytes	Same	Total Cholesterol (TC) HDL-Cholesterol (HDL) Triglyceride (TRG) Glucose (GLU) Alanine amino transferase (ALT) Aspartate amino transferase (AST)
Levels of Controls	Same	2
Matrix	Same	BSA-based buffer
Packaging	Same	Chipboard box with chipboard cut-out insert

Characteristic	Alere Cholestech LDX Calibration Verification **(New Device)**	Cholestech LDX Calibration Verification **(Predicate Device)**
Intended Use	Same	This material is intended for use with any Alere Cholestech LDX cassette type that includes total cholesterol, triglycerides and glucose for verifying the reportable range of tests on the Alere Cholestech LDX System.
Format	Same	Liquid
Analyte(s) Reported	Same	TC HDL TRG GLU
Levels of Controls	Same	4
Matrix	Same	BSA-based buffer
Packaging	Same	Chipboard box with chipboard cut-out insert

Characteristic	Alere Cholestech LDX Multianalyte Controls, New Configuration **(New Device)**	Cholestech LDX Multianalyte Lipid Controls **(Predicate Device)**
Similarities		
Intended Use	Same	Assayed quality control material for the use with the Cholestech LDX system
Format	Same	Liquid
Analyte(s) Reported	Same	TC HDL TRG GLU ALT AST
Levels of Controls	Same	2
Matrix	Same	BSA-based buffer
Differences		
Packaging	Polyethylene clamshell	Chipboard box with chipboard cut-out insert
Number of Vials per package	2 vials of each level	1 vial of each level 3 vials of each level

Characteristic	Alere Cholestech LDX Calibration Verification Materials, New Configuration **(New Device)**	Cholestech LDX Calibration Verification Materials **(Predicate Device)**
Similarities		
Intended Use	Same	This material is intended for use with any Alere Cholestech LDX cassette type that includes total cholesterol, triglycerides and glucose for

		verifying the reportable range of tests on the Alere Cholestech LDX System.
Format	Same	Liquid
Analyte(s) Reported	Same	TC HDL TRG GLU
Levels of Controls	Same	4
Matrix	Same	BSA-based buffer
Differences		
Packaging	Polyethylene clamshell	Chipboard box with chipboard cut-out insert

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

TC, TRG and HDL are traceable to the CDC-modified Abell-Kendall reference method and are CRMLN certified. Glu test have calibration traceability to Aqua Cal from Beckman Coulter on the Beckman Synchron Analyzer. ALT and AST are traceable to IFCC reference method.

Value Assignment:

The mean concentration of each analyte is calculated as the average of 64 test results measured in one day using 8 lots of cassettes on 8 different meters. The upper range is

105% of mean +2 times total error; the lower range is 95% of mean-2 times total error. Total error is the sum of intra-assay variability (cassette to cassette), inter-assay variability (cassette lot to cassette lot), and meter variability.

Stability:

The stability study was performed on Alere Cholestech LDX System. The stability protocol and the acceptance criteria have been reviewed and found to be acceptable.

- Shelf-life stability:

  Real-time testing at 2-8^{o}C is on-going to support/justify a shelf life of 9 months.

- Open-vial stability:

  Real-time testing at 2-8^{o}C verified the open-vial stability of at least 30 days.

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 on the vial labels and 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.