CLIA Waiver by Application Approval Determination

Decision Summary

A. Document Number

CW220017

B. Parent Document Number

K223179

C. CLIA Waiver Type:

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

D. Applicant

Alere San Diego, Inc

E. Proprietary and Established Names

Cholestech LDX™ System

F. Measurand (analyte)

Total cholesterol (TC)
High-density lipoprotein (HDL)
Triglycerides (TRG)
Glucose (GLU)

G. Sample Type(s)

Venous and Capillary (fingertip) whole blood

H. Type of Test

Quantitative, enzymatic photometric

I. Test System Description

1. Overview

The Cholestech LDX™ System is a small, portable analyzer and test cassette system. The system is for in vitro diagnostic use only. The Analyzer uses reflectance photometry (the amount of light reflected from a solid surface) to determine the amount of the analyte in blood. The analyzer measures color changes on four reagent pads within the test cassette. The amount of color formed is converted by the analyzer to a concentration and the

results are shown on the liquid crystal display (LCD) screen. The assays for use on the analyzer include total cholesterol (TC), high-density lipoprotein cholesterol (HDL), triglycerides (TRG), glucose (GLU), and by calculation, low-density lipoprotein (LDL), non-HDL cholesterol, and total cholesterol/HDL cholesterol ratio.

The test system was previously cleared under K922612 and K932727 and CLIA waived under K922612/A004, for use with venous and capillary (fingerstick) whole blood unprocessed samples. The current dual submission (K223179|CW220017) is to modify the bilirubin interference claims for the Cholestech LDX™ test system for all analytes. The updated unconjugated and conjugated bilirubin interference claims for the test system are mitigated by incorporating failure alert mechanisms comprised of revisions to the test system software and labeled limitations. To support the modified device is simple and has an insignificant risk of an erroneous result the sponsor performed a risk analysis and developed and validated the fail-safe and failure alert mechanisms, described below.

2. Test System Components

The test system consists of the Cholestex LDX™ Analyzer and the cassettes (Cholestech LDX Lipid Profile•GLU, Lipid Profile, TC•HDL•GLU, TC•HDL, TC•GLU and TC).

Sample collection kits and quality controls are not included with the assay kit. They are available separately.

J. Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-safe Mechanisms

1. Fail-Safe and Failure Alert Mechanisms

    a. Specimen Integrity and Handling/Results Production

        i. A failure alert mechanism was developed to mitigate the risk of reporting falsely decreased results due to bilirubin (conjugated and unconjugated) interference on the the Cholestech LDX™ system. The alert consist of a limitation message, "Cholestech LDX™ is not for use in children under the age of 2 years or patients with hyperbilirubinemia (elevated bilirubin levels)". The limitation has been included in the devices' labeling and is printed on all paper test results as well as shown on all results sent to the electronic medical record. The alert message notifies the health care provider of potential falsely decreased results.

K. Labeling for Waived Devices

The labeling consists of:

1. Cholestech LDX™ Package Insert

2. Cholestech LDX™ System User Manual

2. The following elements are appropriately present:

- The Cholestech LDX™ Package Insert and Cholestech LDX™ System User Manual are written at no higher than a 7th grade reading level.
- The Cholestech LDX™ System User Manual and Cholestech LDX™ Package Insert identify the test as CLIA waived.
- The Cholestech LDX™ System User Manual and Cholestech LDX™ test cartridge package insert contain a statement that a Certificate of Waiver is required to perform the test in a waived setting.
- The Cholestech LDX™ System User Manual and Cholestech LDX™ Package Insert contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1).
- The Cholestech LDX™ System User Manual and Cholestech LDX™ Package Insert provide instructions for conducting quality control procedures.
- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.