

# Cholestech LDX

## Calibration Verification Material

### Levels 1-4

Calibration Verification Material for use with the Cholestech LDX System

DO NOT FREEZE. Store refrigerated at 2° – 10° C (36° – 50° F). Open vial stable refrigerated, at 2° – 10° C (36° – 50° F), for 30 days. For *in vitro* diagnostic use only.

#### Expected Results

Refer to the Results Sheet for the expected ranges for each analyte. Be sure that the lot number on the vial of Calibration Verification Material corresponds to the lot number on the Results Sheet. The average value for each analyte should fall within the ranges on the Result Sheet.

The target value and expected ranges for each analyte and each level are derived from data using multiple Cholestech LDX analyzers and cassette lots. The expected ranges apply only to this lot of Calibration Verification Material.

If you would like to have a computer generated report, Fax your results to Cholestech Technical Service at 510-732-7227 or mail to:

Cholestech Corporation  
3347 Investment Blvd.  
Hayward, CA 94545-3808  
Attn: Cholestech Technical Service

Cholestech will evaluate your test data and return a summary report to you within 7 working days from the time of receipt. This service is provided at no charge to Cholestech LDX Customers.

If you have any questions about your results contact Cholestech Technical Service for assistance, (800) 733-0404.

#### Limitations of Procedures

The results obtained using the Calibration Verification Material are dependent upon several factors. Erroneous results can occur from improper storage, inadequate mixing, and technique errors associated with the test. For more information, refer to the "limitations" section of the package insert for the test cassette being used.

#### Indications of Product Deterioration

Inability to obtain expected values may indicate product deterioration. Do not use a vial of Calibration Verification Material if there is evidence of a crack in the vial or microbial growth (cloudiness or odor). If the recovered values are not within the expected ranges:

1. Check expiration date on control vial. Discard outdated products.
2. Review the package insert and the operating procedure for the Cholestech LDX and test cassette. Run a third test on the vial of Calibration Verification Material which is out of range.
3. If the values are still outside of the Expected Ranges, call Cholestech Technical Service Department at (800) 733-0404.

#### Intended Use

Assayed Calibration Verification Material is designed to be used for verifying the reportable range of tests on the Cholestech LDX System. This material is intended for use with any Cholestech Cassette type that includes Total Cholesterol, HDL Cholesterol, Triglycerides, and Glucose. Each set consists of four vials with 2 mL of liquid material.

#### Principle

Calibration Verification is optional for CLIA waived systems, such as the Cholestech LDX Analyzer. However local or state regulations may still require that Calibration Verification be run at regular intervals. Using Calibration Verification Material can be an important quality improvement tool.

The results obtained for the each level are to be compared with the assigned ranges given on the Result Sheet, accompanying the package insert, to determine if the procedure meets linearity specifications.

#### Reagents

The Calibration Verification Material is prepared from human constituents in an aqueous preservation medium containing antimicrobial agents.

#### Precautions

1. All human source material used to manufacture this product was nonreactive for Hepatitis B (HbsAg) and negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV) using techniques specified by the U.S. Food and Drug Administration. Because no known test method can assure complete absence of human pathogens, this product should be handled with appropriate precautions.
2. This product should not be discarded in general waste, but should be discarded with infectious medical waste.
3. This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product as supplied invalidates any diagnostic use of the product.
4. This material is not to be used for instrument calibration.

#### Storage and Stability

Stored upright and refrigerated at 2° – 10° C (36° – 50° F). **DO NOT FREEZE** Stored under this condition, unopened vials can be expected to give stable results through the expiration date listed on the box. Opened vials are stable for 30 days refrigerated at 2° – 10° C (36° – 50° F). Minimize exposure to strong light.

#### DO NOT FREEZE

#### Instructions for Use

1. Set your LDX to the "Serum" mode in the configuration menu.
2. Remove vials from the refrigerator and warm to room temperature, 18° – 30° C (64° – 86° F), for 10 minutes before use.
3. Calibration Verification Material should be tested following the same procedure used for testing patient samples
4. Mix each vial by gently inverting 7-8 times immediately before each sample is removed from the vial.
5. Unscrew the vial cap. Use the Mini-Pet pipette and tips provided in the Cholestech LDX Starter Pack to dispense the Calibration Verification Material into the sample well of the test cassette. Use a new tip for each level.
6. Run two test cassettes on each vial of Calibration Verification Material. Record both results for each analyte on the Result Sheet. Calculate the average value of the two results.
7. Be sure to record all relevant information, e.g. LDX Serial number, cassette lot number, operator name and date, for documentation.
8. After use, wipe the top of the vial and replace the cap.
9. Return vials to refrigerated storage.
10. REMEMBER, if necessary, to return the sample type to "whole B." before testing patient whole blood samples

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3347 Investment Blvd., Hayward, CA 94545-3808  
(510) 732-7200