

Cholestech LDX

Level 1 and Level 2 Control

Assayed quality control 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.

Storage and Stability

Cholestech LDX Controls are to be stored upright and refrigerated at 2° – 10° C (36° – 50° F). Stored under these conditions, 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

Indications of Product Deterioration

Inability to obtain expected values may indicate product deterioration. Do not use a vial of control 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 the lot number on the control vial with the lot number on the assay sheet. They should be the same.
2. Check expiration date on control vial. Discard outdated products.
3. Review control product package insert and the operating procedure for the Cholestech LDX and test cassette, then run a test on a new vial of control.
4. If the values are still outside of the Expected Range, call Cholestech Corporation Technical Service Department at (800) 733-0404.

Expected Results

Refer to the Assay Sheet for expected results. Be sure that the lot number on the vial of control corresponds to the lot number on the Assay Sheet.

The value and expected range for each analyte are derived from data using several Cholestech LDX analyzers and cassette lots. The expected range established applies only to this lot of control. If a laboratory prefers to set its own ranges, see the Quality Control section of the Cholestech LDX Procedure Manual for instructions.

Technical assistance may be obtained by contacting Cholestech Corporation Technical Service Department, Hayward, CA 94545, (800) 733-0404.

Summary and Explanation

Cholestech LDX Control Level 1 and 2 are designed to be used for monitoring the performance of test procedures on the Cholestech LDX System.

Principle

The Controls should be run to evaluate the performance of the test procedures at both the low and high levels of each analyte.

The results obtained for the controls are to be compared with the assigned values given on the assay sheet, accompanying the package insert, to determine if the procedure is within control limits.

Reagents

The controls are prepared from human constituents in an aqueous preservation medium containing antimicrobial agents.

Precautions

1. For *in vitro* diagnostic use only.
2. 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.
3. This product should not be discarded in general waste, but should be discarded with infectious medical waste.
4. 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.
5. This material is not to be used for instrument calibration.

Instructions for Use

1. Remove one vial of each of Cholestech LDX Control Level 1 and Level 2 from the refrigerator. (Note date opened on vial labels.)
2. Warm Control Level 1 and Level 2 vials to room temperature (10 minutes).
3. Test one level of control material and then the other level in the following manner:
 - Refer to the Cholestech LDX Control Material Assay Sheet accompanying this product for information regarding the appropriate settings for sample type in the Cholestech LDX Configuration menu. If you need to change the sample setting, see the Cholestech LDX User Manual Section "Setting the Configuration Menu".
 - Mix each vial by gently inverting 7-8 times.
 - Unscrew the vial cap. Use the Mini-Pet pipette and tips provided in the Cholestech LDX Starter Pack to dispense the control material into a test cassette. Use a new tip for each control level.
 - After use, wipe the top of the vial and replace the cap.
 - REMEMBER if necessary, to reset the sample type to the sample type you are using.

Procedure

When vials are at room temperature, the control material is to be used following the directions for the test cassette procedure being used. The controls are to be tested in the same manner a patient's sample would be tested.

Limitations of Procedures

The results obtained using the controls 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.

CHOLESTECH

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