

Cholestech LDX[®]

Lipid Control

L1 L2



Exp: 2011-05-26

L1 (Red Cap)

L2 (Black Cap)

LOT 0146

LOT 01460505

LOT 01460506

Constituent	Expected Range		Expected Range	
	mg/dL	mmol/L	mg/dL	mmol/L
For all Lipid Cassettes				
Total Cholesterol	136-192	3.53-4.96	211-297	5.47-7.69
HDL Cholesterol	26-40	0.67-1.04	51-79	1.31-2.06
Triglycerides	108-159	1.22-1.80	229-338	2.59-3.81
Glucose	101-149	5.60-8.26	222-328	12.34-18.18

Sample Setting

Set the sample type to SAMPLE = "Whole B." in the Cholestech LDX configuration menu.

Cholestech LDX[®]

Lipid Control

L1 L2 IVD

REF 10-982 (1 Vial Set)
10-983 (3 Vial Set)

Professional Use Only

Intended Use

Assays quality control material for use with the Cholestech LDX System.

Summary and Explanation

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

Principles of the Procedure

The controls must 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 and animal constituents in an aqueous preservative medium containing antimicrobial agents.

Precautions

- For *in vitro* diagnostic use.
- All human source material used to manufacture this product was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis (STS) 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.
- This product should not be discarded in general waste but should be discarded with infectious medical waste.
- This product is intended for use as supplied. Adulteration by dilution or addition of any materials to the product supplied invalidates any diagnostic use of the product.

Instructions for Use

- Remove one vial of each Cholestech LDX Level 1 and Level 2 Controls from the refrigerator. (Note date opened on vial labels.)
- Warm vials to room temperature for 10 minutes (18–30°C, 64–86°F).
- 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 setting for sample type in the Cholestech LDX Configuration Menu. If you need to change the sample setting, see the Cholestech LDX System User Manual section "Setting the Configuration Menu."
 - Mix each vial by gently inverting 7–8 times.
 - Unscrew the vial cap. Use the 35µL MiniPet™ Pipette and tips provided in the Cholestech LDX Starter Pack to dispense the control material onto a test cassette. Use a new tip for each control level. Discard tip with infectious medical waste.
 - After use, wipe the top of the vial with a standard, absorbent laboratory wipe and replace the cap.
 - REMEMBER, if necessary, reset the sample type to the sample type you are using.

Materials provided: Control Level 1 and Control Level 2.

Materials not provided: 35µL MiniPet (P/N 11-846), Pipette Tips (P/N 11-010), Cassettes

Procedure

When the vials are at room temperature, the control material can be used. For testing instructions, refer to the package insert for the test cassette you are using. The controls are to be tested in the same manner a patient's sample would be tested. Frequency of testing controls: refer to the package insert for the test cassette you are using.

Storage and Stability

Cholestech LDX Controls are to be stored upright and refrigerated at 2–8°C (36–46°F). Stored under this condition, unopened vials can be expected to give stable results until the expiration date listed on the box. Opened vials are stable for 30 days refrigerated at 2–8°C (36–46°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:

- Check expiration date on control vial. Discard outdated products.
- Review control product package insert and the operating procedure for the Cholestech LDX Analyzer and test cassette, then run a test on a new vial of control.
- If the values are still outside of the expected ranges, call Technical Service at 1.800.733.0404 or 321.441.7200.

Limitations of Procedures

- When pipetting control material remove the pipette tip from the sample well before releasing the plunger or control material may be removed from the sample well causing erroneous results.
- Check the control assay sheet for the correct sample setting for running controls.
- Verify that the lot number on the control vial and the assay sheet are the same. Each control lot has different control ranges.
- Erroneous control results may occur if the control material is not stored according to the storage instructions or if controls are used past the closed or open vial expiration date.
- Discard any vial if there is evidence of product deterioration such as cloudiness or odor.
- This control material is not to be used as a standard or for instrument calibration.
- For more information, refer to the "Limitations" section of the package insert for the test cassette being used or the "Precautions and Warnings" section of the Cholestech LDX System User Manual.

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 Cholestech LDX System Procedure Manual section "Quality Control" for instructions.

Technical assistance may be obtained by contacting Technical Service at 1.800.733.0404 or 321.441.7200.

U.S. Patents 5,614,414 and 5,770,451

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IVD • For In Vitro Diagnostic Use	REF • Catalog Number	L1 L2 • Level 1 and Level 2	 • Consult instructions for use • Temperature Limitation
 • Biological Risks	LOT • Lot Number	Professional Use Only • Professional Use Only	 • Manufacturer • Use By

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