Introduction

The Cholestech LDX is a small, portable analyzer and test cassette system. It is easy to use, and gives fast and reliable results. To run a test, just add a sample to the cassette and place it in the Analyzer. In a few minutes, the results will appear on the screen.

The Cholestech LDX System is for in vitro diagnostic use only. This guide contains information intended to familiarize and instruct the user in the proper use and care of the Cholestech LDX System.

System Components

Cholestech LDX Analyzer

Printer

Test Cassette

Capillary Tubes/Plungers

Lancets

Blood from a fingerstick sample is collected into a capillary tube with heparin anticoagulant. The black plunger dispenses the sample into the sample well in the cassette.

PLEASE NOTE: Even though the Cholestech LDX is a “CLIA-waived” test system, each laboratory or testing site using the Cholestech LDX must have a CLIA Certificate of Waiver. To obtain a Certificate of Waiver, call your state department of health or Cholestech for an application. Failure to operate the Cholestech LDX in accordance with the manufacturer’s instructions will void the waived status. The tests will then be considered highly complex.

Cholestech Corporation and our distributors will provide every customer with technical support and training needed to properly use the Cholestech LDX System. Cholestech maintains a staff of qualified Technical Service Representatives who are available 24 hours a day, 7 days a week.

For ordering information or other customer service–related questions, contact Cholestech Customer Service from 6:00 AM to 5:00 PM Pacific time, Monday through Friday.

Please feel free to contact us at:

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Quick Reference Guide

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Take the time to examine and familiarize yourself with the contents of the Cholestech LDX System.

1. Connecting the Cholestech LDX to the Printer
   - Plug the printer power supply into the printer and the wall power strip. Connect the end of the printer cable labeled “To Printer” to the printer.
   - Plug the power supply into the Cholestech LDX and the wall power strip. Insert the end of the white cable labeled “The Cholestech LDX” into the Analyzer.

2. Configuration Menu
   - Before starting to test, press and hold STOP to enter the Configuration Menu. Select options for language, units, sample type, printer, risk assessment, date, and time.
   - The DATA button allows you to select choices for each of the menu items in the Configuration Menu. Press the DATA button when the choices are displayed and the red light is on to enter your choices. Go back by pushing the DATA button one more time to return to the previous selection.

3. Optics Check
   - Run the Optics Check Cassette
     - Press the RUN button on the Analyzer. The cassette drawer will open, and the screen will display “LDX Cassette and Press RUN.”
     - Place the Optics Check Cassette into the cassette drawer. Press the RUN button again to close the drawer.
     - The drawer will open, and the scree will display: “RUN.

4. Running Controls
   - Cholestech Level 1 and 2 Controls
     - Controls must be run according to manufacturer’s recommendations. Controls must be at room temperature before testing. Verify that the test number on the control vial and the assay sheet are the same. Mix each vial by gently inverting 7–8 times immediately before use. Store controls in the refrigerator when not in use.
     - Testing QC Material
       - Use the MiniPet™ Pipette and tips to measure and dispense the control sample into the cassette. Place the cassette in the drawer immediately and press RUN. Record results on the Quality Control Log. Results must be within established ranges before patient samples can be tested.

5. Insert the Cassette
   - Immediately place the cassette into the Analyzer. Press the START/STOP button again to close the drawer and the brown magnetic stripe on the right.

6. Begin the Test
   - Press RUN. The drawer will close. When the test is finished, the Analyzer will beep and the drawer will open. Put everything that touched the blood sample into a biohazardous waste container.

7. View the Results
   - Print the results when the test is finished.

FAQ
Frequently asked questions about the use of the Cholestech LDX

How do I get a CLIA Certificate of Waiver?

Even though the Cholestech LDX is a “CLIA-waived” test system, each laboratory or testing site using the Cholestech LDX must have a CLIA Certification of Waiver before starting testing. To obtain a Certificate of Waiver, call our state department of health or Cholestech Technical Service (1.800 733.0404) for an application (form HCFA-116). Cholestech Technical Service can give you the phone number of your state department of health and assist you in filling out the application.

Remember: The Cholestech LDX System is only waived for fingerstick or venous whole blood.

How often do I have to run the controls?

If you are testing under CLIA-waived status, you must follow the manufacturer’s recommendations for running controls. Cholestech recommends that you run controls:

- With each new shipment of controls (even if cassette are from the same lot previously received).
- With each new lot of cassettes.
- As otherwise required by your laboratory’s standard quality control procedures.
- If you are not running the Cholestech LDX under CLIA-waived status, or if your local or state regulations require more frequent testing of quality control material, your quality control must be performed in compliance with those regulations.

How should I store my cassettes?

Do not allow any bubbles to enter the capillary tube. Do not use a cassette past the expiration date. The cassettes are stable at room temperature for 30 days. Do not use a cassette past the expiration date. Do not return cassettes to the refrigerator once they have been stored at room temperature.