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

Cholestech LDX Analyzer 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:

Cholestech Corporation
3347 Investment Blvd.
Hayward, CA 94545 U.S.A.
Tel 1.800 733.0404
Fax 1.510 732.7227
www.cholestech.com

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MiniPet is a trademark of Tri-Continent Scientific, Inc.
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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.

2. Configuration Menu
   - Before starting to test, press and hold STOP to enter the Configuration Menu and 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. The RUN button exits your choices and advances you to the next menu item.

3. Optics Check
   - Run the Optics Check Cassette
     - Press the RUN button.
     - The drawer will open.
     - Place the Optics Check Cassette in the cassette drawer.
     - Press the RUN button again to close the drawer.
   - Record Results
     - Check to see that the four numbers are within the acceptable range printed on the Optics Check Cassette.
     - Record the results on the Optics Check Log. Results must be within the acceptable range printed on the cassette.

4. Running Controls
   - Cholesterol Level 1 and 2 Controls
     - Controls must be run following manufacturer’s recommendations.
     - Controls must be at room temperature before testing.
     - Verify that the lot 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
   - Insert the Cassette into the AutoAnalyzer drawer.
   - Place the cassette level after the sample has been applied.
   - The cassette will be temporarily disabled until another Optics Check Cassette is run. Testing QC Material must be run after each new shipment of cassettes (even if cassettes are from the same lot previously received).

6. Begin the Test
   - Immediately place finger in the Analyzer drawer. Apply pressure to the brown magnetic stripe on the right.
   - Gently squeeze the finger to obtain a large drop of blood.
   - After clearing the selected site with alcohol and drying it thoroughly, firmly press the site with a lancet.
   - Do not allow any bubbles to enter the capillary tube.

7. Print the Results
   - The results will print when the test is finished.
   - Do not return cassettes to the refrigerator once they have been stored at room temperature.

FAQ
Frequently asked questions about the use of the Cholestech LDX

1. 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 Certificate of Waiver before starting testing. To obtain a Certificate of Waiver, call your state department of health or Cholestech Technical Service (1.800 733.0404) for an application (form HCFA-116).
   - How do I get a CLIA Certificate of Waiver?

2. 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:
     - With each new shipment of cassettes (even if cassettes 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.

3. How should I store my cassettes?
   - How should I store my cassettes?