

# Routine Operating Procedures

## Introduction

This is a summary of the recommended procedures for operation of the Cholestech LDX® System. This information may change from time to time as the Cholestech LDX System is updated and enhanced. Please call Cholestech Technical Service if you have any questions regarding current recommendations, or consult the Cholestech LDX System User Manual and video training tape for more complete instructions.

## Start-up

1. Connect the Analyzer's power supply to an electrical outlet.
2. The screen should then display the following messages in order:
  - "Testing memory"
  - "Selftest running"
  - "Selftest OK"
  - "Initial Warm Up"

3. When the screen goes blank, you are ready to start testing.

**Note:** Alternately, you can leave the Analyzer plugged in all the time. This option is preferred because it will extend the life of the Analyzer's internal battery.

## Optics Check

1. Press the RUN button to open the drawer.
2. Remove the Optics Check Cassette from the case and place in the drawer. Press RUN to initiate the optics check test.
3. Record the results of the optics check test on the appropriate form

in your Cholestech LDX Procedure Manual. Return the Optics Check Cassette to the case. The Optics Check Cassette should be stored in its case in a stable area at **room temperature**.

4. If the optics check results are out of the expected range, retest. If results are still out of range, retest with a new Optics Check Cassette, if it is available. Otherwise, call Cholestech Technical Service at 800-733-0404.

## Patient Testing

1. Follow the appropriate procedures in your User Manual and Product Inserts for testing patient samples.
2. Make sure you are using proper fingerstick techniques: make sure hands are warm, wipe the first drop of blood from finger, and gently massage finger to increase blood flow. **Do not milk the finger!**
3. Remember to transfer blood from the capillary tube to the test cassette as soon as possible.
4. Once you have placed the sample into the cassette well, place the cassette in the drawer and press RUN **immediately**.
5. Dispose of all blood collection materials and cassettes in a biohazardous waste container.

6. Record patient results.

## Quality Control

1. In January, 1996, the Cholestech LDX System was given waived status by the Centers for Disease Control and Prevention (CDC). Under waived status quality control testing is

optional. However, Cholestech recommends that controls continue to the run with the following frequency:

- With each new shipment of cassettes, to verify that shipping did not affect performance.
- With each new lot of cassettes, to validate the performance of the lot.
- Any time you are not sure if the cassettes have been stored properly.

Controls may need to be run more frequently to satisfy the regulatory requirements in your state or local area.

2. Remove 2 cassettes of the type (TC and HDL, Lipid Profile, etc.) you will be using, as well as 1 vial of each level of Cholestech Control Material. Allow these materials to sit out for 10 minutes to reach room temperature. You may remove all the cassettes you will be using that day at this time. Make sure you are not using any cassettes or controls beyond their expiration date.
3. To run the control material:
  - a. Gently invert the control material 7-8 times prior to opening the vial.
  - b. Press the RUN button of the Cholestech LDX Analyzer to open the drawer.
  - c. Tear open the pouch and remove a test cassette. Place the cassette on the counter.

- d. Use the Mini-pet 2 Pipette with a yellow pipette tip attached to draw up a sample of control material.
  - e. Dispense the sample into the well of the cassette.
  - f. Remove the pipette tip from the sample well before releasing the plunger.
  - g. Place the cassette into the open tray and press the RUN button to start.
  - h. Dispose of all pipette tips and cassettes in a biohazardous waste container.
  - i. Recap the vials after use and return the unused control material to the refrigerator.
  - j. Record the results of the control tests on the appropriate form in your Cholestech LDX Procedure Manual.
  - k. Repeat this procedure with a new yellow pipette tip and cassette using the second level of control material.
4. If the control results are out of the expected range, try another cassette and/or another vial. If the control is still out of range, contact Cholestech Technical Service at 800-733-0404.
5. As part of your quality assurance program, remember to record room and refrigerator temperatures.

**To assist you with any  
further questions, please call  
Technical Service:  
800-733-0404**

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