

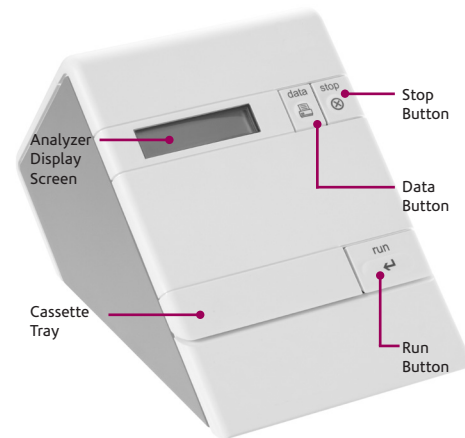
Introduction

The Alere Cholestech LDX® System consists of 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 Alere 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 Alere Cholestech LDX® System.

System Components

Analyzer

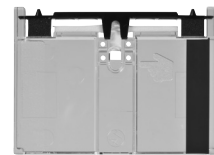


Printer



Results from each cassette will print out on the Alere™ Thermal Printer. One, two or three labels may be printed.

Test Cassette



Blood from a fingerstick sample is placed into a single-use, disposable cassette.

Capillary Tubes/Plungers



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.

Lancets



A single-use lancet is used to perform a fingerstick to collect a blood sample for testing on the Alere Cholestech LDX® System.

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

Our distributors will provide every customer with product support and training needed to properly use the Alere Cholestech LDX® System. We maintain a staff of qualified Product Support Specialists who are available 24 hours a day, 7 days a week.

Alere™ Product Support

Contact one of the following Alere™ Product Support Care Centers or your local distributor if you have any questions regarding the use of your Alere™ product. You may also contact us at www.alere.com.

Europe & Middle East

+ (44) 161 483 9032 EMEproductsupport@alere.com

Asia Pacific

+ (61) 7 3363 7711 APproductsupport@alere.com

Africa, Russia, & CIS

+ (972) 8 9429 683 ARCISproductsupport@alere.com

Latin America

+ (57) 01800 094 9393 LAprouductsupport@alere.com

Canada

+ (1) 613 271 1144 CANproductsupport@alere.com

US

+ (1) 877 308 8289 USproductsupport@alere.com

Alere™ Customer Service

Contact the following Alere™ Service Care Center or your local distributor for order and billing assistance. You may also contact us at www.alere.com.

Phone

+ (1) 877 441 7440

E Mail Address

clientservices@alere.com



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Alere San Diego, Inc.
San Diego, CA 92121 USA
www.alere.com

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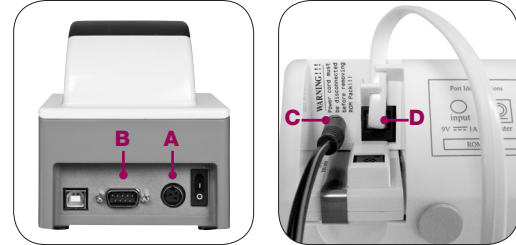
Cholestech LDX®

Quick Reference Guide

Setup

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

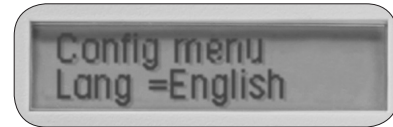
1 Connecting the Alere Cholestech LDX® Analyzer to the Printer



Plug the printer power supply **A** into the printer and the wall or power strip. Connect the end of the printer cable **B**, labeled 'To Printer' to the printer.

Plug the power supply **C** into the Alere Cholestech LDX® Analyzer and the wall or power strip. Insert the end of the white printer cable **D**, labeled 'To Cholestech LDX®,' into the analyzer. Loop through the cable support.

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 enters 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 into 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. If the numbers are outside the range, the analyzer will be temporarily disabled until another optics check is run that falls within range. The Optics Check Cassette is used to check the optical system of the analyzer. Run the Optics Check Cassette: once each day before patient samples are tested and after the Alere Cholestech LDX® Analyzer has been moved or serviced.



4 Running Controls

Alere™ 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 at least 7 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 a Quality Control Log. Results must be within established ranges before patient samples can be tested.



Test Procedure

1 Open the Drawer



Press the **RUN** button on the analyzer. The cassette drawer will open, and the screen will display:

Load cassette
and press RUN

2 Perform a Fingerstick



After cleaning the selected site with alcohol and drying it thoroughly, firmly prick the site with a lancet. Gently squeeze the finger to obtain a large drop of blood. **Wipe off the first large drop of blood.**

5 Insert the Cassette



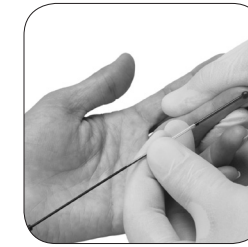
Immediately place the cassette into the analyzer drawer with the black reaction bar toward the analyzer and the brown magnetic stripe on the right.

6 Begin the Test



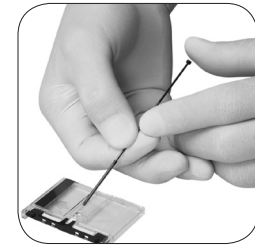
Press **RUN**. The drawer will close. When the test is finished, the analyzer will beep and the drawer will open. **Put everything that touched the blood sample into a biohazardous waste container.**

3 Collect the Sample



Squeeze the finger gently again until a large drop of blood forms. Hold the capillary tube horizontally by the end with the plunger. Touch it to the drop of blood without touching the skin. **Fill the capillary tube within 10 seconds. Do not allow any bubbles to enter the capillary tube.**

4 Dispense the Sample



Place the end of the capillary tube into the sample well and dispense the sample by pushing down on the plunger. Keep the cassette level after the sample has been applied.

7 View the Results



Press the **DATA** button on the analyzer once or twice (depending on the test cassette) to view remaining results.

8 Print the Results



The results will print when the test is finished.

This reference guide provides a brief summary of the testing procedure. For more information, see the test cassette and control package insert or the Alere Cholestech LDX® System User Manual.

FAQ

Frequently asked questions about the use of the Alere Cholestech LDX® System.

How do I get a CLIA Certificate of Waiver?

Even though the Alere Cholestech LDX® System is a "CLIA-waived" test system, each laboratory or testing site using the Alere Cholestech LDX® System must have a CLIA Certificate of Waiver before starting testing. To obtain a Certificate of Waiver, call your state department of health or Alere (1.877.441.7440) for an application (form CMS-116). Alere can give you the phone number of your state department of health and assist you in filling out the application.

Remember:

The Alere Cholestech LDX® System is only waived for fingerstick or venous whole blood.

How often do I have to run the controls?

Controls should be tested:

- With each new lot of cassettes;
- With every new shipment of cassettes, even if the lot has been received previously;
- When reagents may have been stored or handled in a way that can degrade their performance;
- As otherwise required by your laboratory's standard quality control procedures;
- As otherwise required by federal, state and local guidelines.

How should I store my cassettes?

When stored refrigerated at 36–46°F (2–8°C), the cassettes are stable until the expiration date printed on the cassette pouch and box. Cassettes can be stored 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.