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.

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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.

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PN: 26203 Rev. A  2011/04
**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.

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 new items in the Configuration Menu. The RUN button enters your choices and advances you to the next menu item.
   - Press the RUN button on the analyzer. The cassette drawer will open, and the screen will display:
     - **Load cassette and press RUN**

3. **Optics Check**
   - 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 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 daily before testing. After a new shipment of cassettes is received, test to ensure the quality of the new lot.

4. **Running Controls**
   - Press the RUN button 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.
   - **Alero™ Level 1 and 2 Controls**
     - Immediately place the cassette into the analyzer drawer with the black reaction bar toward the analyzer and the brown magnetic stripe on the right.
     - 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.

5. **Insert the Cassette**
   - Fill the capillary tube within 10 seconds. Do not allow any bubbles to enter the capillary tube.
   - 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.
   - Press the RUN button once or twice (depending on the test cassette) to view final results.

6. **Begin the Test**
   - When the test is finished, the analyzer will beep and the drawer will open. Place the cassette past the expiration date. Do not return cassettes to the refrigerator once they have been stored at room temperature.
   - Press the DATA button on the analyzer once or twice immediately before testing.
   - The results will print when the test is finished.

**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 clearing 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.

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.

**FAQ**

**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). An Alere representative will guide you through the application process and provide the necessary forms.

**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 every new lot of cassettes;
- With each new lot of cassettes;
- When reagents may have been stored or handled in a way that can degrade their performance;
- With every new shipment of cassettes, even if the lot has been received previously;
- With each new lot of cassettes;
- 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.