

## Standing Orders for Cholesterol Point of Care Testing

### PURPOSE

To provide cholesterol screening to adult patients following clinical guidelines and according to manufacturer's instructions.

### II. RESPONSIBILITY

All health care providers and clinical staff are responsible to screen and follow-up the results.

### III. POLICY

It is the policy of Zufall Health Center to screen cholesterol annually for male patients 35 and older and female patients 45 and older. In addition, patients who have started new statin therapy or have had changes to statin dosage will have Cholesterol testing two months after medication start or adjustment.

### IV. EQUIPMENT AND SUPPLIES FOR ALERE-CHOLESTECH-LDX CASSETTE

Alere Cholestech LDX® Lipid Profile

Materials required but not provided

- Alere Cholestech LDX® System
- Alcohol swabs and gauze for cleaning puncture site
- Lancets for capillary blood collection
- Alere Cholestech LDX® 40 µL Lithium Heparin Capillary Tubes
- Alere Cholestech LDX® Capillary Plungers
- Gloves
- Biohazard waste containers
- Quality control material
- MiniPet® Pipette and tips or micropipetter that will deliver 40 µL for use with venipuncture samples and quality control material
- Vacuum collection tubes, needles, tube holders and sample tubes if the sample is to be collected by venipuncture

### V. REAGENT STORAGE AND STABILITY

- Cassette Storage and Stability Cassettes must be stored in the sealed foil pouches.
- Place cassettes in the refrigerator after receipt.
- Cassettes may be used until the date printed on the pouch when stored in a refrigerator (36–46°F / 2–8°C).
- The cassettes may be stored for up to 30 days at room temperature (48–86°F / 9–30°C).
- The new expiration date is the date the cassettes are placed at room temperature plus 30 days. Write the new expiration date on the side of the cassette box in the space provided. NOTE: Once the cassettes have been stored at room temperature, they should not be returned to the refrigerator.
- Do not use a cassette beyond the printed expiration date.

## Standing Orders for Cholesterol Point of Care Testing

- Do not use a cassette that has been stored at room temperature for more than 30 days.
- Do not reuse cassettes.
- Cassettes should sit at room temperature for 10 minutes before opening the pouch.
- Use the cassette as soon as the pouch is opened.

### VI. QUALITY CONTROL

- External quality 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.
- Record the results in a Quality Control Log. The quality control results should be in range before testing patient samples. See the Alere Cholestech LDX® System User Manual if they are not. Please call Alere Product Support to report any problems or if you have any questions about quality control.
- Manufacturer recommends the following quality control procedures for the Alere Cholestech LDX® System.
  - Choice of Materials Liquid Level 1 and Level 2 controls that work well with the Alere Cholestech LDX® System are available.
  - If you use other controls, you will need to establish ranges for the Alere Cholestech LDX® System. Handling
  - Follow the instructions that come with your controls.
  - Check the expiration date before use. Do not use if expired.
  - See "Running a Test" for the procedure.
  - External Quality Control External control material should be used to demonstrate that the reagents and the assay procedure perform properly.
  - Good Laboratory Practice principles suggest that controls should be run whenever the laboratory director has any question about test system integrity, reagent storage conditions, or the reliability of any test result.
  - If the controls do not perform as expected, repeat the test or contact Alere Product Support before testing patient samples.

### VII. PROCEDURES

#### Sample Type:

- The Alere Cholestech LDX® System is CLIA waived for fingerstick or venous whole blood unprocessed samples only.
- Sample Requirement
- Sample Volume: 40 µL of whole blood.

#### Fingerstick whole blood:

- When testing triglycerides the subject should fast for 9-12 hours before the sample is collected. Subjects should fast for at least 8 hours for glucose tests before the sample is collected.
- Confirm patient identity using 2 identifiers (Name, Date of Birth)

## Standing Orders for Cholesterol Point of Care Testing

- Collect the sample from a fingerstick into a Alere Cholestech LDX® 40 µL Capillary Tube.

## Fingerstick Procedure:

- The patient should sit quietly for five minutes before the blood sample is collected.
- Put a capillary plunger into the end of a Alere Cholestech LDX® 40 µL Capillary Tube with the red mark. Set aside.
- Choose a spot that is on the side of one of the center fingers of either hand. The fingers and hands should be warm to the touch. To warm the hand, you can:
  - Wash the patient's hand with warm water, or...
  - Apply a warm (not hot) compress to the hand for several minutes, or...
- Gently massage the finger from the base to the tip several times to bring the blood to the fingertip. Clean the site with an alcohol swab.
- Dry thoroughly with a gauze pad before pricking the finger.
- Firmly prick the selected site with a lancet.
- Squeeze the finger gently to obtain a large drop of blood. Wipe away this first drop of blood as it may contain tissue fluid.
- Squeeze the finger gently again while holding it downward until a second large drop of blood forms. Do not milk the finger. The puncture should provide a free-flowing drop of blood. Too much squeezing of the finger may cause inaccurate results.
- Hold the capillary tube horizontally or at a slightly descending angle by the end with the plunger. Touch it to the drop of blood without touching the skin. The tube will fill by capillary action to the black mark. Do not collect air bubbles. If it is necessary to collect another drop of blood, wipe the finger with gauze then massage again from base to tip until a large drop of blood forms.
- Fill the capillary tube within 10 seconds.
- Wipe off any excess blood from the finger and have the patient apply pressure to the puncture until the bleeding stops.

Using the Minipet® Pipette Use this procedure to apply a venous blood sample, or control, calibration verification or proficiency testing materials to the cassette. Any pipette that can deliver 40 µL may be used.

- Confirm patient identity using 2 identifiers
- Collect blood into a green-top tube (heparin anticoagulant). NOTE: Do not use a tube with any other additives because it may cause inaccurate results.
- Use a pipette and tip to place blood into the cassette.
  - Firmly attach the pipette tip to the end of the 40 µL MiniPet® Pipette.
  - Use a new tip for each sample.
  - To fill the pipette, push the plunger down as far as you can. Place the pipette tip midway into the sample and slowly release the plunger. Confirm that no air bubbles are in the pipette tip.
  - Place the pipette tip into the cassette sample well. Dispense the sample into the cassette sample well by pressing the plunger down. Move the pipette tip out of the sample well before releasing the plunger again.

## Standing Orders for Cholesterol Point of Care Testing

- Remove the pipette tip and throw it away in a biohazard waste container.
- NOTE: If the plunger is released before the pipette tip is out of the sample well, it will remove the sample just dispensed.
- NOTE: Keep the cassette horizontal at all times after applying the sample. Place the blood into the cassette within 8 minutes after collection.
- Whole blood should be used within 30 minutes.
- Samples should be at room temperature for testing.
- Mix all samples by gently inverting at least 7 times before testing.

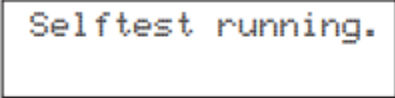
### Test Procedure for Alere-Cholestech LDX Cassette

#### Calibration

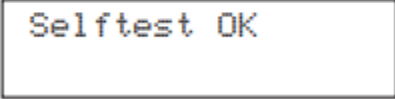
- No calibration is performed by the user.
- Test information is encoded on the brown stripe of the cassette.
- The brown magnetic stripe is read by the Alere Cholestech LDX® Analyzer each time a cassette is run.
- An Optics Check should be run on the analyzer each day that patient samples are tested.
- See the Alere Cholestech LDX® User Manual for instructions.

#### Running a Test

- If the cassettes have been refrigerated, allow them to come to room temperature (at least 10 minutes) before opening.
- Make sure the analyzer is plugged in and has warmed up.
- Remove the cassette from its pouch. Hold the cassette by the short sides only. Do not touch the black bar or the magnetic stripe. Place the cassette on a flat surface.
- NOTE: Gloves should be worn whenever working with blood samples.
- Press RUN.
- The analyzer will do a self test, and the screen will display:

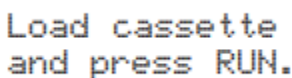


Selftest running.



Selftest OK

- The cassette drawer will open, and the screen will display:



Load cassette  
and press RUN.

- Place the sample into the cassette well.
- Use an Alere Cholestech LDX® Capillary Tube for fingerstick samples. Use a 40 µL pipette for venous blood samples and quality control, calibration verification, and proficiency testing materials.
- NOTE: Fingerstick samples must be applied within eight (8) minutes or the blood will clot.

## Standing Orders for Cholesterol Point of Care Testing



- Keep the cassette flat after the sample has been applied. **WARNING:** Allowing the sample to sit in the cassette will cause inaccurate results. Immediately place the cassette into the drawer of the analyzer. The black reaction bar must face toward the analyzer. The brown magnetic stripe must be on the right.



- DO NOT PUSH IN THE DRAWER.** Press RUN. The drawer will close. During the test, the screen will display:

```
[Test Name(s)]
Running***
```

- Put everything that touched the blood samples or control, calibration verification, or proficiency testing material into a biohazardous waste container.

When the test is complete, the analyzer will beep, and the screen will display

```
[Test Name]=###
warnings
```

- Press DATA to view additional results. 12. When the results are outside the measuring range of the test, the screen will display:

```
[Test Name]>###
```

or

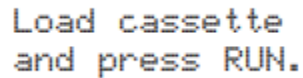
```
[Test Name]<###
```

- If there is a problem with the test, a message will appear on the screen. See the

## Standing Orders for Cholesterol Point of Care Testing

Troubleshooting section of the Alere Cholestech LDX® System User Manual if this happens. Please call Alere Product Support to report any problems or if you have questions about the operation of the Alere Cholestech LDX® System. When the drawer opens, remove the cassette, and put it in a biohazardous waste container. Leave the analyzer drawer empty when not in use.

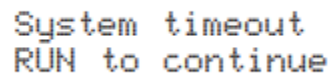
- Record the results in eCW.
- To run another cassette, press RUN. The screen will display



```
Load cassette  
and press RUN.
```

Repeat step 3, and steps 6 through 15.

NOTE: If you do not want to run another test and the drawer is open, press STOP to close the drawer. Otherwise, after four minutes a beep will sound and the screen will display:



```
System timeout  
RUN to continue
```

If necessary, press the DATA button to view the results from the last cassette used.

NOTE: Pressing the RUN button will erase the previous result

### VIII. Maintenance and Cleaning

Note: Unplug Alere Cholestech LDX Analyzer prior to cleaning

- No maintenance is required other than routine cleaning
- Routine Cleaning:
  - Clean the outside of the Alere Cholestech LDX Analyzer cases with a clean, damp cloth. If necessary, a mild detergent or disinfectant (such as a 5% bleach solution) may be used. Do not immerse the analyzer in water or other cleaning fluid. Do not use an abrasive cleaner.
  - When necessary, clean inside the cassette drawer with a cotton swab moistened with water, a 70% isopropyl alcohol solution, a 5% bleach solution or disinfectant. Dry with a second (unused) cotton swab.

### IX. REFERENCES

Alere-Cholestech LDX Cassette Package Insert

<https://stat-technologies.com/wp-content/uploads/2018/12/Alere-Cholestech-LDX-Cassette-Package-Insert.pdf>