

OREGON HEALTH & SCIENCE UNIVERSITY
Hospitals and Clinics
Point of Care

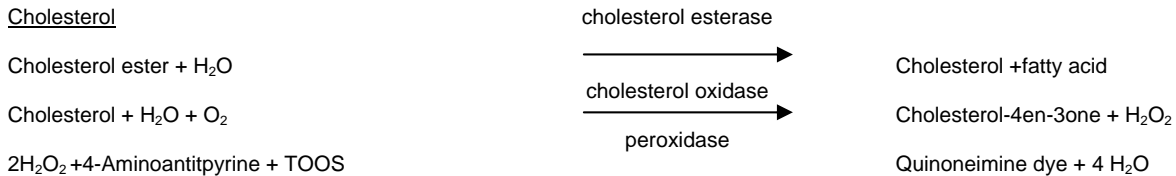
**Lipid Set
by ITC Cholestech LDX**

Principle

The lipid panel test cassette measures the following: Cholesterol, HDL cholesterol and triglycerides in finger stick blood on the Cholestech LDX analyzer. The lipids are measured by colorimetric enzymatic reactions that take place on the test cassette. The results that are obtained during the use of this instrument are for screening purposes only.

Summary of test reactions are as follows:

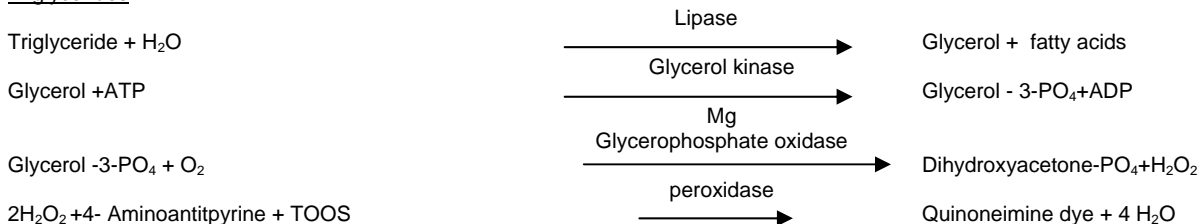
Cholesterol



HDL-C



Triglycerides



Lipid measurements are used in the diagnosis and treatment of lipoprotein metabolism and lipid disorders (such as diabetes mellitus), atherosclerosis, and various renal and liver diseases. Many studies have demonstrated that cholesterol plays a significant role in coronary heart disease and that lowering cholesterol to acceptable levels significantly reduces the risk of developing coronary heart disease. The same studies have shown that small, but significant, increases in HDL-C is associated with additional reduction in coronary heart disease risk. Increasingly, the measurement of HDL-C is being used as an

indicator of risk and may be a strong predictor of heart disease, especially in women and older individuals. Elevated triglycerides may also be a risk factor for coronary heart disease. As part of a lipid profile, total cholesterol, HDL-C and triglyceride levels are used in the calculation of an estimated LDL-C value. The National Institutes of Health has recommended aggressive efforts to identify and treat those at risk for coronary heart disease.

Specimen Requirements

1. 35 µL of whole blood from finger stick (capillary tube should be completely filled in less than 10 seconds to ensure proper mixing).

The blood should be dispensed from the capillary tube within two minutes of collection. Blood from the finger stick should flow freely. Too much squeezing of the finger may cause inaccurate test results. If blood flow is poor and the sample cannot be collected in the prescribed time, then another finger stick procedure must be undertaken.

2. If fasting levels are required, the patient should not eat for 9 to 12 hours prior to the test.

Interferences

1. No hematocrit interference was observed for samples between 30 and 52% HCT for any of the tests.
2. Blood collection tubes with glycerol should not be used for testing.
3. Hand creams and soaps with glycerol may cause falsely high triglyceride results.

Analytical Measurement Range (Linearity)

Analyte	AMR
Total Cholesterol	100-500
HDL	15-100
Triglycerides	45-650

Results exceeding Cholestech's measurable range are displayed as either a greater than (>) or less than (<) symbol.

Reference Ranges

Total Cholesterol: None

HDL-C: High Risk < 40 mg/dL (High risk for CHD*)
 Desirable > 60 mg/dL (Low risk for CHD*)
 *CHD- Coronary Heart Disease

Triglycerides: Normal < 150 mg/dL
 Elevated 150-199 mg/dL
 High 200-499 mg/dL
 Very High > 499 mg/dL

LDL-C: Optimal < 100 mg/dL
 Near Optimal 100-129 mg/dL
 Elevated 130-159 mg/dL
 High 160-189 mg/dL
 Very High > 189 mg/dL

LDL-C is a calculated value and is only valid if the triglyceride level is 400 mg/dL or below.

Critical/Alert Values

None

Quality Control

1. Optics check: There are four optical channels inside the Cholestech LDX. An optics check cassette confirms the correct operation of the optical system. The optics check cassette must be run each day before patient samples are tested, and anytime after moving or cleaning the Cholestech LDX.

To Run:

- a. Press RUN and confirm the Self test OK message.
- b. The cassette drawer will open and the message: "**Load cassette and press RUN**" will appear.
- c. Put the Optics Check cassette into analyzer.
- d. Press RUN button.
- e. Record the optics check results in your optics check log. The results for the four channels should fall within 80-105 range.

If the numbers fall outside of this range the analyzer will be disabled until another optics check had been run that falls within range. Call Cholestech Technical Service 1-877-441-7440.

2. Liquid Controls (Liquid Level 1 and Level 2) are tested to verify the performance of the entire test system: Cholestech LDX analyzer and test cassettes. Control testing is used to ensure that all the parts of the test system are working properly together and

that the test results are accurate and reliable within the limits of the system. Call POCT for fresh aliquots of QC material (4-5497).

Liquid Controls are tested in the following situations:

1. With each new shipment of cassettes (even if the cassettes are from the same lot).
2. With each new lot number of cassettes.

IMPORTANT: Do not use control solutions that have expired. Check the expiration date printed on the aliquot tubes.

Please refer to the patient testing procedure on how to run a test:

If results are not in range:

1. Make sure that neither the test cassettes nor the controls are past the expiration date printed on the label.
2. Repeat the test again using fresh materials.
3. Record results in the Quality Control Log.
4. If rerun is still out call Point of Care (4-5497).

Patient Testing Procedure

1. If cassettes are stored in the refrigerator the cassettes must sit out at room temperature for 10 minutes prior to testing.
2. Remove the cassette from its pouch. Hold the cassette by the front or left side only. Do not touch the black bar or the brown magnetic stripe. Put the cassette on a flat surface.

Note: Gloves should be worn when working with blood samples.

3. Press **RUN** if the analyzer has been idle for more than 4 minutes. Then the cassette drawer will open and the screen will display: '**Load cassette and press Run**'.
4. Place the sample into the cassette. Use a Cholestech LDX Capillary Tube for finger stick samples.
5. Keep the cassette flat after the sample has been applied. Immediately Place the cassette into the drawer of the analyzer with the black bar facing the analyzer. The brown stripe must be on the right.
6. Press **RUN**. The drawer will close. During the test the screen will Display (5-6 minutes running time):

Lipids Running * * *

7. Dispose everything that touched the blood/control sample in a biohazard waste container.
8. When the test is complete, the analyzer will beep, and the drawer will open.
9. Once the cassette is remove the test results will print.
10. If there is a problem with a test, a message will appear on the screen. See the troubleshooting section in the Cholestech LDX System User manual.
11. When the drawer opens, remove the cassette. Place in a biohazard waste container. Leave drawer empty when not in use.

12. Record the results.
13. If another cassette is not loaded within 15 seconds, the drawer will close.

Calculations

$$\text{LDL-C (calculated)} = \text{Cholesterol} - \text{HDL-C} - (\text{Triglycerides}/5)$$

TC/HDL-C Ratio

The TC/HDL-C Ratio can be a useful summary of CHD risk. A ratio of 4.5 or less is desirable. A ratio greater than 6.0 suggests higher risk of CHD.

Only LDL-C is a calculated value and is only valid if the triglyceride level is 400 mg/dL or below.

Reporting Results

The results that are obtained during the use of this instrument are for screening purposes only.

Maintenance

No maintenance is required other than routine cleaning when necessary.

1. Clean the outside of the Cholestech LDX analyzer case with a clean, damp, non-abrasive cloth. Most spills and stains will be removed with water or mild detergent. An alcohol wipe or 5% bleach is appropriate cleaning agents.
2. When necessary, clean the cassette drawer with a cotton swab moistened with water or 5% bleach.
3. Document in maintenance log.

Calibration

1. No calibration is done by the user. Test information is on the brown stripe of the cassette.
2. An optics check should be run on the analyzer each prior to patient testing.
3. Calibration Verification material and patient correlations will be run every 6 months by Point of Care. This is done to verify instrument function and validate the linearity of the machine.

Reagents

1. Lipid Cassette: Stored in refrigerator (2-8°C) are good until expiration date on package.
 - a. Cassettes may be stored at room temperature (9-30°C) for 30 days. Write the new expiration date on the cassette box.
 - b. Once cassettes have been stored at room temperature, they should not be returned to the refrigerator.

2. Lipid Controls: Aliquoted controls stored in refrigerator (2-8°C) are good for 14 days. Call Point of Care for controls (4-5497).

References

1. Cholestech LDX Cholesterol Test package insert.
2. Cholestech LDX System User Manual.

Updated 7/8/11