

CHOLESTEROL COMPLETE

*Read all instructions carefully before beginning the test.
If you have any questions, please call our Technical Assistance at: 1-800-482-2907.*

Specimen Collection and Preparation

The **Cholesterol Complete** Test must be performed using FRESH finger stick Whole Blood. The Whole Blood specimens should be tested immediately after draw. The finger stick device is a single use lancet; one (1) lancet should be able to provide enough whole blood to fill 2 blood collection droppers (“droppers”) in order to complete both the Total Cholesterol and HDL tests. The included droppers must be used to ensure that the required volume of whole blood is obtained for each test.

Important Pre-Test Preparation

Before beginning the test procedures:

1. Do not open the Foil Pouch until ready to use.
2. Visually inspect the Foil Pouch to confirm date of use is prior to expiration date.
3. Store and keep the device at Room Temperature 18-27°C (64-81°F). **DO NOT** open the foil pouch or perform the test in a humid environment, such as a steamy bathroom, or in direct sunlight.
4. Have a stopwatch, clock or wristwatch with a sweep second hand ready.

Note: If you will be performing **both** the Total Cholesterol and HDL tests, you will need to fill two (2) droppers.

Test Procedure

Step 1 - Preparing for the Test

- a. Open a Test Foil Pouch and remove the test cassette. Find the words **“Place Blood Here,”** followed by an arrow. Lay the cassette on a dry table with these words facing up (**Figure 1**). The large circles below the numbers “1” and “2” are the Sample Circles where you will place your blood in **Step 3**. **Note:** Make sure the test strips have not moved in handling, and that the round test pads of the test strips are in the center of the sample circles.

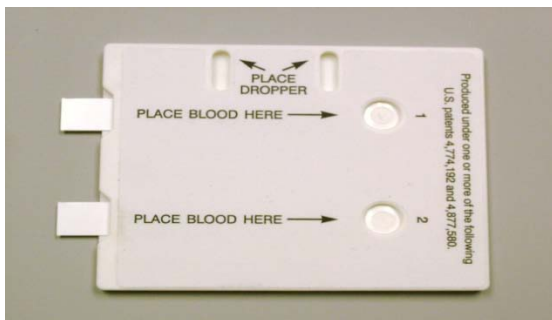


Figure 1

NOTE: Do *not* place anything on the table under the cassette including tissues, napkins or paper towels.

- b. Remove the two (2) clear plastic droppers, one (1) lancet and one (1) alcohol prep pad from the test kit box.
 - Hold one dropper by the bulb end and insert the bulb end into one of the slots in the area marked, “Place Dropper”. Using your index finger, push the bulb firmly into the slot. (**Figure 2**).

- Repeat with the second dropper. The droppers will sit at a slight angle if positioned properly. (**Figure 2**)

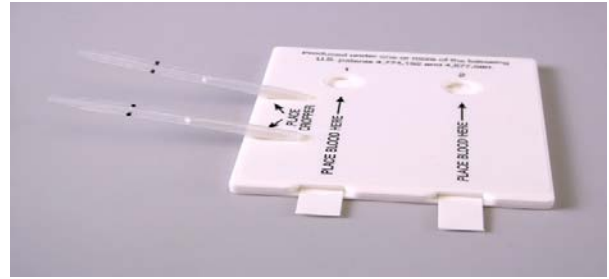


Figure 2

- c. Wash hands thoroughly with soap and warm water. Dry completely. If your hands are cold, rub them together to warm them.
 - Remove the protective plastic cap from the lancet and lay the lancet on the table. Open up an alcohol prep pad and place the pad on the pouch for easy access.
- d. Select the finger from which you will obtain the blood sample. Make sure your finger is warm and callous-free.
 - If you are right-handed, select the “middle” or “ring” finger of your left hand.
 - If you are left-handed, select the “middle” or “ring” finger of your right hand.
- e. Wipe the selected finger with the alcohol prep pad provided. To increase blood flow, let your arm hang down at your side while the alcohol dries.

Step 2 - Obtain Blood Sample



Figure 3

- a. **Place selected finger flat on the tabletop.** With the thumb of your opposite hand, massage or “milk” the selected finger, five or six times, to push blood to the tip (**Figure 3**).



Figure 4

- b. Place the raised end of the lancet firmly against the **side of the selected finger**.

Press the lancet against your finger until you hear a “click”. You may feel a slight sting. (**Figure 4**).



Figure 5

- c. With the thumb of your opposite hand, massage or “milk” your finger until a **large drop of blood forms**. (**Figure 5**).



Figure 6

d. Gently touch the drop of blood to the tip of one dropper (**Figure 6**). Be sure to touch the drop of blood directly over the puncture site. The dropper will start to fill with blood.

e. **Fill the dropper until the blood reaches the black line.**

If necessary, massage your finger to get more blood.

NOTE: The dropper **WILL NOT** fill past the black line.

f. Repeat steps **2d** & **2e** to fill the second dropper with blood to the black line. **IMPORTANT NOTE: IT IS IMPORTANT THAT AT THIS STAGE, YOU COLLECT SUFFICIENT BLOOD TO PERFORM BOTH TESTS SIMULTANEOUSLY.**

Step 3 - Run Test

- Gently pick up a dropper by the bulb end, **NOT** the tip. **DO NOT** squeeze the dropper.
- Hold the dropper above Sample Circle "1". Squeeze the bulb gently to empty **all** of the blood, **at one time**, onto the test pad located in the center of the Sample Circle (**Figure 7**).

If necessary, lightly touch the dropper tip to the Test Pad of Sample Circle "1", to dislodge the blood drop. **DO NOT** poke the strip with the dropper.

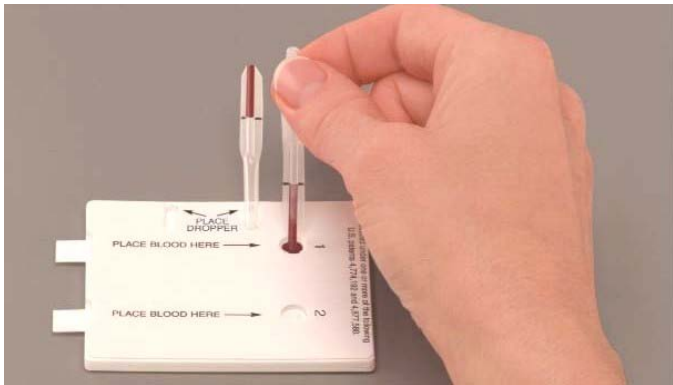


Figure 7

- Immediately begin timing.
- Using the second dropper, repeat steps **3a** & **3b** to dispense the second blood sample on to Test Pad of Sample Circle "2".
- Wait 1 minute** to turn the cassette over to the side with the **HDL and Total Cholesterol** Color Charts.

Step 4 - Read Result

NOTE:

- Complete Step 4 under bright light, but **NOT** in direct sunlight.
- The color of each Result Circle should have changed from the pre-test yellow or cream color to a shade of green.
- Complete the color determination of the HDL Cholesterol test **before** starting the Total Cholesterol comparison.

- Read the **HDL Cholesterol** test **FIRST**. **Read after 1 minute** but **before 3 minutes** have passed.
 - Read the **TOTAL Cholesterol** test **SECOND**. **Read after 3 minutes** but **before 5 minutes** have passed.
- Make sure the Result Circle is at the lowest value on the corresponding Color Chart. Slide each test strip (white tab) **along** the Chart to compare the color in the Result Circle with each Color Block.
 - Look for the best color match. **DO NOT** try to match how dark or intense the color appears.

NOTE

- Look closely to identify any green shading in the Result Circle. Choose the best shade of yellow-green, green, or blue-green.
 - The Result Circle may not match one color block exactly, and may appear to be between two color blocks.
 - The Result Circle may also be unevenly colored (light and dark patches of green). If so, use the darkest shade of green color to determine your Test Result.
- Determining your Test Result:
 - If the Result Circle matches one Color Block, the number printed next to the Color Block is your Test Result.
 - If the Result Circle seems to be *between two color blocks*, follow the black arrow separating the two blocks. The number printed next to the arrow is your Test Result.

Record your Test Result.

See **Figure 8** for a Test Result Example.

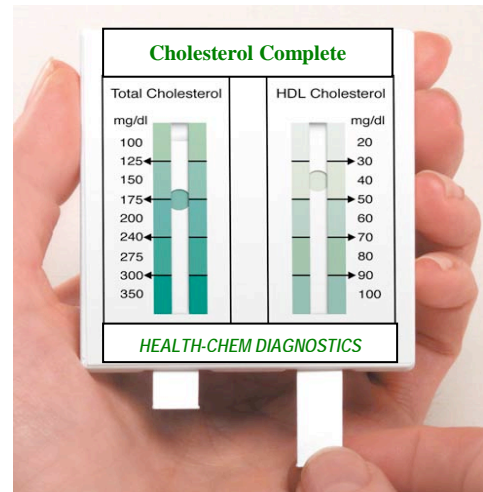


Figure 8

In **Figure 8**, the HDL Test Circle matches the color block at 60 mg/dL. The Total Cholesterol Test Circle appears slightly darker than 150 mg/dL, but lighter than the 200 mg/dL color block. Therefore, it is correctly positioned on the line between these 2 color bars, indicating a value of 175 mg/dL.

- After you have completed the desired test(s), discard all test materials.

Intended Use

The **Cholesterol Complete Test** is intended for *in-vitro* diagnostic for the semi-quantitative determination of Cholesterol and High-Density Lipoprotein (HDL) in whole blood. The test also allows for the approximation of Low-Density Lipoprotein (LDL) through a simple calculation.

The **Cholesterol Complete Test** is used to screen for elevated cholesterol as a risk factor in coronary artery disease. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

This test provides preliminary analytical results. All results indicating elevated blood cholesterol levels should be verified by a confirmatory method. Clinical considerations and professional judgment should be applied to the interpretation of results by this test.

Summary and Explanation

Cholesterol, a lipid, is associated with the pathogenesis of atherosclerosis and coronary artery disease, and the measurement of cholesterol blood levels is used to classify patients according to coronary heart disease risk, to diagnose and treat various primary or secondary hyperlipidemias, and to monitor changes resulting from treatment.

Principle of the Test

The **Cholesterol Complete** Test includes test strips that are treated with chemical reagents. A whole blood sample is absorbed on a receiving pad on the back of a test strip. The blood sample absorbs through to the front of a test strip and reacts with the reagents. The reaction area produces color that can be related to the cholesterol concentration in the blood by comparison with a supplied color chart.

Materials Provided

(1) Test Kit containing:

- 1 **Cholesterol Complete** Test Cassette including:
 - 1 *Total Cholesterol Test*
 - 1 *HDL Cholesterol Test*
- 1 Finger Stick Lancet
- 1 Alcohol Prep Pad
- 1 Adhesive Bandage
- 2 Blood Collection Droppers
- 1 Package Insert

Materials Required But Not Provided

Timing Device (stopwatch, clock or wristwatch with a sweep second hand)

Storage Conditions

Store at Room Temperature 18-27°C (64-81°F), out of direct sunlight, in the sealed pouches. The test can be used up until the expiration date indicated on the pouch label.

Do not open pouch in a steamy bathroom. Once the package is opened, the tests should be used immediately.

NOTE: If you choose to perform only one test, the cassette should be disposed of once the result of the single test has been obtained.

Warnings and Precautions

- For *in-vitro* diagnostic use only.
- For external use only. Keep out of reach of children.
- Never use a lancet or dropper that was used by another person.
- Not recommended for use by hemophiliacs or individuals taking medicines that thin blood (anticoagulants).
- Individuals who are colorblind should have another person read their test result(s).
- Do not run the test within 4 hours after taking acetaminophen (Tylenol®) or Vitamin C tablets (500 mg or more).
- If you are taking Viagra® or a similar drug, have another person read the test result if you are performing the **Cholesterol Complete** Test procedure within 6 hours of taking the drug; these drugs may temporarily affect your perception of blue and green colors.
- Use only with fresh blood. Do not use with other body fluids. Do not use for testing food or animals.
- Use before the expiration date on the package.
- Do not open the foil pouch until you are ready to run the test.
- Do not reuse lancet, droppers, or test cassette.

• **NEVER ADJUST YOUR MEDICATION BASED ON YOUR *Cholesterol Complete* Test RESULT(S).**

UNDERSTANDING YOUR TEST RESULT

TOTAL CHOLESTEROL

Your test result will place you in one of 3 medical risk groups defined by the National Cholesterol Education Program.

Result less than 200 mg/dL (5.2 mmol/L):

“Desirable” Group

You are most likely at low risk for heart disease. If you have no other risk factors, you should re-check your Total Cholesterol level every 6 months,

Result between 200-239 mg/dL (5.2 - 6.2 mmol/L):

“Borderline-High Group”

You may be at increased risk for heart disease,

Result 240 mg/dL (6.2 mmol/L) or above

“High” Group

You may be at increased risk for heart disease, whether or not you have additional risk factors.

1. The National Cholesterol Education Program recommends averaging two or three cholesterol test results. One cholesterol test may not give a definitive or typical result.
2. Your cholesterol level may vary if you are pregnant, take birth control or estrogen replacement pills, or if you have certain medical conditions or recent illnesses.
3. A high Total Cholesterol level is just one risk factor for heart disease. Other risk factors include smoking, high blood pressure, a family history of heart disease, a diet high in saturated fats, and insufficient exercise.

HDL/LDL CHOLESTEROL

The cholesterol in your blood consists of HDL Cholesterol (often called “good cholesterol”) and LDL Cholesterol (often called “bad cholesterol”). Your risk of heart disease is related to your HDL level, your total cholesterol level (HDL plus LDL), and other risk factors. The National Cholesterol Education Program guidelines state that a low level of HDL (“good”) cholesterol is associated with an increased risk of heart disease.

The HDL Cholesterol test strip measures your HDL (“good”) cholesterol level. **If your test result is 40 mg/dL (1 mmol/L) or less**, you may be at increased risk for heart disease, whether or not you have additional risk factors.

If your test result is above 40 mg/dL (1.0 mmol/L), you cannot evaluate your risk of heart disease based on your HDL Cholesterol level alone. If you have other risk factors, such as a high Total Cholesterol level, you may be at increased risk for heart disease. You can also measure your Total Cholesterol level with this Cholesterol Complete test kit.

The **Cholesterol Complete Test kit** allows you to approximate your LDL Cholesterol level. A simple calculation of your Total Cholesterol minus your HDL Cholesterol level will provide an approximation of your LDL Cholesterol level. This calculation is based on an assumed normal Triglyceride level. When Triglycerides are elevated, the LDL level may be different than the above calculation.

If your LDL Cholesterol level is 130 mg/dL or less, you are at a desirable level. An LDL level of 130 mg/dL or above is considered borderline high and may suggest an increased risk of heart disease.

Important Notes:

- One HDL Cholesterol test may not give a definitive or typical result. The National Cholesterol Education Program recommends averaging two or three cholesterol test results. The program also recommends that you re-check your Total and HDL Cholesterol levels every six months.
- Your HDL cholesterol level may vary if you are pregnant, take birth control or estrogen replacement pills, or if you have certain medical conditions or recent illnesses.

- A low HDL Cholesterol level is just one risk factor for heart disease. Other risk factors include smoking, high blood pressure, a high total cholesterol level, a family history of heart disease, a diet high in saturated fats, and insufficient exercise.
- The **Cholesterol Complete** Test cassette has a window on both sides. The window on the side of the strip marked “**PLACE BLOOD HERE**” is to receive the blood sample. The window on the reverse side will display the color produced by the reaction of the blood sample.

QUESTION AND ANSWER SECTION

Can the Result Circle change color without giving me a correct reading?

Yes, you may get an incorrect result if:

- ✓ You compared colors **before** 1 minute or **after** 3 minutes for the HDL test and **before** 3 minutes or **after** 5 minutes for the Total Cholesterol test.
- ✓ You performed the test in direct sunlight, or in a steamy bathroom.
- ✓ You wiped your finger with something other than the alcohol swab provided.
- ✓ The test cassette was stored or used above the maximum room temperature (27°C or 81°F).
- ✓ You did not use sufficient blood to perform the test
- ✓ You did not fill out both pipettes at the same time, with the proper amount of blood

Do I need to fast before I run the test, or do I need to run it at a specific time of day?

- ✓ No. You do not have to fast, and you can run the test at any time.

Will common foods, alcohol, vitamins or medicines affect my test results?

- ✓ No. Foods and beverages (including orange juice), and most medications (including aspirin and vitamins) will not interfere with the test. However, do not run the test within 4 hours after taking acetaminophen (Tylenol®) or Vitamin C tablets (500 mg or more). Also, if you are taking Viagra® or a similar drug, have another person read the test result if you are performing the **Cholesterol Complete Test** procedure within 6 hours of taking the drug; these drugs may temporarily affect your perception of blue and green colors.

in whole blood. The test also allows for the approximation of low-density lipoprotein (LDL) through a simple calculation. The **Cholesterol Complete** Test should be used as a screening test. Your healthcare professional may require additional testing for diagnosis and treatment.

The procedure outlined in the “Test Procedure” section **must** be followed closely by the user.

*Tylenol® is a registered trademark of McNeil-PPC, Inc.
Viagra® is a registered trademark of Pfizer, Inc.*

For Technical Assistance with questions about the Test Procedure, please call 1-800-482-2907.

Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC,
3341 SW 15th Street
Pompano Beach, Florida 33069 - USA
US FDA & ISO Certified Facility



FM77504

ISO CMCAS 13485:2003

FDA Registration No: 1048532



LIMITATIONS

The **Cholesterol Complete** Test is used for the semi-quantitative determination of cholesterol and high-density lipoprotein (HDL)