

TOTAL CHOLESTEROL

**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 **Total Cholesterol** Test must be performed using FRESH finger stick Whole Blood. The Whole Blood specimen 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 the blood collection dropper in order to complete the Total Cholesterol test. The included dropper must be used to ensure that the required volume of whole blood is obtained for this 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.

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 circle on the device is the Sample Circle where you will place your blood in **Step 3**. Note: Make sure the test strip has not moved in handling, and that the round test pad of the test strip is in the center of the sample circle.

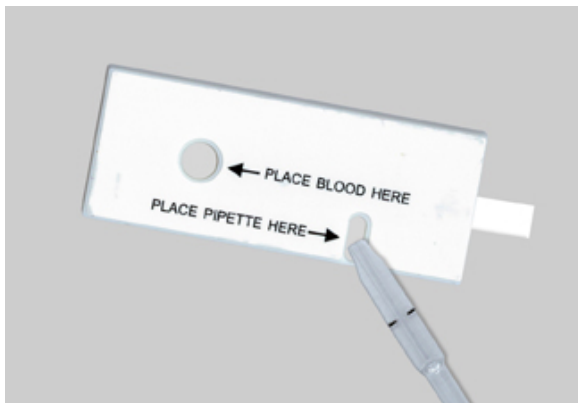


Figure 1

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

- b. Remove the clear plastic dropper (pipette), lancet and alcohol prep pad from the test kit box.

- Hold the dropper (pipette) by the bulb end and insert the bulb end into the slot in the area marked, **“Place Pipette Here”**. Using your index finger, push the bulb firmly into the slot. (**Figure 2**).

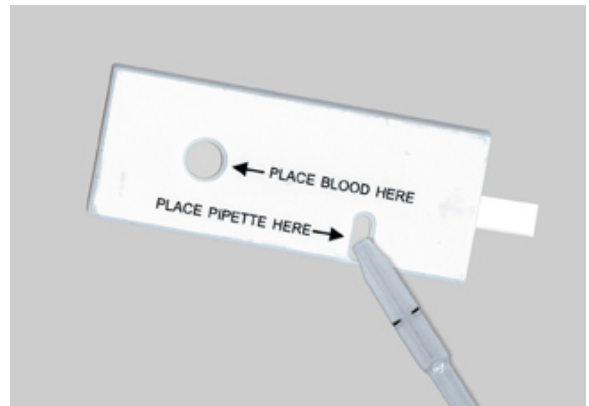


Figure 2

- 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.
- c. Wash hands thoroughly with soap and warm water. Dry completely. If your hands are cold, rub them together to warm them.
- 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

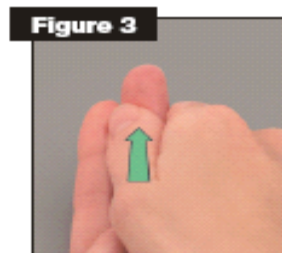


Figure 3

- 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**).

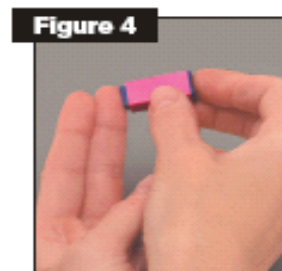


Figure 4

- 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**).

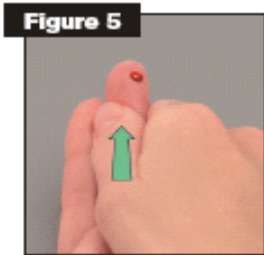


Figure 5

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 the 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.

Step 3 - Run Test

- Gently pick up the dropper by the bulb end, **NOT** the tip. **DO NOT** squeeze the dropper.
- Hold the dropper above the Sample Circle. 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, to dislodge the blood drop. **DO NOT** poke the test pad with the dropper.

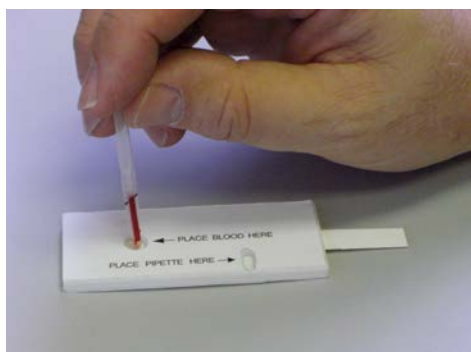


Figure 7

- Immediately begin timing.
- Wait 3 minutes** to turn the cassette over to the side with the **Total Cholesterol** Color Charts.

Step 4 - Read Result

NOTE:

- Complete Step 4 under bright light, but **NOT** in direct sunlight.

- The color of the Result Circle should have changed from the pre-test yellow or cream color to a shade of green.
 - Read the **Total Cholesterol** test **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 Total Cholesterol Test most closely matches the 200 mg/dL color block. This is the test result indicated.

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

Intended Use

The **Total Cholesterol Test** is intended for *in-vitro* diagnostic for the semi-quantitative determination of Total Cholesterol in whole blood.

The **Total Cholesterol 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 **Total Cholesterol** Test includes a test strip that is 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 **Total Cholesterol** Test Cassette including:
 - 1 *Total Cholesterol Test*
- 1 Finger Stick Lancet
- 1 Alcohol Prep Pad
- 1 Adhesive Bandage
- 1 Blood Collection Dropper (pipette)
- 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: 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 **Total Cholesterol** 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 *Total Cholesterol* 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.

- 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 **Total Cholesterol** 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** 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 the pipette 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.

LIMITATIONS

The **Total Cholesterol** Test is used for the semi-quantitative determination of cholesterol in whole blood. The **Total Cholesterol** 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,
POMPANO BEACH, FLORIDA
Website: www.healthchemdiagnostics.com
ISO 13485 & US FDA Certified Facility
FDA – Establishment Registration No.: 1048532

