



**Total Cholesterol Test
Package Insert**

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Total Cholesterol Home Screening Test

Thank you for buying the Total Cholesterol Home Screening Test. This box contains everything you need to run a total cholesterol screening test. Please read all instructions before running the test. If you have any questions, please call the **Customer Care Help Line at: 0800 0430318**.

Principle of the Test

The Total Cholesterol Home Screening 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 chemistry used is the very well established cholesterol esterase/cholesterol oxidase enzymatic reaction to produce hydrogen peroxide followed by the peroxidase catalyzed reaction hydrogen peroxide with a colourless indicator which thereby produces colour. The colour produced on the reaction pad can be related to the cholesterol concentration in the blood by comparison with a supplied color chart. The deeper the colour is, the higher the Cholesterol level.

Materials Provided

1 Total Cholesterol Test Strip, 1 Finger Stick Lancet, 1 Alcohol Prep Pad, 1 Adhesive Bandage, 1 Blood Collection Pipette, 1 Package Insert.

Materials Required But Not Provided

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

Storage and handling

- Store the test in a cool, dry place at room temperature of 18-27°C (64-81°F) out of direct sunlight, in the sealed pouches. The test can be used until the expiration date indicated on the pouch label. Do not freeze.
- Do not open pouch in a steamy bathroom. Once the package is opened, the test should be used immediately.
- Keep away from heat and direct sunlight.
- Use the test as soon as you have removed it from the foil pouch.

Warnings and Precautions

- For *in-vitro* diagnostic use only. Intended for self-testing
- For external use only. Keep out of reach of children. Do Not Ingest.
- Never use a lancet or Pipette that was used by another person.
- Not recommended for use by hemophiliacs or individuals taking medicines that thin blood (anticoagulants).
- Individuals who are colour blind 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 Home Screening 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, pipettes, or test cassette.
- **NEVER ADJUST YOUR MEDICATION BASED ON YOUR TEST RESULT(S)**

INSTRUCTIONS FOR USE

Please read all directions carefully before running the test - Keep out of reach of children - For in vitro diagnostic use only.

- Open the box and remove the materials needed to run the test
- Do not open the foil pouch until you are ready to run the test.
- Run the test on a well-lit table, but not in direct sunlight. You will need a clock or wristwatch with a second hand.

Step 1: GET READY

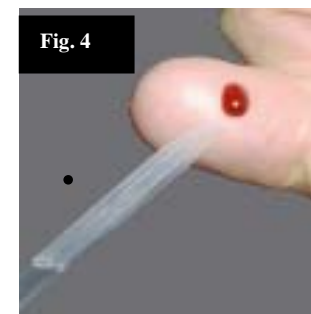
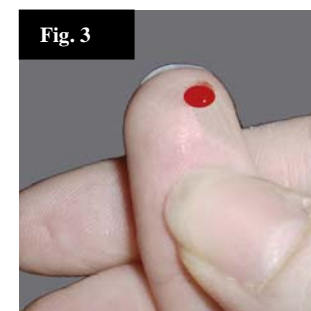
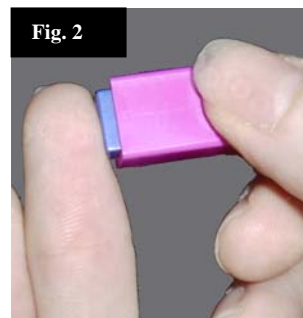
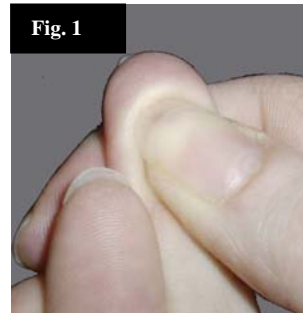
- Wash your hands with soap and warm water, and dry. If your hands are cold, briefly rub your hands together to warm them.
- Open a test strip foil pouch. Lay the test strip on a dry table. The words "Place Blood Here" must be face up.
- Have a clock or wristwatch with second hand ready.

Notes:

- Do not open the pouch in a steamy bathroom.
- Do not place tissues or napkins under the test strip.
- The large circle next to the words "Place Blood Here" is the Test Circle. It should be off-white in color. If it is any other colour, call the Customer Care Help Line at 0800 0430318.

Step 2: GET BLOOD (Figs 1, 2, 3 & 4)

Warning: Never use a lancet that has been used by another person!



- If you are right-handed, you should get blood from the "middle" or "ring" finger of your left hand. Reverse if left handed.
- Wipe your finger with an alcohol swab. Let your finger hang down at your side while the alcohol dries.
- Press your fingertip with your thumbnail (Fig. 1). Place finger flat on tabletop. Place the hole in the bottom of the lancet against your fingertip. Press the lancet firmly against your fingertip (Fig. 2).

Notes:

1. Pick a finger that is callous-free.
2. Use the alcohol swab provided to wipe your finger.

Step 3: RUN TEST

- Warning: Never use a pipette that has been used by another person!
- Squeeze blood toward your fingertip using the thumb of your other hand (push from palm toward fingertip), until you get a **large** drop of blood (Fig. 3).
- Place the pipette on the edge of a table with the tip exposed. Gently touch the blood drop to the tip of the pipette (Figure 4). The pipette will start to fill with blood, Do not pick up the pipette while it is filling (Fig 4).
- **Fill the pipette up to the black dot.** If necessary, squeeze your finger to get more blood.
- Gently pick up the pipette by the bulb (not the tip). Hold the pipette above the Test Circle. Squeeze the bulb gently to empty of the blood onto the Test Circle. Do not poke the Test Circle with the pipette tip.
- Begin timing. **Wait 3 minutes before reading test result.**

Notes:

1. If the last blood drop does not fall by itself, lightly touch the bottom of the blood drop to the Test Circle.
2. Do not pick up or turn over the test strip.

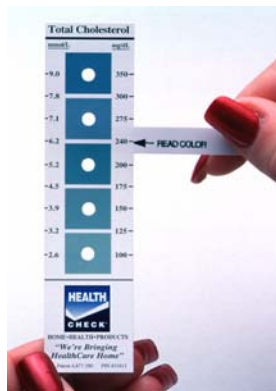
Step 4: READ RESULT

- After 3 minutes, turn the test strip over. The Result Circle (next to the arrow with the words “Color” will be either yellow-green, green, or blue-green.
- Place the test strip **behind** the Colour Chart so the words “Read Color” are facing you. Slide the test strip up and down so the Result Circle appears in each of the 5 windows on the Color Chart.
- Compare the color of the Result Circle to each of the 5 color blocks. Look for the best **colour** match (the correct shade of yellow-green, green, or blue-green). Do not try to match how dark (intense) the colors are. The color of the Result Circle may be between two colour blocks. Read colours under bright light, but not in direct sunlight.
- Hold the test strip so the Result Circle shows through the window of the best-matching colour block. (If the color of the Result Circle is between two colour blocks, hold the strip between those two blocks) The arrow on the test strip will point to a number printed on the edge of the Color Chart. **THIS IS YOUR TOTAL CHOLESTEROL TEST RESULT**

TEST RESULTS

Results are displayed in both, millimoles per liter (mmol/L) and in milligrams per deciliter (mg/dL). The mmol/L is used in Europe and many other countries around the world, while the mg/dL measurement is a US version

Hint: Look carefully for any blue shading in the Result Circle. For example, if the “Result Circle” has some blue in it, but not as much blue as the “7.1” color block, hold the test strip between the “5.2” and “7.1” color blocks. The arrow will point to a Total Cholesterol test result of 6.2 mmol/L. If you are not sure about the best color match, look at the Result Circle through the lowest of the 5 windows. The yellow-green background of this color block may help you see any blues or greens in the Result Circle.



Notes:

1. Do not read results before 3 minutes or after 4 minutes.
2. **In countries using mmol/L units, use the numbers printed on the right side of the Colour Chart.** In the United States, use the numbers printed on the left side of the Color Chart to read your cholesterol result.
3. After you have finished the test, discard the used test materials in your household waste.

UNDERSTANDING YOUR TEST RESULT

Your test result will place you in one of 3 medical risk groups

Result less than 5.0 mmol/L: “Desirable” Group

You are most likely at low risk for heart disease. If you have other risk factors for heart disease, you should talk with your doctor as a lower level may be recommended. If you have no other risk factors, you should recheck your total cholesterol level every 6 months.

Result between 5.0 — 6.0 mmol/L “Borderline-High” Group

You may be at increased risk for heart disease. You should talk with your doctor.

Result 6.0 mmol/L or above: “High” Group

You may be at increased risk for heart disease, whether or not you have additional risk factors. You should ask your doctor for immediate advice.

Important Notes:

1. It is recommended that two or three cholesterol test results are averaged over a period. 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. **Consult your doctor if you have any questions about the meaning of your total cholesterol test result – You should NEVER adjust your medication based on your test results.**
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. Ask your doctor for advice about how you can reduce your overall risk of heart disease.

LIMITATIONS

The Total Cholesterol Home Screening Test is used for the semi-quantitative determination of cholesterol in whole blood. This test should be used as a screening test. Your healthcare professional may require additional testing for diagnosis and treatment.

The procedure outlined in the “Instructions for use” section **must** be followed closely by the user.

QUESTION AND ANSWER SECTION

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

Yes, you may get an incorrect result if:

- You matched colours before 3 minutes or after 4 minutes.
- You performed the test in direct sunlight, or in a steamy bathroom.
- You used a Colour Chart that did not come with your test strip.
- You wiped your finger with something other than the alcohol swab provided.
- The test strips were stored or used above room temperature (77°F or 25°C).

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 a Vitamin C tablet (500 mg or more). Also, males should not run the test within 6 hours after taking Viagra® or other ED medication, since these drugs may temporarily affect your perception of blue and green colors.

WARNINGS

For external use only. Keep out of reach of children.

- Never use a lancet or pipette that was used by another person.
- Not for use by hemophiliacs, or by individuals who are colorblind or taking medicines that thin blood (anticoagulants).
- 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 pipettes or test strips.

Never adjust your medication based on a Cholesterol Home Screening Test result. Consult your doctor.

This product is protected by U.S. patents 4,774,192, and 4,877,580 and by Canadian patent 1317532; other patents pending.

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

	Attention, see instructions for use		Tests per kit		Manufacturer
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #

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