

Total Cholesterol Test

Package Insert

REF CHOL104 English

Thank you for buying the Total Cholesterol 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 ROI 0818 333181**.

INTENDED PURPOSE

The Total Cholesterol Test is intended for the semi-quantitative determination of cholesterol in whole blood. It is intended for self testing only. Routine measurement of blood cholesterol is recommended for men over 35 years old and women over 45 years if there are no other risk factors. If other risk factors are present, testing is recommended for all those over 20 years old.

PRINCIPLE OF THE TEST

The Total Cholesterol Test includes test strips that are treated with chemical reagents. A sample of whole blood is absorbed on to a receiving pad on the back of the test strip. The blood sample absorbs through to the front of the test strip and reacts with the reagents. The chemistry uses the well established cholesterol esterase/cholesterol oxidase enzymatic reaction to produce hydrogen peroxide which, catalysed by peroxidase, converts a colourless indicator to a coloured product. The colour produced on the reaction pad can be related to the cholesterol concentration in the blood by comparison with a supplied colour chart.

STORAGE AND HANDLING

- Store the test in a dry place at room temperature (18-27°C; 64-81°F) out of direct sunlight.
- Do not open the foil pouch until you are ready to perform the test.
- DO NOT use the test after the expiration date indicated on the pack.
- Do not freeze.
- Keep away from heat and direct sunlight.
- Do not open the foil pouch in a steamy bathroom.
- Use the test as soon as you have removed it from the foil pouch.

WARNINGS AND PRECAUTIONS

- This test is for (*in-vitro*) self-testing only.
- For external use only.
- Keep out of reach of children.
- Do not ingest.
- Not recommended for use by haemophiliacs or individuals taking medicines that thin blood (anticoagulants).
- Individuals who are colour blind should have another person read their test result.
- Do not use the test after an acute illness until at least 1 month of convalescence has elapsed.
- Do not run the test within 4 hours after taking paracetamol (acetaminophen) 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 within 6 hours of taking the drug as these drugs may temporarily affect your perception of blue and green colours.
- Use only with fresh blood.
- Do not use with other body fluids.
- Do not use for testing food or animals.
- Do not use if the foil pouch has been damaged (opened or split).
- Do not reuse the lancet, pipette, or test strip.
- Used test materials should be disposed of in household waste.
- Use only the pipette supplied to transfer blood to the test strip.
- NEVER ADJUST YOUR MEDICATION BASED ON YOUR TEST RESULT(S)**

IMPORTANT PRE-TEST PREPARATION

PLEASE READ ALL DIRECTIONS CAREFULLY BEFORE RUNNING THE TEST.

- Do not open the foil pouch until ready to use.
- Check the foil pouch to confirm the test has not expired.

MATERIALS PROVIDED

- 1 x Foil Pouch Containing: 1 x Total Cholesterol Test Cassette and 1 x Blood Collection Pipette,
- 1 x Finger Stick Lancet,
- 1 x Alcohol Swab,
- 1 x Adhesive Plaster,
- 1 x Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

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

TEST PROCEDURE

Step 1: PREPARING FOR THE TEST

- Wash hands thoroughly with soap and warm water. Dry completely. Open the foil pouch and remove the test cassette. Lay the cassette on a dry table with the words “PLACE BLOOD HERE” facing up



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

- Remove the blood collection pipette from the foil pouch.

- Remove the lancet and alcohol swab from the test kit box.

- Insert the bulb end of the pipette into the slot in the area marked “PLACE PIPETTE HERE”. Using your index finger, push the bulb firmly into the slot.
- If your hands are cold, rub them together to warm them and stimulate blood flow.**
- 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.
- Make sure your finger is warm and callous-free.
- Wipe the selected finger with the alcohol swab provided. To increase blood flow, let your arm hang down at your side while the alcohol dries.

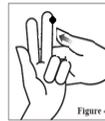
Step 2: OBTAIN BLOOD SAMPLE



- 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 2)



- Place the protruding end of the lancet firmly against the side of the selected finger. Press the lancet against your finger until you hear a “click”. (Figure 3) You may feel a slight sting. **This is a single use lancet and cannot be reused.**



- With the thumb of your opposite hand, massage or “milk” your finger until a large drop of blood forms. (Figure 4)

- Gently touch the drop of blood to the tip of the pipette (Figure 5). Be sure to touch the drop of blood directly over the puncture site. The pipette will start to fill with blood.

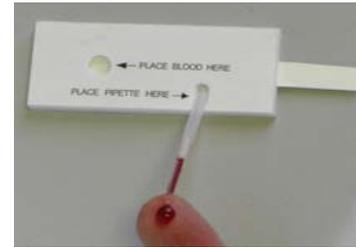


Figure 5

- Fill the pipette until the blood reaches the black line. If necessary, massage your finger to get more blood. **NOTE: The pipette WILL NOT fill past the black line. Do not use if the blood does not reach the line.**

Step 3: RUN TEST

- Gently pick up the pipette by the bulb end, NOT the tip. **DO NOT** squeeze the pipette.

- Hold the pipette above the Sample Circle. Squeeze the bulb gently to empty all of the blood at one time, onto the test pad located in the centre of the Sample Circle. If necessary, lightly touch the pipette tip to the Sample Circle to dislodge the blood drop. **DO NOT** poke the strip with the pipette.
- Begin timing immediately.
- Wait 3 minutes then turn the cassette over to the side with the Total Cholesterol Colour Charts.
- While waiting on results open the plaster and place on the puncture site.

Step 4: READ RESULT

Read under bright light, but NOT in direct sunlight. The colour of the Result Circle should have changed from the pre-test yellow or cream colour 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 Colour Chart. Slide each test strip (white tab) along the Chart to compare the colour in the Result Circle with each Colour Block.

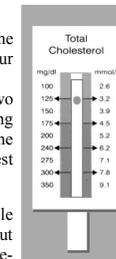
Look closely to identify any green shading in the Result Circle. **Choose the closest shade of yellow-green, green or blue-green.** The Result Circle may not match one colour block exactly, and may appear to be between two colour blocks. The Result Circle may be speckled, giving light and dark patches of green. If so, use the darkest shade of green colour to determine your Test Result.

Determining your Test Result.

If the Result Circle matches one Colour Block, the number printed next to the Colour Block is your Test Result.

If the Result Circle seems to be between two colour 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 6 for a Test Result Example.

In Figure 6, the Total Cholesterol Test Circle appears slightly darker than 2.6 mmol/L, but lighter than the 3.9 mmol/L colour block. Therefore, it is correctly positioned on the line between these 2 colour bars, indicating a value of 3.2 mmol/L.



- After you have completed the test, discard all test materials.

UNDERSTANDING YOUR TEST RESULT

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

•In all cases it is recommended that two or three cholesterol tests are carried out over a period and the results averaged before taking further action. **A single cholesterol test may not give a definitive or typical result.**

1.Result less than 5.2 mmol/L: “Desirable” Group

You are likely to be at low risk for heart disease. If you have other risk factors for heart disease however, you should talk with your doctor.

2.Result between 5.2 - 6.2 mmol/L “Borderline-High” Group

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

3.Result 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. You should seek advice from your doctor immediately.

Important Notes:

1.Your cholesterol level may vary if you are pregnant, take birth control or oestrogen 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 – Consult your doctor.**

2.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.

3.If you have no other risk factors, it is recommended that you test your cholesterol level every 5 years. If you have other risk factors it is advisable to check your cholesterol more frequently.

LIMITATIONS

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

2.As with all biochemical tests, Total Cholesterol may on occasions produce false results and identify an incorrect risk group. This possibility can be minimised by carrying out two or three tests over a period and averaging the results.

QUESTION AND ANSWER SECTION

1Q. Can the Result Circle change colour without giving me a correct reading?

A. Yes, you may get an incorrect result if:

- You matched colours before 3 minutes or after 5 minutes.
- 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 strips were stored or used outside the temperature parameter (18-27°C; 64-81°F).
- YOU DID NOT USE SUFFICIENT BLOOD TO PERFORM THE TEST.**

2Q. Do I need to fast before I run the test, or do I need to run it at a specific time of day?

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

3Q. Will common foods, alcohol, vitamins or medicines affect my test results?

A. No. Foods and beverages (including orange juice), and most medications will not interfere with the test. However, do not run the test within 4 hours of taking paracetamol (acetaminophen) or Vitamin C (500mg or more). Also, males should not run the test within 6 hours after taking Viagra® or other erectile dysfunction medication, since these drugs may temporarily affect your perception of blue and green colours.

4Q. If I am Pregnant, does this affect the results of the test?

A. Yes. Cholesterol is high during pregnancy. Women should wait at least 6 weeks after the child is born to perform the cholesterol test.

This product is protected by U.S. patents 4,774,192, and 4,877,580 and

SYMBOLS USED ON PACKAGING

	Attention, see instructions for use		Manufacturer		Tests per kit
	For <i>in vitro</i> use only		Do not re-use		Use by
	Store between 18-27°C		Catalogue #		Lot Number


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