



INSTRUCTIONS FOR USE

CHOLESTEROL TEST

Easy to use rapid Self-Test for the detection of total cholesterol level in blood

Thank you for buying PRIMA® Cholesterol home test. This box contains everything you need to run a cholesterol screening test. Please read all instructions before running the test. If you have any questions please call the Customer Care at 1-855-405-8374.

INTENDED USE

The PRIMA® Cholesterol home test is intended for home use by people who have not previously had a cholesterol test to give them an indication of whether one's cholesterol level is high enough to visit their doctor for further advice; and/or to monitor cholesterol levels at home if one has already been told by the doctor that it is elevated. The test is a single use test that can provide semi-quantitative determination of total cholesterol in whole blood. It does not diagnose any medical condition.

A high cholesterol level is one of the major risk factors of heart disease. Other risk factors which can increase the likelihood of heart disease are smoking, high blood pressure, a diet high in saturated fats, insufficient exercise. The Canadian Cardiovascular Society recommends routine measurement of blood cholesterol for men over 40 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 25 years old.

Registered trademarks

1049U - Itd - 1.0/02

www.primahometest.com

HEALTHY EUROPE S.R.L.
MILANO - ITALY

REF 1049R

Prevention at home.

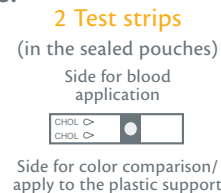
PRINCIPLE OF THE TEST

The PRIMA® Cholesterol home test includes test strips that are chemically pre-treated with enzymes. A sample of finger pricked 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. Cholesterol in the blood sample converts a colorless indicator to a colored product. The color produced on the reaction pad can be compared with a supplied comparative color chart.

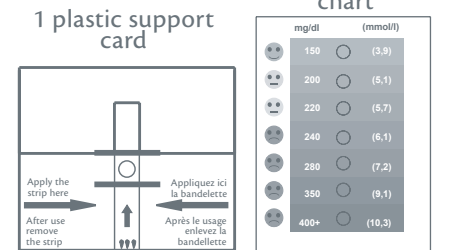
CONTENT

THE BOX CONTAINS ALL THE NECESSARY TO PERFORM 2 TESTS:

2 sterile finger stick lancets



1 package insert



MATERIALS REQUIRED BUT NOT PROVIDED: A timing device (stopwatch, timer or clock)

STORAGE AND HANDLING

Keep the test in a dry place at room temperature (from 4°C to 30°C) out of direct sunlight. The test can only be used until the expiration date indicated on the box.

Do not freeze.

Keep away from heat and direct sunlight.

Do not open the foil pouch in a steamy bathroom.

Do not open the foil pouch until the test strip is required for running the test. Use the test strip as soon as you have removed it from the foil pouch.

WARNINGS AND PRECAUTIONS

For *in-vitro* diagnostic use only. Intended for self-testing only.

For external use only. Keep out of reach of children. Do not ingest.

Not recommended for use by individuals taking medicines that thin the blood (anticoagulants) or by the individuals with disorders such as hemophilia.

Individuals who are color blind should seek help to read the test results.

Acute illness may cause false positive results. Do not use the test after an acute illness until at least one month of convalescence has elapsed.

Do not run the test within 4 hours after taking Tylenol (acetaminophen) or Vitamin C tablets (500 mg and more).

Use only with fresh finger prick blood. Do not use other body fluids (plasma, serum, urine, saliva etc).

Do not use for testing food or animals.

Do not use after the expiration date indicated on the box.

Do not open the foil pouch until you are ready to run the test. Do not use the test if the foil pouch has been damaged (opened or split).

Do not reuse the lancet or test strip.

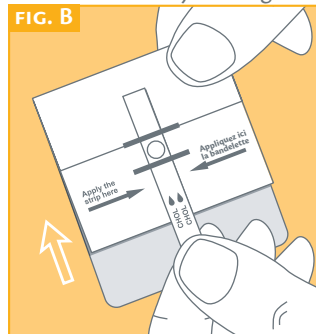
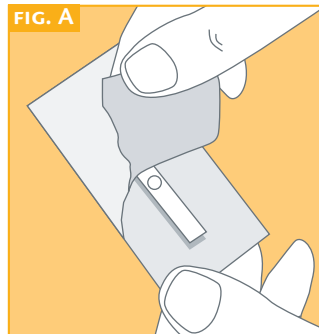
Used test materials may be disposed of in household waste.

Never adjust your heart medication based on your test results.

TEST PROCEDURE

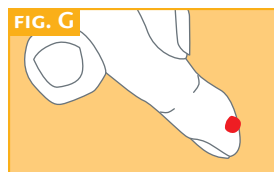
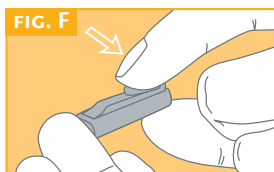
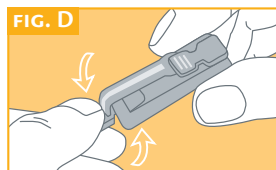
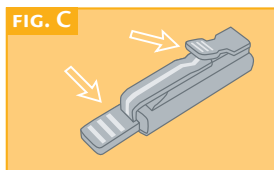
STEP 1: PREPARING FOR THE TEST.

- Wash your hands well with warm water and dry thoroughly. If your hands are cold rub them together to warm them in order to increase blood flow to your fingers.



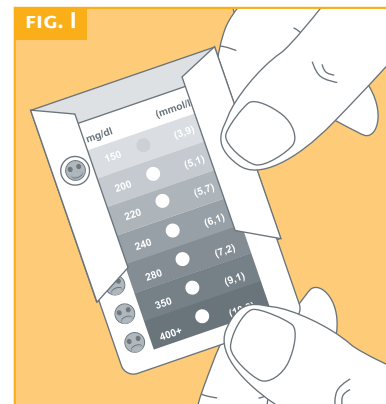
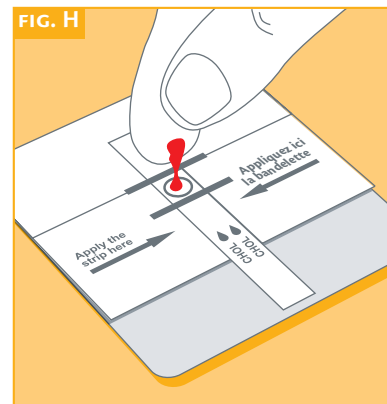
- Open the foil pouch and remove the test strip - **FIG. A**
- Lay the supportive card on a dry table with the side that says “apply the strip here” facing up.
- Place the test strip on the supportive card as shown in - **FIG. B**
- Do not place anything on the table under the supportive card including tissues, napkins or paper towels.

STEP 2: OBTAINING AND APPLYING THE BLOOD SAMPLE.



- Remove a sterile lancet from the test kit box
- Remove the protective cap of the lancet by twisting as shown in - **FIG. C, D, E**. Be careful not to push the trigger to avoid premature activation of the lancet.
- 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.
- Place the selected finger flat on the tabletop. With the thumb of your opposite hand, massage the selected finger several times to push blood to the tip.

- Place the open end of the lancet firmly against the side of the selected finger. Press the side lever on the lancet until you hear a “click” - **FIG. F**
- With the thumb of your opposite hand, massage your finger until a large drop of blood is formed - **FIG. G**



- Place this drop of blood on the strip. Make sure the drop completely covers the inside the loading zone - **FIG. H**
- Wait 40 seconds.
- When 40 seconds are up quickly turn the card over and compare the color shade and intensity through the hole with the matching colors on the comparative chart. This should be done within 25 seconds of turning the card.
- The numerical value next to the matching color gives your cholesterol level - **FIG. I**

STEP 3: INTERPRETING THE RESULTS.

- Each color block on the comparative chart corresponds to a total cholesterol value. If the result circle matches one color block, the number printed next to the color block is your test result.
- Record your results.
- Dispose the used strip and used lancet as a regular household garbage. Keep the plastic support card and the comparative color chart for the second test.

STEP 4: UNDERSTANDING YOUR TEST RESULTS.

Your test results will place you in one of the three risk groups.

“DESIDERABLE” group: less than 5.2 mmol/L (200 mg/dL)

You are likely to be at low risk for heart disease. Please continue maintaining a healthy diet, exercise regularly and monitor your cholesterol from time to time.

“BORDERLINE-HIGH” group: results between 5.2 – 6.2 mmol/L (200-250 mg/dL)

You may be at increased risk for heart disease because this is a moderate risk group. Test yourself again in 1-8 weeks. If the results are consistently “borderline-high” you should consult with your doctor.

“HIGH” group: results above 6.2 mmol/L (250 mg/dL)

You may be at increased risk for heart disease whether or not you have additional risk factors. You should talk to your doctor immediately for advice.

Invalid results: below 3.6 mmol/L (125 mg/dL)

The test is invalid if the result indicator has not turned green. Possible reasons for the invalid results are mistakes when performing the test not according to the provided instructions. Repeat the test with the new test kit. If no color change is observed when repeated, your cholesterol might be at or below **3.6 mmol/L** or there are still unresolved problems with the test procedure. Please contact the distributor.

F.A.Q. - QUESTIONS AND ANSWERS

CAN THE TEST GIVE INACCURATE RESULTS?

Yes, you may get incorrect results if:

- You matched colors before 40 seconds incubation was up or you waited too long to read the results after flipping the card.
- You performed the test in direct sunlight or in high humidity (in a steamy bathroom)
- You wiped your fingers with something other than the alcohol swab.
- Your kit was stored or used above or below room temperature.
- You did not use sufficient blood sample to perform the test.
- You used a comparative color chart from other kits and not the one that came with your test strip.

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 don't need 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 grapefruit juice), and most medications (including aspirin and vitamins) will not interfere with the test. However, do not run the test within 4 hours of taking Tylenol (acetaminophen) or Vitamin C (500mg or more).

CAN THE TEST CHECK FOR GOOD AND BAD CHOLESTEROL?

Cholesterol travels in the bloodstream in “packages” of fat and protein called lipoproteins. The two main types are HDL and LDL. HDL (High Density Lipoprotein) - often called “good” cholesterol because it appears to clear excess cholesterol from the arteries. LDL (Low Density Lipoprotein) - often called “bad” cholesterol, because it tends to build up on artery walls.

PRIMA® Cholesterol home test can only determine total cholesterol levels and is only intended to be used as a screening tool. If the test results put you in the high risk category then a more detailed investigation of the cholesterol panel (HDL and LDL) is warranted.

SYMBOLS

In vitro diagnostic device

Read the instructions before use

Store between +4°C and +30°C

Expiry date (last day of the months)

Do not reuse

List number

Lot number

Legal manufacturer

Lancet: **STERILE** **R**

