

CE 0197 [IVD] For self-testing use

QUCARE® Self Total Cholesterol

Simple & Quick Total Cholesterol Test

INTENDED USE

The QUCARE® Self Total Cholesterol test is intended for in-vitro diagnostic for the semi-quantitative determination of cholesterol in fresh capillary whole blood. Suitable for self-testing use

GENERAL INFORMATION

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 can be used to identify elevated blood cholesterol levels associated with increased risk of coronary artery disease.

QUCARE® Self Total Cholesterol test provides preliminary semi-quantitative analytical test results. All results indicating elevated blood cholesterol levels should be verified by a quantitative cholesterol method.

If your test result is not consistent with your expectations symptoms, you should contact your healthcare professional and follow his or her treatment advice.

READY TO TEST

Materials Provided:
2 x Test strips, 2 x Capillary tubes, 4 x Disposable Lancets,

Materials required (but not provided):
Watch or Other Timing System
Alcohol swab or Clean dry tissue

WARNING AND PRECAUTIONS

For in vitro diagnostic use only.
Use only fresh capillary whole blood from the fingertip.

Never use a lancets or capillary tube the was by another person
Do not reuse lancet, capillary tube and test strip.
Do not use the test strips on babies and infants.
Do not use serum or plasma.

Check pouch for expiration date before beginning the test.
The used strip should be discarded according to local regulations after testing.

All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

Specimen collection and preparation

The QUCARE® Self Total Cholesterol test is prepared using fresh capillary whole Blood collected from a fingerstick
The Whole Blood specimens should be tested immediately after draw.

Fingerstick samples must be obtained from free flowing capillary blood.
Excessive squeezing or milking can procedure somewhat lower results.

Test Procedure

<Preparation>

Step 1.

Check the package materials and read the package insert thoroughly.



Step 2.

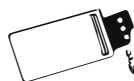
Wash your hands with warm water and soap, carefully drying your hands afterwards.

Warning
Use of lotions and hand creams should be avoided before testing.



Step 3.

Open the foil pouch and check the test kit.



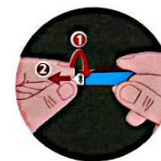
Warning
Please check which side of the test kit you need to apply the blood sample to before testing



<Getting a drop of blood>

Step 4.

Hold the lancet body and twist the lancet cap until it is removed.



Warning

You need to be careful when removing the cap of the lancet that you twist it off. If you pull it, then it will prematurely fire the lancet rendering it unusable. Similarly, if you snap the cap off without twisting it, then you will break off the stem of the cap, again making the lancet unusable.

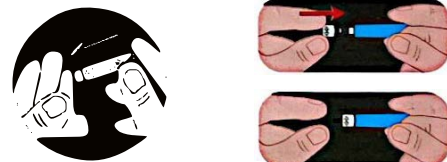
Step 5.

Massage your hand from the wrist to the fingertip to increase blood flow.



Step 6.

Hold the safety lancet against the patient's fingertip and press down firmly to draw blood. Push the cap back into the used safety lancet until the cap is fully secured, and then dispose of it in a waste container.



Step 7.

Wipe away the first drop of blood with a clean tissue.



<Running a test >

Step 8.

Collect the second drop of blood with the capillary tube.



Warning

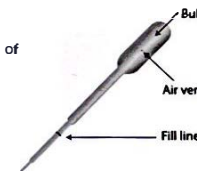
Please check how to use capillary tube first before using it.

Tips !

- 1) Hold the capillary tube slightly downward and horizontally.
- 2) Touch the tip of the pipette to the blood drop.
- 3) Capillary action will automatically draw the blood sample to the fill line and stop.
- 4) Do not squeeze or block the air vent during collection of the blood sample.
- 5) Collect the blood up to the fill line.

Warning

It is important not to squeeze the bulb of the capillary tube when collecting the blood sample. Only squeeze the bulb when it comes to adding the blood to the test strip.



Step 9.

Apply the blood sample onto the test hole and wait 2 minutes before turning the test kit over. **DO NOT** turn over the test kit before 2 minutes.



Warning

Squeeze the bulb until all the blood in the capillary tube is applied.

Warning

If you don't apply the additional blood sample onto the test hole, the result may be inaccurate.



Warning

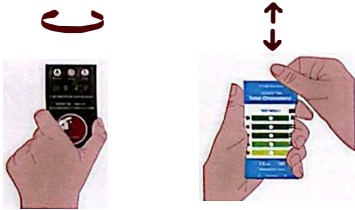
The sample window should be completely covered with blood. If the blood sample was smeared or too little blood was applied, you should dispose of the test strip and repeat the test with a new strip. At least 10 uL of sample is required for one test.



Step 10.

Turn over the test kit after 2 minutes and find the closest matching colour for the result within 30 seconds.

The test result **MUST** be read within 2 minutes and 30 seconds of applying the blood sample.



**** measurement range** 250mg/dL (2.6–6.5 mmol/L)



The colour should be compared after 2 minutes.

You may get inaccurate results if you read too early as the colour may still be developing. Similarly, if you read it too late, then the colour may fade.

Precise timing is essential to ensure optimal results. If the colour of the test result is between two tones of colour on the colour table, calculate the average.

A test area that appears lighter than the 99mg/dL colour block should be interpreted as a cholesterol result of less than 99mg/dL.

A test area that appears darker than the 250mg/dL colour block should be interpreted as a cholesterol result greater than 250mg/dL.



Step 11.

The used strip, capillary, alcohol swab and Lancet should be discarded according to local regulations after testing.

FAQs

Q) Can the result circle change color without giving me a correct reading?

Yes, you may get an incorrect result if:

- ✓ You compared colors before 2 minutes or after 2 minutes and 30 seconds.
- ✓ You performed the test in direct sunlight, or in a steamy bathroom.
- ✓ The test strip was stored or used above the maximum room temperature (30°C)
- ✓ You did not use sufficient blood to perform the test.

Q) Do I need to fast before testing?

In general, fasting before your test isn't required, unless you are already taking a cholesterol medication.

Q) What do my total cholesterol numbers mean?

Your test result will place you in one of 3 medical risk groups (Refer to Expected Values) defined by the National Cholesterol Education Program.

- ✓ The National Cholesterol Education Program recommends averaging two or three cholesterol test results. One test may not give a definitive or typical result.
- ✓ 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.
- ✓ 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.

Expected Values

->Adult (In all adults aged 20 years or older)



Adults

<200 mg/dL (<5.18 mmol/L) : Desirable
200-239 mg/dL (5.18-6.19 mmol/L) : Borderline high
≥ 240 (≥ 6.22 mmol/L) : High

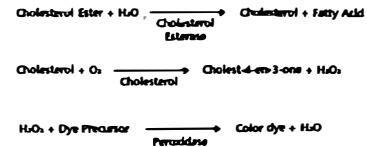


Children

<170 mg/dL (<4.40 mmol/L) : Desirable
170-199 mg/dL (4.40-5.15 mmol/L) : Borderline high
≥ 200 (≥ 5.18 mmol/L) : High

Test Principle

QUCARE® Self Total Cholesterol test strips are based on enzymatic reaction to measure total cholesterol. When whole blood is applied on QUCARE® Self Total Cholesterol test strips, a chemical reaction happens and causes colour change of the test area.



Chemical Composition

Cholesterol esterase 200 Unit
Cholesterol oxidase 45 Unit
Peroxidase 100 Unit
Aminoantipyrine 0.1mg

STORAGE AND HANDLING

Store test strip at 2-30 °C until the expiration date printed on the foil pouch or box.

Do not freeze.

Keep away from heat and direct sunlight.

Do not use after the expiration date.

Do not touch the reagent area of the strip.

LIMITATIONS OF PROCEDURE

Studies were performed to test for substances that may interfere with these tests. The results are below:

Know interfering substances

No significant effect was observed to the following concentration for each substance.

Ascorbic acid: 3 mg/dL

Bilirubin: 20 mg/dL

Creatinine: 30mg/dL

Hemoglobin: 400mg/dL

Urea: 500mg/dL

EDTA (Anticoagulant): 640mg/dL

Heparin-Lithium, (Anticoagulant): 100mg/dL

Hematocrit: Between 30–55% have no effect on test results.

Drug: Dopamine, Gentsic acid and methyl dopa may cause the low test results.

Performance Characteristics

Repeatability / Reproducibility

A study was conducted using known cholesterol value samples. Each sample was tested ten times with the QUCARE® Self

Total Cholesterol test kit. The agreement of results was above 93%.

Accuracy

A clinical study was conducted comparing the QUCARE® Self Blood Total Cholesterol test kit with the reference method (BECKMAN COULTER AU5800). This clinical study was performed using 80 venous blood samples.

A comparison results between professional and laymen revealed a very high concordance of between 90-96%.

NOTES ON SYMBOLS

	Warning
	Consult instructions for use
	In vitro diagnostic
	Use By / Expiry Date (YYYY-MM-DD)
	Do not reuse
	Store at
	Keep away from sunlight
	Number of test strips
	EU Authorized Representative

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