

# QUCARE® Self Total Cholesterol

Simple & Quick Total Cholesterol Test



### INTENDED USE

The QUCARE® Self Total Cholesterol test is intended for home use. The test strip for the semi-quantitative determination of cholesterol in fresh capillary whole blood.

### GENERAL INFORMATION

The determination of cholesterol levels provides initial information on the state of the patient's lipid metabolism. This information serves as a basis for further diagnostic measures, therapeutic decisions or monitoring the progress of the patient. However, self-monitoring is not to be seen as a substitute for regular monitoring by a physician. The results of self-monitoring should be noted down and discussed with the physician.

### READY TO TEST

Materials Provided:  
2 x Test strips, 2 x Capillary tubes, 4 x Disposable Lancets,  
Materials required (but not provided):  
Stopwatch, Clean tissue.

### LIMITATIONS OF PROCEDURE

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

**Drugs:** Dopamine, Gentisic acid and methyl dopa may impact the results of the test.

**Metabolites:** Extremely high doses of ascorbic acid (vitamin C) may impact the results of the test.

**Hematocrit:** Between 30~52% has no effect on the test result.

**Neonatal use:** There is no data generated to validate the use of this system with neonatal samples.

## INSTRUCTION FOR USE

### <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

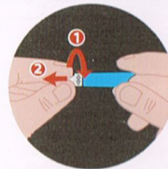
Please check which side of the test kit you need to apply the blood sample to before testing.



### <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.

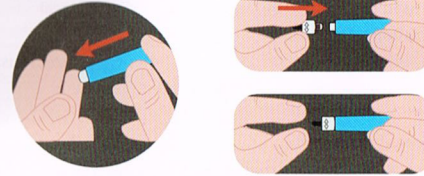
#### Step 5.

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.

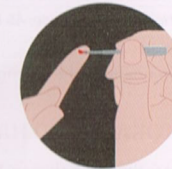
Wipe away the first drop of blood with a clean tissue.



### <Running a test >

#### Step 8.

Collect the second drop of blood with the capillary tube.



#### Warning

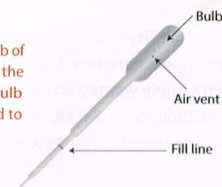
Please check how to use capillary tube first before using it.

### 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.

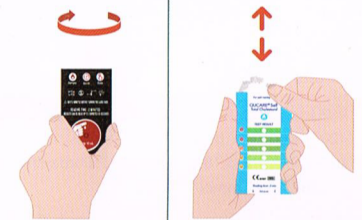
Notes : The sample window should be completely covered with blood. If the blood sample was smeared or too little blood was applied, you should dispose of the test strip and repeat the test with a new strip. At least 10 uL of sample is required for one test. The colour should be compared after 2 minutes. 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.

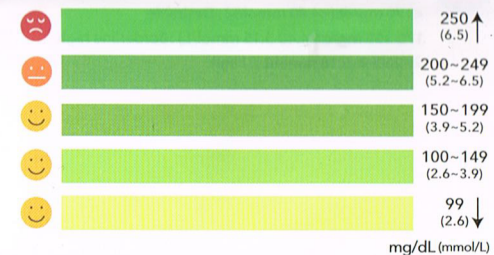
A test area that appears lighter than the 99mg/dL colour block should be interpreted as a cholesterol result of less than 99mg/dL. A test area that appears darker than the 250mg/dL colour block should be interpreted as a cholesterol result greater than 250mg/dL.

#### Step 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)



## FAQs!

**Q) I did not apply the full amount of blood sample to the test kit - can I apply additional blood to the test area afterwards?**



No, you have to apply the correct amount of blood sample at once. If you don't, the result may be inaccurate.

**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?**

### Expected Values

#### Guidelines of the National Cholesterol Education Program (NCEP)

All results of 200mg/dL or greater should be repeated by a quantitative laboratory method before a diagnosis of hypercholesterolemia is made.

In addition, if an individual's blood cholesterol level does fall into a borderline high or high cholesterol category, it is recommended that a lipid profile be completed to determine the extent of the risk for Coronary Artery Disease (CAD); taking into account other risk factors such as hypertension, cigarette smoking and family history.

### Adults

dangerous      Borderline high      Desirable

<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

dangerous      Borderline high      Desirable

<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

## WARNING AND PRECAUTIONS

For in vitro diagnostic use only.

Use only fresh capillary whole blood from the finger tip.

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.

Apply all of the blood to the test strip at once.

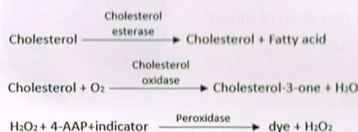
The used strip should be discarded according to local regulations after testing.

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

### 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 the test between 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.

## Performance Characteristics

### Precision

A study was conducted using five levels of whole blood samples.

Each sample was tested ten times with the QUCARE® Self

Total Cholesterol test kit. The agreement of results was 90.7%.

### Repeatability (within-run impression):

A study was conducted using two levels of whole blood samples.

Each sample was tested twenty times with the QUCARE® Self

Total Cholesterol test kit.

The agreement of results was 95.7%.

## 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 50 venous blood samples.

Analyte	No. of sample	Slope	Y-intercept	Coefficient of correlation
Total cholesterol	50	0.907	9,140	0.952

## 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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