

MiraTes Cholesterol HomeTest + - Information

Introduction

In Western countries, coronary heart disease is the leading cause of death. An elevated blood cholesterol level is one of the major risk factors for coronary heart disease. However, not only the concentration of the total cholesterol is important, but also the ratio between the "good" HDL cholesterol and the "bad" LDL cholesterol.

The MiraTes Cholesterol HomeTest + consists of two tests which enables you to calculate your total cholesterol/HDL cholesterol ratio. This ratio gives a reliable impression of your personal risk for coronary heart disease.

What is cholesterol?

Cholesterol is an important structural component for the human body and plays an important role in the production of hormones and bile acids. Cholesterol is taken up from our nutrition, however, the majority of the cholesterol in our body (approximately 75%) is produced by the liver.

In order to transport cholesterol to those parts of the body where it's needed, the liver produces the HDL and LDL. The LDL transports the cholesterol to several parts of the body. During this transport, LDL easily sticks to the interior side of blood vessels. This may lead to damage and narrowing of these blood vessels, and eventually may lead to atherosclerosis and possibly heart attack. Therefore, LDL is also referred to as "bad" cholesterol. HDL is called "good" cholesterol, because HDL removes the surplus of the cholesterol from the interior side of the blood vessels and transports it back to the liver, where it will be excreted from the body through feces.

In normal circumstances, the liver keeps a balance between the absorption and excretion of cholesterol. This balance can be disturbed when food contains a lot of saturated fat, or when someone suffers from certain diseases, such as diabetes.

Why test for total cholesterol and HDL cholesterol?

A single measurement of only the total cholesterol does not tell anything about the relation between "good" HDL cholesterol and "bad" LDL cholesterol. By measuring the total cholesterol and the HDL cholesterol, you do not only get more information about both separate values, but also provides information about their relation to one another. Worldwide research has shown that this total cholesterol/HDL ratio is a reliable value to determine the risk for coronary heart disease.

Who should use the MiraTes Cholesterol HomeTest +?

Because the risk for coronary heart disease can be reduced rather easily by adjusting eating and living habits, it is advisable to measure cholesterol levels on a regular basis. This especially applies for people with a high risk for coronary heart disease, such as:

- People with diabetes (diabetes mellitus);
- People with a high blood pressure;
- People with a genetic predisposition for high cholesterol (familial hypercholesterolaemia);
- People who smoke, eat fat, are overweighted, drink too much alcohol or do not exercise enough;
- People who already have had coronary heart disease, or people with a family history of coronary heart disease at a younger age (younger than 60 years).

How does the MiraTes Cholesterol HomeTest + work?

The MiraTes Cholesterol HomeTest + consists of two different testcassettes, which enables you to determine your personal risk for coronary heart disease. One testcassette measures total cholesterol in the blood sample, the other testcassette measures HDL cholesterol. Both testcassettes work identical.

In order to determine the risk factor for coronary heart disease, you only have to divide the result of the total cholesterol measurement by the result of the HDL cholesterol measurement. This total cholesterol/HDL ratio can be compared with the table on the other side. Please take into account that results are different for gender.

The MiraTes Cholesterol HomeTest + is very easy to use and can be performed at any time or place. With the convenient finger pricker you can easily and rather painless obtain the required drops of blood.

How to interpret the test result?

The MiraTes Cholesterol HomeTest + measures the total cholesterol and the HDL cholesterol. With the enclosed yellow conversion charts the test result has to be converted into mmol/L (millimol per liter).

Total Cholesterol

< 5 mmol/L	healthy total cholesterol
5 to 6,5 mmol/L	slightly elevated total cholesterol
6,5 to 8 mmol/L	elevated total cholesterol
> 8 mmol/L	strongly elevated total cholesterol

HDL Cholesterol

Male (♂)	< 1,0 mmol/L	elevated risk
	> 1,0 mmol/L	no elevated risk
Female (♀)	< 1,1 mmol/L	elevated risk
	> 1,1 mmol/L	no elevated risk

Next, divide the value of the total cholesterol by the value of the HDL cholesterol:

$$\frac{\text{Total Cholesterol}}{\text{HDL Cholesterol}}$$

Finally, your personal risk factor for coronary heart disease can be determined by comparing your total cholesterol/HDL cholesterol ratio with the table on the other side of this page.

Counseling

If you are concerned about the test results or if you have any questions regarding your cholesterol level, we advise you to contact your family doctor. It is important to keep the following facts in mind:

One determination of the cholesterol level can not be interpreted as a final reading. Cholesterol levels may vary from day to day. In addition, cholesterol levels may also vary as a result of weight loss, stress, illness and pregnancy.

The MiraTes Cholesterol Test + is very suitable to make an risk assessment for coronary heart disease. However, in addition to cholesterol levels there are a number of factors that influence your risk for coronary heart disease, such as:

- age, older people are generally at more risk for coronary heart disease;
- myocardial infarction, in many cases the causes of a myocardial infarction are still present, even after the myocardial infarction. These people have a greater risk for re-occurrence;
- diabetes, diabetes causes an elevated level of total cholesterol;
- high blood pressure, a high blood pressure deteriorates the condition of the blood vessels;
- family, if there is a history of family member with high cholesterol and/or coronary heart disease;
- stress, it seems that people who are sensitive to stress have a greater risk for coronary disease, however this has not been scientifically proven;
- menopause, because of the loss of the protecting estrogen, cholesterol levels rise;
- unhealthy lifestyle, for example smoking, not enough physical exercise, eating too much fat, obesity.

Warning before use

The MiraTes Cholesterol HomeTest + is not to be used by:

- haemophiliacs;
- people taking medicines that thin blood (anticoagulants);
- people who have taken 500 mg or more Vitamin C or a standard dose of acetaminophen (e.g. Tylenol) or Naproxen, within 4 hours before performing the test.

Recent illness, pregnancy and hormonal contraceptives may influence cholesterol levels. Do not adjust your medication based on these test results.

Storage and stability

Read the instructions carefully before performing the test. Find a quiet place to perform the test, preferably sitting down at the table.

The MiraTes Cholesterol HomeTest + is designed for in vitro use only. Keep out of reach of children. The test should be stored between 4 to 30°C in the sealed pouch at room temperature. Do not freeze the MiraTes Cholesterol HomeTest +.

Do not use beyond the expiration date, which can be found on the sealed pouch.

Product guarantee

MiraTes Europe BV unconditionally guarantees the quality of this test, if used following the enclosed instructions. If the packing of this test has not reached you unopened, if any parts as described on the instruction sheet are missing or damaged, please return the unused components of this test to the address below. It will be replaced free of charge.

More Information

For more information, or repeat orders of the MiraTes Cholesterol HomeTest + or other tests of MiraTes Europe BV, please refer to our detailed internet site www.mirates.com or contact us through the following address and phone number:

MiraTes Europe BV
Cairostraat 60
3047 BC Rotterdam
The Netherlands

T 00 31 (0) 10 262 1338
F 00 31 (0) 10 262 4371
E info@mirates.com



Visit our website for more information about our products:

www.mirates.com

Other products of MiraTes Europe BV. are the MiraTes Prostate HomeTest, the MiraTes Hepatitis C HomeTest, the MiraTes HIV/HCV Combo HomeTest, the MiraTes HIV HomeTest, the MiraTes Cholesterol HomeTest, the MiraTes Allergy HomeTest Total, the MiraTes H Pylori HomeTest, the MiraTes Allergy HomeTest Indoor, the MiraTes Menopause HomeTest and the MiraTes Pfeiffer HomeTest

MiraTes Cholesterol Hometest + – Instructions for use

Materials provided

- 1 white foil pack with a test cassette for Total Cholesterol
- 1 white foil pack with a test cassette for HDL Cholesterol
- 1 yellow conversion chart for Total Cholesterol
- 1 yellow conversion chart for HDL Cholesterol
- 3 orange fingerprickers
- 2 band-aids
- 1 instructions for use

Step 1: Opening the package

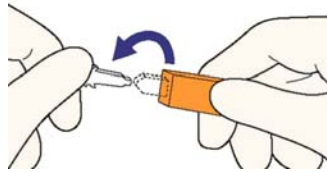
When stored in refrigerator, allow the MiraTes Cholesterol Hometest + to equilibrate to room temperature (15-30°C) prior to testing. Open the first white foil pack and use the test as soon as possible. Do not open the foil pack of the second test before you are ready to perform the second test. It does not matter which test you decide to take first. Both tests are performed in the same manner. The silica gel (absorbing pack) should not be used and can be thrown away.

Step 2: Preparations for the finger pricker

Wash your hands with soap and warm water. Rinse and dry them well before starting the test. Find a quiet place to perform the test, preferably sitting down in front of a table. In the meanwhile, warm up your hands by massaging them. To increase blood flow even more, let your hand hang down for approximately 30 seconds.

Step 3: Finger pricker

Attention! The finger pricker is for single-use and can not be re-used in order to avoid contamination.



Turn the white protective tab at least two times completely round.

Subsequently, pull the white protective tab carefully from the finger pricker.

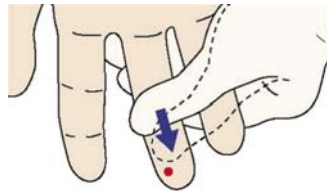


Press the finger pricker firmly against the side of your fingertip.



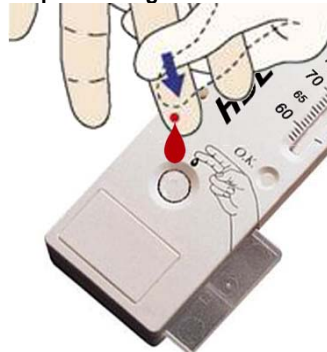
While pressing the fingerpricker against your finger, push the white button firmly until a click is heard.

The needle will retract into the finger pricker for safe disposal.



Gently massage your finger towards the finger tip.

Step 4: Adding blood



The blood needs to be added within 5 minutes.

Hold your finger above the black circle. Massage your finger gently in the direction of your fingertip, so that a drop of blood appears.

Attention: Do not massage your finger too hard, this can influence the test result.

Let the drop of blood fall on the bottom of the test, proceed until the black circle is no longer visible. If the black circle is still visible you should continue adding blood.

When the black circle is no longer visible, you need to wait 3 to 4 minutes before you proceed with step 5.



Not enough blood

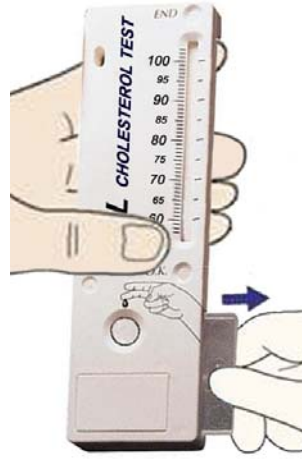


Not enough blood



Enough blood

Step 5: Activating the test



Hold the test firmly in your hand. Pull the transparent tab on the right side of the test until the arrow is fully visible. **PULL HARD!!** Do not worry about breaking the tab or spilling the blood. Put the test on the table.

Tab the test with the bottom of the test (where the transparent tab is) on the table a couple of times. Then lay down the test horizontally on a flat surface (the table).

The O.K. indicator will get purple after a couple of minutes. Then a purple line will flow through the window next to the scale. The "END" indicator will turn green after about 12 minutes.

Read the results of the test after both the O.K. indicator and the END indicator have colored.

Step 6: Reading the test result

Read the result under good, bright light. Look for the outmost end of the blue/purple line, even when this becomes faint at the end. Next, read the matching value on the scale next to the line. This value is the test result not your cholesterol level.

With the yellow conversion charts you will be able to read your cholesterol level (in mmol/L), matching the value you found on the scale next to the blue/purple line. Write your cholesterol level in mmol/L down.

Attention: Use the yellow conversion chart matching the test cassette to determine your cholesterol level. Only use the inserted conversion charts. Charts of other tests may give incorrect results.

Disposal

After use place the different components of the MiraTes Cholesterol Hometest + into the original box and secure the lid. Dispose the box carefully in your dustbin.

Interpreting the risk for coronary disease

When you have performed both tests and written down both cholesterol levels, you may determine your risk for coronary disease. Therefore, divide the total cholesterol level (in mmol/L) through the HDL cholesterol level (in mmol/L):

$$\frac{\text{Total Cholesterol}}{\text{HDL Cholesterol}}$$

For example:

The level of your total cholesterol is 5,5 mmol/L.

The level of your HDL-Cholesterol is 1,8 mmol/L..

Your risk factor for coronary disease is 5,5 : 1,8 ≈ 3

In the risk chart below you can see that the risk for coronary disease is not elevated at the total cholesterol/HDL cholesterol ratio of 3.

Total Cholesterol / HDL Cholesterol Ratio

	MAN (♂)	FEMALE (♀)
No elevated risk	< 5,0	< 4,5
Slightly elevated risk	5,0 – 6,5	4,5 – 5,9
Elevated risk	6,5 – 8,0	5,9 – 7,3
Strong elevated risk	> 8,0	> 7,3

More Information

For more information, or repeat orders of the MiraTes Cholesterol HomeTest + or other tests of MiraTes Europe BV, please refer to our detailed internet site www.mirates.com or contact us through the following address and phone number:

MiraTes Europe BV
Caïrostraat 60
3047 BC Rotterdam
The Netherlands

T 00 31 (0) 10 262 1338
F 00 31 (0) 10 262 4371
E info@mirates.com



Visit our website for more information about our products:

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