

Total Cholesterol Test Strips

Use only with GIMACARE Multi-Functional Monitoring System.

Warnings

- For in vitro diagnostic use (outside of the body) only.
- For single use only.
- Healthcare professionals and other users testing multiple patients with this system should handle everything that comes into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- Please read this manual and your GIMACARE Multi-Functional Monitoring System Owner's Manual before you begin. Only use GIMACARE Total Cholesterol Test Strips with GIMACARE Multi-Functional Monitoring System to obtain accurate results, and be covered by the manufacturer's warranty.
- Results may be inaccurate when testing on patients with abnormally low blood pressure, or those who are in shock.
- For patients with impaired peripheral circulation, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological total cholesterol level.
- Keep test strips and lancets away from young children. If swallowed, consult a doctor immediately.

Intended Use

GIMACARE Total Cholesterol Test Strips, when used together with GIMACARE Multi-Functional Monitoring System, allow you to measure total cholesterol levels by yourself at home or by healthcare professionals. Users should only obtain fresh capillary whole blood samples from the fingertips. This system should not be used for diagnosis or screening of diseases.

Limitations

- Hematocrit: The hematocrit level is limited to between 20% and 60%. Please ask your healthcare professional if you do not know your hematocrit level.
- In vitro L-DOPA up to 1 mg/dL, dopamine up to 2.5 mg/dL, uric acid up to 10 mg/dL and ascorbic acid up to 5 mg/dL showed no interference.
- Altitude Effects: Altitudes up to 11,500ft (3,500m) do not affect test results

Storage and Handling

- Do not use the test strips if they have expired.
- Test strips expire 6 months after first opening. Write the first opening date on the test strip vial when you first opened it. (For strip vial only)
- Store the test strips in a cool, dry place between 2°C and 30°C (35.6°F and 86°F) and between 10% and 85% relative humidity.
- Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- Store the test strips in their original vial ONLY. Do not transfer them to a new vial or any other containers. (For strip vial only)
- Do not touch the test strips with wet hands.
- Use each test strip immediately after taking it out of the vial or individual foil packet. Close the vial immediately after taking out a strip. (For strip vial only)
- Keep the vial closed at all times. (For strip vial only)
- Do not bend, cut, or alter the test strip.

Strip Appearance

- Absorbent Hole**
Apply blood sample here. The blood will be automatically absorbed.
- Confirmation Window**
This is where you can confirm if enough blood has been applied to the absorbent hole in the strip.
- Test Strip Handle**
Hold this part to insert the test strip into the slot.
- Contact Bars**
Insert this end of the test strip into your meter. Push it in firmly until it will not go any further.

Calibration

Calibrate the meter every time whenever begin to use a new package of test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the meter does not match the number printed on your test strip vial label/packet.

Code Chip

- Insert the code chip with the meter switched off. Wait until a number and "CHOL" appears on display.
- Remove the code chip. The display will show "OFF", and then the meter will automatically switch off.

Checking the Code Number

Make sure that the number and "CHOL" displayed on the meter matches the number on your test strip vial label/packet before you proceed. If the numbers match, you can proceed with the test. If they do not match, please stop testing and insert the correct code chip. If the problem persists, contact customer service for help.

Testing Your Total Cholesterol

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING. ALWAYS REFER TO THE OWNER'S MANUAL AND LANCET INSERT ON HOW TO COLLECT A BLOOD SAMPLE.

- Insert the test strip fully into the slot of your meter until it will not go any further. When the strip is fully inserted, the meter will perform several self-checks.
- Collect a blood sample with the test strip. Wipe off the first drop of blood with a clean cotton swab. Make sure there is a sufficient quantity of blood in order to provide accurate test results. Apply the blood drop to the absorbent hole of the test strip, and wait until the confirmation window is fully filled. The meter will start counting down. Do NOT apply a smeared blood sample. NEVER try to add more blood to the test strip after the drop of blood has moved away.
- In less than 60 seconds, the meter will display your total cholesterol level. The last reading will be automatically saved in the meter. The meter will turn off automatically after the test strip is removed. Make sure to dispose the used lancet and test strip carefully.

The used lancet and test strip are potentially biohazardous. Please dispose them carefully according to your local regulations. Please refer to your Owner's Manual for further information.

Reading Your Result

Your total cholesterol readings deliver plasma equivalent results and are displayed in milligrams of total cholesterol per deciliter of blood (mg/dL) or in millimoles of total cholesterol per liter of blood (mmol/L). The measurement unit is based on the actual meter you use.

Reference Values

Total Cholesterol (mg/dL or mmol/L)	
Desirable	< 200 mg/dL (5.1 mmol/L)
Borderline High	200 - 239 mg/dL (5.1 - 6.1 mmol/L)
High	≥ 240 mg/dL (6.2 mmol/L)

A healthcare professional will recommend an appropriate value that are specific for individual patient. At least two measurements in separate occasions should be performed before a medical decision is made, since a single reading may not represent a patient's usual cholesterol concentration. An elevated cholesterol level is only one risk factor for heart disease. There are many others. A cholesterol level less than 200 mg/dL is desirable.

Source: National Cholesterol Education Program. ATP III Guidelines At-A-Glance Quick Desk Reference. National Institutes of Health. National Heart, Lung and Blood Institute. NIH Publication No. 01-3305, May 2001.

Please consult your doctor to determine a target range that works best for you.

Questionable or inconsistent results

If your test results are unusual or inconsistent with how you are feeling:

- Make sure the confirmation window of the test strip is completely filled with blood.
- Check the expiration date of the test strips.
- Check the performance of your meter and test strip with the control solutions.

Δ If your test results are significantly different from what you expect, or in unusually high or low levels, please repeat the test with a new test strip or contact your healthcare professional.

Expiry Date Reminder

For your convenience, the expiry date reminder will activate and notify you the number of days remaining until the strip's expiry date shown on the vial label or on the foil packet. The count down begins from 30 days to 1 day, which will be shown at the center of the display screen. When you see the date reminder, please use the remaining test strips before they expire.

Δ The error message E-2 will appear in the following situations:

- The test strip is expired;
- The code chip is expired; or
- On the initial set-up, the date has been set incorrectly on the meter.

If the error message E-2 appears, please repeat the test with a new lot of test strip to get accurate results.

Chemical Components:

Cholesterol esterase (Pseudomonas sp.) ≥ 0.1 U

Cholesterol oxidase (Streptomyces sp.) ≥ 0.1 U

Electron shuttle 50%

Enzyme protector 8%

Non-reactive ingredients 34%

Quality Control Testing

Our control solutions contain a known amount of total cholesterol that will react with the test strips. If you are concerned about the meter or test strips are not working properly, you can check the performance of meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial or on the test strip package. Please refer to the Owner's Manual for the step-by-step quality control test instructions.

Δ The reference range of the control solutions may vary with each new vial or package of test strips.

Make sure you check the range on the label of your current vial or on the current package.

Additional Information

Always wear gloves and follow your local biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only.

Sample Size: 3 µL

Reaction Time: 60 seconds

System Measurement Range: 100 to 400 mg/dL (2.5 to 10.3 mmol/L)

Hematocrit Range: 20% to 60%

Accuracy

Accuracy describes how well the readings from a testing system (meter and test strips) agree with the readings from an internationally accepted reference system (laboratory analyzer) and is performed according to an internationally recognized standard. The prepared samples were then tested on this meter and compared to the readings from the Cobas C311 analyzer.

Total Cholesterol	n = 480	
	Capillary samples	Range, mean
Regression	$y = 0.9715x + 9.3218$ $R^2 = 0.9606$	Range: 105.8 to 388.0 mg/dL Mean: 210.0 mg/dL

User performance

Total Cholesterol	n = 160	
	Capillary samples	Range, mean
Regression	$y = 0.9661x + 10.446$ $R^2 = 0.9636$	Range: 115.4 to 359.6 mg/dL Mean: 206.0 mg/dL

Precision

Total Cholesterol	Concentration		
	180 mg/dL	240 mg/dL	350 mg/dL
Promedio	184.6	243.3	349.4
SD	5.433	7.118	10.367
CV (%)	2.94	2.93	2.97

Symbol Information

Symbol	Referent	Symbol	Referent
	In vitro diagnostic medical device		Humidity limitation
	Consult instructions for use or consult electronic instructions for use		Manufacturer
	Temperature limit		Model number
	Use-by date		Do not re-use
	Batch code		Unique device identifier
	Caution		CE mark
	Authorized representative in the European Community		

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Per l'autotest.
For self-testing.
Pour l'autocontrôle.
Para autodiagnóstico.

