

MediCare

Blood Cholesterol Test Strips

For in vitro diagnostic use only

Important

Please read this information and the **MediCare** Monitoring System User's Manual before using the **MediCare** Blood Cholesterol Test Strips. If you have any questions or need assistance, please contact our authorized distributors in your country.

Intended Use

MediCare Blood Cholesterol Test Strips are designed for in vitro diagnostic use with **MediCare** series meters for self-testing the quantitative measure of cholesterol level in fresh capillary whole blood. This system is suitable for hypercholesterolemia management at home or professional use.

Compatible Meters

ET-1004

Summary

The **MediCare** Blood Cholesterol Monitoring System quantitatively measures cholesterol level in fresh capillary whole blood. This measurement is based on determination of the current changes caused by the reaction of cholesterol with the reagent on the electrode of the strip. When the blood sample gently touches the sample target area, the blood is automatically drawn into the reaction zone of the strip. The meter displays the test result in **150** seconds.

Measurement Range

The measurement range of the **MediCare** Monitoring System is from 100 to 400 mg/dL (2.5 mmol/L to 10.4 mmol/L) for cholesterol.

Reagent

Each **MediCare** Blood Cholesterol Test Strip contains the following reagent:

Cholesterol oxidase	≥3 IU
Non-reactive ingredients	≥2.1 mg

Storage and Handling

- Store the test strips between 4°C to 30°C (40°F to 86°F).
- Keep away from direct sunlight and heat.
- Do not use the test strips after the expiration date.
- Mark the first opening date on the vial. Use the test strips within **2 months** after first opening.
- Tightly seal the vial cap immediately after removing a test strip.
- Do not handle the test strips with wet or dirty hands.
- Do not cut, bend, scratch, or alter the test strips in any way.

Warnings and Precautions

- Discard each test strip after single use.
- If your blood cholesterol test results are not consistent with your expected results and you have followed all instructions described in the **MediCare** Monitoring System User's Manual, call your healthcare provider.
- Never make significant changes to your hypercholesterolemia control program or ignore physical symptoms without consulting with your healthcare provider.
- Be sure to follow your local regulation for proper disposal of used test strips and lancets.
- Keep the test strip vial away from children. The cap or vial may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation. In the unlikely event that the drying agent beads leak from the vial cap, do not use the test strips or handle the beads.
- Critically ill patients should not be tested at home using a blood cholesterol monitor.
- Do not use tincture of iodine to disinfect your fingertip.
- Code (calibrate) the **MediCare** Meter to match the code number printed on the blood cholesterol test strip vial.

Materials Needed to Test Your Cholesterol

Included

- **MediCare** One Blood Cholesterol Meter
- **MediCare** One Blood Cholesterol Test Strips
- **MediCare** One Blood Cholesterol Monitoring System User's Manual
- Puncturer (lancing device)
- Lancets
- Log Sheet

Not Included

- Alcohol swab

Sample Collection and Preparation

The **MediCare** Blood Cholesterol Monitoring System is designed to determine cholesterol level in fresh capillary whole blood (e.g., from fingertip). To obtain a drop of blood, follow these steps:

- Step 1:** Wash your hands with soap and warm water, then dry thoroughly.
- Step 2:** Prepare puncturer according to the instructions.
- Step 3:** Use an alcohol swab, and make sure that your finger is completely dry before lancing your finger.
- Step 4:** Use the puncturer to obtain a drop of blood. Avoid excessive squeezing of the puncture site.

Coding the meter

When you use a new vial of test strips, the meter must be calibrated with the new code key packaged in the box for obtaining an accurate blood cholesterol test result.

1. Find the code number on your strip vial
2. Insert the code card into the strip slot on the meter.
3. Wait for the meter to beep, then press "M" button. Make sure the number on the display matches the code number on the

test strip vial you used.

4. Meter displays "OK" indicates the coding complete. The meter then turns off automatically.
5. If the code numbers do not match, please contact your local distributor.

Blood Cholesterol Testing

Step 1: Insert Test Strip. Remove a test strip from the vial and immediately seal the vial cap. Insert the test strip into the test strip slot, and the meter turns on automatically. Then the code number then appears briefly. Make sure the code number on the screen matches the code number on the test strip vial. If the code number does not match, insert the correct code key.

Step 2: Apply sample. Obtain a drop of blood using the sample collection procedure described above. When the meter displays the "📌" symbol, apply your blood sample to the sample target area of the test strip. The test strip automatically draws the blood sample into the reaction zone. The meter then begins measuring your blood cholesterol level.

Step 3: Read the result in 150 seconds. Your cholesterol measurement appears on the screen in **150** seconds. The results are automatically stored. Turn the meter off by removing the test strip. For detailed information on the procedure, please refer to the **MediCare** Blood Cholesterol Monitoring System User's Manual.

MediCareheck with Control Solution

It is recommended to check the performance of the **MediCare** Blood Cholesterol Monitoring System under the following conditions:

- When your blood cholesterol test results are not consistent with what you expected, or when you feel your results are not accurate.
 - Whenever you suspect that the meter or test strips are not working correctly.
 - When you drop the meter.
 - When you first open a new vial of test strips.
- To check the performance of the meter, test strips and your testing technique, run the control solution test by following the instructions detailed in the **MediCare** Blood Cholesterol Monitoring System User's Manual. **MediCare** Cholesterol Control Solution is designed for use only with **MediCare** Blood Cholesterol Test Strips. Other control solutions may provide incorrect results.

When **MediCare** Cholesterol Control Solution test results fall within the expected ranges printed on the test strip vial label, the system is performing properly.

If your control solution test results are not within the expected range, repeat the control solution test. **DO NOT** use the system to test your blood until you get a control solution test result within

the expected range. Results that fall outside the range may be caused by:

- Error in performing the test
- Expired or contaminated control solution
- Test strip deterioration
- Meter not coded properly

Test Results

The unit of blood cholesterol test results displayed on the screen is either mg/dL or mmol/L. The mmol/L results always include a decimal point, whereas mg/dL results do not. If you have any questions or inconsistent results, consider the following items, and then repeat the test.

1. Be sure the drop of blood completely filled the reaction zone of the test strips.
2. Check if the strips are within the expiration date.
3. Check meter and test strip performance with **MediCare** Cholesterol Control Solution.
4. Check if the code number of the test strips matches the code number displayed on the screen.

When test results are still questionable or inconsistent, consult your healthcare provider before making any changes to your hypercholesterolemia medication program.

Caution

If your cholesterol test results are abnormal, or you do not feel comfortable with your results, repeat the test with a new strip. If your test result is not consistent with your expectation, you should contact your healthcare provider and follow his or her treatment advice. Only adapt treatment if you have received the appropriate training from your healthcare provider. The **MediCare** Blood Cholesterol Monitoring System should not be used for the diagnosis of hypercholesterolemia or to test newborns.

Limitations

MediCare Blood Cholesterol Test Strips are designed only for use with **Fresh Capillary Whole Blood Samples**.

- DO NOT use serum or plasma samples.
- DO NOT use venous or arterial blood samples.
- The system is designed for use between 14°C to 40°C (57.2°F to 104°F). Outside this range, the system may yield false results.
- Extremes in humidity may affect the results. Relative humidity greater than 85% or less than 20% may cause false results.
- The system is not recommended for use at altitudes greater than 2,400 meters (8,000 feet) above sea level.
- Do not use sodium fluoride or iodoacetic acid as a preservative for blood samples.
- Hematocrit:
The test strip results are not significantly affected by hematocrit from 30% to 55%. Hematocrit levels less than 30% may cause false high readings while hematocrit levels greater than 55% may cause false low readings. If you do not know your hematocrit level, consult your healthcare provider.
- Neonatal:

MediCare Blood Cholesterol Test Strips used for testing newborn blood specimens are not validated.

- Results may be inaccurate if blood specimens containing substances at given concentration described below:

Interference	Cholesterol
Acetaminophen	20 mg/dL (0.5 mmol/L)
Ascorbic acid	10 mg/dL (0.3 mmol/L)
Bilirubin	21.2 mg/dL (0.5 mmol/L)
Dopamine	10 mg/dL (0.3 mmol/L)
L-Dopa	5 mg/dL (0.1 mmol/L)
Uric acid	19.5 mg/dL (0.5 mmol/L)

- Patients who are undergoing oxygen therapy may yield false results.
- Lipaemic samples (Cholesterol up to 500 mg/dL or triglycerides up to 3000 mg/dL) have not been tested and are not recommended for testing with the **MediCare** Blood Cholesterol Monitoring System.
- Test results may be false if the patient is severely dehydrated or severely hypotensive, in shock or in hypoglycemic-hyperosmolar state (with or without ketosis). Critically ill patients should not be tested at home using the **MediCare Simple** Blood Cholesterol Monitoring System.

Expected Values

The expected cholesterol value for a normal person is as follows: <200mg/dL (< 5.2 mmol/L)

The above range is just a reference, and it's not suitable for every person. Consult your physician for the range appropriate for you. The **MediCare** Blood Cholesterol Monitoring System is plasma-calibrated, which means you can conveniently compare your results to laboratory results.

Consult your doctor for the appropriate range for you.

Performance Characteristics

The performance of the **MediCare** Blood Cholesterol Monitoring System has been evaluated in both laboratory and clinical tests. This system used a Hitachi 7050 analyzer as reference.

1. Accuracy:

The specimens ranged from 100 mg/dL to 414 mg/dL (2.6 mmol/L to 10.7 mmol/L)

Number of Samples	100
Range (mg/dL)	100~414
Slope	0.8754
Intercept (mg/dL)	21.41
r ² (corr. coef.)	0.9581

2. Precision:

The precision data was obtained in a laboratory study using the **MediCare** Blood Cholesterol Monitoring System to analyze fresh heparinized venous blood samples (n=100 per level):













Average (mg/dL)	126	152	233	329
-----------------	-----	-----	-----	-----

S.D. (mg/dL)	6.3	7.4	8.5	10.2
CV (%)	5	4.9	3.8	3.1

References

1. Tietz, N.: Fundamentals of Clinical Chemistry, 3rd Ed., W.B. Saunders Co., Philadelphia, PA, 1987, p. 427.
2. Biosensors: Microelectrochemical Devices, Institute of Physics Publishing, Bristol, Philadelphia and New York, 1992.
3. Burtis, C.A. & Ashwood, E.R., Clinical Chemistry, 3rd Edition, Philadelphia, W.B. Saunders Co. (1999) p. 1815.

Labeling and Information

	Do Not Reuse
	In Vitro Diagnostic Device
	Batch Code
	Use By
	Manufacturer
	Keep Away From Sunlight
	Consult Instructions For Use
	Temperature Limitation
	Catalogue Number (Product Number)
	EU Representative
	Control
	Keep Dry

One
Cholesterol
Monitoring System

MEDICARE

L-Tac MediCare Pte Ltd
25 Mandai Estate, #07-11
Innovation Place Tower 1
Singapore 729930

Tel : (65) 6863 8191
Fax : (65) 6863 8190
<http://www.medicare-l-tac.com.sg>
Customer Services
(65) 6334 2273

Bioptik Technology, Inc.
No. 188, Jhonghua South Road,
Jhunan Township, Miaoli County,
Taiwan 35057
E-mail: service@bioptik.com.tw

EC REP

MT Promedt Consulting GmbH
Altenhofstrasse 80,
66386 St. Ingbert/Hassel, Germany
Tel: +49-6894-581020

CE 0197

Rev.A2 10/16
P/N 12020570