



## Total Cholesterol Test Strip Packing instructions

REF C906005

English

### PRINCIPLE AND INTENDED USE

Total cholesterol test strip can only be used with dedicated test meter, the enzyme on the cholesterol test strip will produce a microcurrent when it comes into contact with blood, the strength of the current will change according to the high and low cholesterol, and finally the final result value of cholesterol will be converted according to the current value, Acuteck total cholesterol test strip is used to quantitatively measure the concentration of total cholesterol (TC).

Cholesterol levels may be used to help detect hyperlipidemia or as a screening test for hypothyroidism and hyperadrenal. Cholesterol results are most useful when analyzed in conjunction with other clinical chemistry tests. This test is used to quantitatively determine total cholesterol (TC) in fresh capillary blood and venous whole blood. The test strip is for professional use only.

### PACKAGING SPECIFICATIONS

5 tablets/bottle, 10 tablets/bottle, 25 tablets/bottle, 50 tablets/bottle

### COMPOSITION

Main chemical components: cholesterol oxidase (> 0.5U), cholesterol esterase (> 0.3U)

### STORAGE AND HANDLING

- Store test strips in their protective vial. Store them with their cap closed tightly. This keeps them working properly.
- Store in a cool, dry place between 2-30°C and keep out of direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips between 10-40°C. This provides accurate results.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners with bleach.
- Do not transfer the test strips to a new vial or any other container.
- Use the test strip as soon as it is removed from the vial.
- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.
- A new vial of test strips may be used for 3 months after first opening. After 3 months they will expire. Write the opened expiration date on the vial label after opening.

### WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use. The test strips are only to be used outside the body for testing purposes.
- All components that come into contact with blood samples are considered biohazards capable of transmitting viral disease, even after disinfection.
- Remember to follow the required pre-cleaning procedure. Please refer to the corresponding section in the user's manual of the meter. This procedure is important to prevent the potential transmission of infectious diseases.
- Do not use test strips that are torn, bent or damaged.
- Do not reuse test strips.
- Apply sample only to the tip of the test strip. Do not apply to the top of the test strip. This may result in a false reading.

- Check the code number before running a Total Cholesterol test. Make sure the code number on the vial of test strips you are using matches the code number that appears on the meter display.
- Discard the vial and any unused test strips 3 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This can cause false readings.
- Keep the test strip vial away from children and animals.
- Consult with your doctor before making any changes to the treatment plans.
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give an incorrect result.

### MATERIALS

#### MATERIALS PROVIDED

- Test Strips
- Code chip
- Package Insert
- Sterile Lancets

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Lancing Device

### ADAPTATION MODEL

The *Acuteck* Total cholesterol test strips is designed for below dedicated test meters. DO NOT use other brand of test meters with *Acuteck* Total cholesterol test strips.

- *Acuteck* Total Cholesterol Test Meter
- *AcuteckGUC* Blood Glucose and Uric Acid and Total Cholesterol Test Meter
- *AcuteckMultiGX* Multi-functional Monitor I
- *AcuteckMultiFlex* Multi-functional Monitor
- *Acuteck* Blood Glucose and Uric Acid and Total Cholesterol and Triglyceride Test Meter

### SAMPLE COLLECTION AND PREPARATION

The specimen type could be fresh capillary whole blood from the finger.

For fresh capillary whole blood from the finger: fresh capillary blood should be used immediately. To obtain a drop of blood, follow these steps:

Step 1: Wash and dry your hands thoroughly.

Step 2: Prepare lancing device according to the manual.

Step 3: Use an alcohol swab. Make sure that your finger is entirely dry before lancing.

Step 4: Puncture and get a drop of blood. Avoid pressing too hard against the punctured site

### EXAMINATION PROCEDURE

See the User's Manual for complete instructions for blood sample collection before use.

1. Open the cap of the test strip vial. Remove a test strip. Replace the cap immediately. This protects the test strips from moisture in the air.
2. Perform the test following the instructions in the User 's Manual.
3. The test result will be shown on the meter display screen.

For detailed information on the test procedure, please refer to the User 's Manual.

## READINGS

If "LO" appears on the screen, your total cholesterol level is below 2.59 mmol/L(100 mg/dL). If "HI" appears, your total cholesterol level is higher than 10.35mmol/L(400 mg/dL). When in doubt about the reading material, check the following items first and then repeat the test. If the results remain in doubt, consult your healthcare professional:

1. If it is within the validity period.
2. Make sure the blood drops are all over the reaction area.
3. Use total cholesterol control solutions to check the performance of meters and test strips.

## LIMITATIONS

Reference values are listed in the chart below:

Tests	Desirable	Borderline High	High
<b>Total Cholesterol(TC)</b>	<5.2mmol/L ( <200mg/dL )	5.2-6.2mmol/L ( 200-240mg/dL )	>6.2mmol/L ( > 240mg/dL )

## QUALITY CONTROL

For best results, Performance of test strips should be confirmed by testing known specimens/controls whenever a new test is performed or whenever a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance. Contact your local distributor for information on specific controls for this product.

## PERFORMANCE CHARACTERISTICS

**System Measurement Range:** 2.59-10.35 mmol/L

**Blood Sample Size:** 2 µL

**Test Time:** 30 seconds

### 1. The accuracy of measurement results for total cholesterol :

Range of sample	<u>Allowable deviation</u>
<3. 88 mmol/L (<150mg/ dL)	Within ±1 mmol/L (±38.6mg/dL)
≥3. 88 mmol/L (≥150mg/dL)	Within ± 20%












### 2. The repeatability of measurement result for total cholesterol:

Range of sample	Precision
<3. 88 mmol/L (<150mg/ dL)	SD<0.58mmol/L (<22. 4mg/dL)
≥3. 88 mmol/L (≥150mg/dL)	CV<15%

### 3. Packed cell volume

Hematocrit range: Samples with hematocrit in the range of 30%-55% would affect total cholesterol test strip insignificantly. Hematocrit below 30% may cause higher results, and hematocrit above 55% may cause lower results.

## INDEX OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	<i>In vitro</i> diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse		
	Authorized representative in the European Community		
	CE marking according to IVD Medical Devices Directive 98/79/ECdevices		

**Acuteck™**



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