AT™ Cholesterol Test Strips
Package Insert

for 3 in 1 test strip

OCHO-401/411 | **English**

CE IVD

For testing Cholesterol in human whole blood, plasma and serum.

For professional in vitro diagnostic use only.

【INTENDED USE】

The Cholesterol Test Strips are used in conjunction with the cholesterol meter to quantitatively detect the content of total cholesterol, high-density lipoprotein and triglyceride in human whole blood, plasma and serum.

The test strips are for professional use only.

【SUMMARY】

Cholesterol is the general term for neutral fats (triglycerides) and lipid (phospholipids, glycolipids, sterols, steroids) in plasma, which are widely present in the human body. They are essential substances for the basic metabolism of living cells.

【PRINCIPLE AND REFERENCE VALUES】

The sample to be tested is added to the sample adding area of the test strip, and it infiltrates evenly and rapidly. During the infiltration process, in the case of whole blood, the blood cells are filtered, and the plasma diffuses to the meter on the reaction later and the enzymes and chemicals in the reaction layer. The product reacts and develops color, and the color intensity is proportional to the concentration of the meter. The Cholesterol meter detects the color intensity of the reaction end point at the wavelength of 635nm, and uses the reflection coefficient to calculate the concentrations of total cholesterol, high-density lipoprotein, triglyceride, and low-density lipoprotein

【REAGENTS】

Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances.

Reagent	Composition
Total Cholesterol(TC)	Cholesterol Esterase＞0.3U
	Cholesterol Oxidase＞0.16U
	4-Aminoantipyrine＞0.06mg
High-density Lipoprotein(HDL)	Cholesterol Esterase＞0.3U
	Cholesterol Oxidase＞0.16U
	4-Aminoantipyrine＞0.06mg
	Dextran Sulfate＞0.5mg
Triglyceride(TG)	Lipoprotein Esterase＞0.35U
	Glycerol Kinase＞0.5U
	Glycerol phosphate oxidase ＞0.1U
	4-Aminoantipyrine＞0.09mg

【PRECAUTIONS】

- For *in vitro* diagnostic use only.
- The strip should remain in the closed packaging bag until use.
- Do not use after the expiration date.
- Do not touch the reagent area of the strip.
- Discard any discolored or damaged strips.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip should be discarded according to local regulations after testing.
- Check the code chip before performing a test. Make sure to use the code chip that is included with the packaging bag of strips. Insert the code chip into the code chip slot. The code chip slot is located on the meter.

【STORAGE AND STABILITY】

Store as packaged in the closed packaging bag, either at room temperature or refrigerated (2-30 °C). Keep out of direct sunlight. Strips are stable through the expiration date printed on the package. **DO NOT FREEZE**. Do not use beyond the expiration date.

Note: Stability may be reduced in high humidity conditions.

【SPECIMEN COLLECTION AND PREPARATION】

- Acceptable specimens include human whole blood, plasma and serum.
- Whole blood, plasma and serum specimens collected without anticoagulant should be tested immediately.
- Whole blood specimen with EDTA or heparin sodium anticoagulants may be used. Plasma specimen with sodium heparin anticoagulant can be used, **avoid plasma specimen with anticoagulant other than** sodium heparin.
- Separate the human serum and plasma from blood as soon as possible to avoid hemolysis.
- Specimens with anticoagulant must be kept in a closed container and used **within 8 hours** at room temperature after collection; if specimens are not to be tested temporarily, specimens can be stored at 2-8 °C for up to 16 hours, avoid using the hemolyzed specimen.
- **Do not freeze whole blood, serum and plasma specimens.**
- Allow the specimens to equilibrate to room temperature, and mixed thoroughly prior to testing.

【MATERIALS】

Materials Provided

·Test strips ·Code chip ·Package insert

Materials Required But Not Provided

·Lancing device ·Sterile lancet ·Cholesterol meter
·Latex gloves ·Alcohol swab ·Capillary dropper
·Gauze for puncture site

【DIRECTIONS FOR USE】

Allow the strip, specimen to reach room temperature (15-30 ºC) prior to testing. Refer to the Cholesterol Meter's User Manual for detailed instructions.

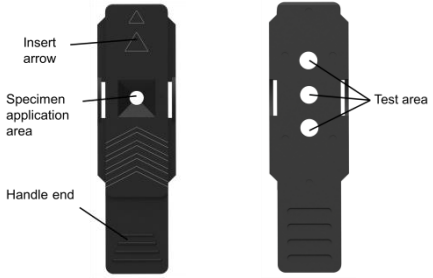
1. Insert the code chip into the meter and code the meter correctly. Refer to Coding the Meter in the User's Manual for details. Compare the code number on the code chip with the code number printed on the test

strip packaging bag, and ensure the two numbers are identical to avoid inaccurate results.

2. Remove the strip from the packaging bag.
3. Wait for the strip symbol flashes on the meter screen. Insert the strip completely into the end of the Strip Holder in the same direction as the arrows on the test strip.
4. While the meter is flashing the blood drop symbol, add **35μL of whole blood, plasma or serum** to the Specimen Application Area by using a capillary dropper or pipette (Refer to the Meter User Manual for details). 3 dashed lines will appear on the meter to show the test is in progress.

   Note: The air vents on the dropper bulb should be covered while releasing the blood sample.

Front view Back view



5. Read the results on the screen **at 120 seconds**. Refer to the Meter User Manual for detailed test procedures.
6. Remove the used test strip, the screen will automatically return to the interface to be tested.

【INTERPRETATION OF RESULTS】

The Cholesterol Meter automatically measures total cholesterol, high-density lipoprotein, triglyceride, and low-density lipoprotein concentration. In the event of unexpected or questionable results, the following steps are recommended:

Confirm that the strips have been used within the expiration date printed on the packaging bag.

Compare results to controls with known levels and repeat the test using a new strip.

If the problem persists, discontinue using the strips immediately and contact your local distributor.

【PERFORMANCE CHARACTERISTICS】

Testing Time: ≤120s

Scope of test:

Total Cholesterol(TC)	2.59-12.93mmol/L(100-500mg/dL)
High-density Lipoprotein(HDL)	0.39-2.59mmol/L(15-100mg/dL)
Triglyceride(TG)	0.51-7.34mmol/L(45-650mg/dL)

【QUALITY CONTROL】

Each laboratory should establish its own goals for adequate standards of performance.

【INTERFERENCE SUBSTANCES】

The following substances do not interfere with test results:

Substance	Conc.	Substance	Conc.
Bilirubin	20mg/dL	Acetaminophen	20mg/dL
Creatinine	5mg/dL	Ascorbic acid	10mg/dL
Hemoglobin	300 mg/dL	Lipid-lowering benzoyl	10mg/dL
Lactate dehydrogenase	250U/L	Dopamine	0.09mg/dL
Total protein	12g/dL	Glyburide	1mg/dL
Uric acid	10mg/dL	Ibuprofen	50mg/dL
Low-density lipoprotein	500mg/dL	Methyldopa	1.5mg/dL
Triglycerides	600mg/dL	Salicylic acid	60mg/dL

【BIBLIOGRAPHY】

1. Henry, J. B. Clinical Diagnosis and Management by Laboratory Methods. (2001) 24:479-481
2. Dacie and Lewis, Practical Haemotology, Tenth Edition, 2006

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/ European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not re-use
2°C 30°C	Temperature limit	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		

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Number: H145007300
Revision date: 2024-01-18