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# Self Test Colesterolo Totale (Sangue Intero)



PRODOTTI ISCRITTI AL

*Ministero della Salute*

contiene 1 test

# **Technical File**

## **Total Cholesterol Test Card (Whole Blood)**

Document No.:

**HANGZHOU ALLTEST BIOTECH CO., LTD**

Address: # 550, Yinhai Street, Hangzhou Economic & Technological Development Area,

Hangzhou-310018, P.R. China

# CATALOGUE

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## 1 General description

### 1.1 Intended Use

Suitable for Semi-quantitative detection of Total Cholesterol in human whole blood.

### 1.2 Summary

Cholesterol is a lipid that is an important component of cell membranes, hormones, and vitamin D, and is a risk factor for cardiovascular disease. Through blood tests, we can know a person's total cholesterol level so that we can manage our health.

### 1.3 Principle

The tested sample is added to the sample adding area of the test card, and it infiltrates evenly and rapidly. During the infiltration process, the blood cells are filtered, and the plasma diffuses to the reaction later and the enzymes and chemicals in the reaction layer. The product reacts and develops color, and compare with the color chart for eye reading judgment.

### 1.4 Reagent

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

### 1.5 Precautions

- For self-testing in vitro diagnostic use only.
- The card should remain in the closed packaging bag until use.
- Do not use after the expiration date.
- Do not touch the sample area of the card.
- Discard any discolored or damaged card.
- The used card should be discarded according to local regulations after testing.

### 1.6 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. Cards are stable through the expiration date printed on the package. DO NOT FREEZE. Do not use beyond the expiration date.

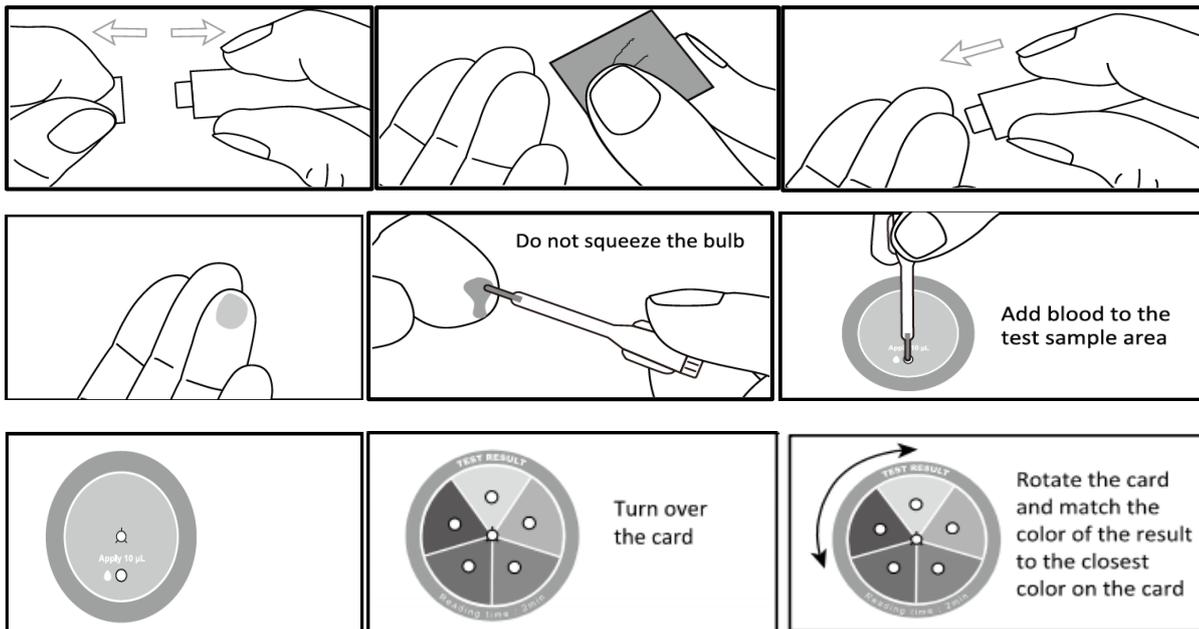
Note: Stability may be reduced in high humidity conditions.

### 1.7 Specimen collection and preparation

1. Acceptable specimens include capillary whole blood from the fingertip.
2. Whole blood specimens should be tested immediately after lancing.
3. Fingertip sample must be obtained from a free spontaneous blood flow after the puncture.
4. Do not collect capillary blood by pressing or squeezing the finger too hard as this will push fluid from the tissue into the blood and may cause false results.

## 1.8 Standard testing procedure

1. Wash your hands with soap and rinse with clear warm water.
2. Bring the pouch to room temperature before opening it. Open the pouch, remove the test card and place it on a clean and level surface. Run the test within one hour and best results will be obtained if the test is performed immediately after opening the foil pouch. Remove the dropper, lancet and alcohol pad, place them close to the test card.
3. Carefully pull off and dispose the released cap of the lancet.
4. Use the provided alcohol pad to clean the fingertip of the middle or ring finger as the puncture site. Allow to air dry.
5. Press the lancet, on the side from where the cap was extracted; the tip retracts automatically and safely after use. Massage the hand without touching the puncture site by massaging the hand towards the fingertip of the middle or ring finger to be punctured.
6. Keeping the hand down massage the end that was pricked to obtain a blood drop.
7. Without squeezing the capillary dropper bulb, put it in contact with the blood. The blood migrates into the to the line indicated on the capillary dropper. You may massage again your finger to obtain more blood if the blood does not reach the indicated line. Avoid of air bubbles.
8. Release the blood collected into the sample well of the card by squeezing the dropper bulb.
9. Wait for the blood to be totally dispensed in the well and wait 2 minutes before turning the test kit over. DO NOT turn over the test kit before 2 minutes.
10. Turn over the test kit after 2 minutes and rotate the card and match the closest matching color within 30 seconds.
11. The test result must be read within 2 minutes 30 seconds of applying the blood sample.



## 1.9 Interpretation of results

The color card on the back of the product shows the total cholesterol concentration range corresponding to different colors. By comparing the color of the test result with the color on the color card, the range of total cholesterol concentration where the result is located can be obtained.

### **1.10 Composition of Product**

- Test Card
- Dropper
- Package Insert
- Safety lancet
- Alcohol pad

## 2 Technical Report for Total Cholesterol Test Card (Whole Blood)

### 2.1 Materials:

Total Cholesterol Test Card(Whole Blood) of Hangzhou Alltest Biotechnology Co., Ltd:

Lot1:ATTCH25020001

Lot2: ATTCH25020002

Lot3: ATTCH25020003

### 2.2 Repeatability

#### Method

Three batches of total cholesterol test cards were used. Each batch was tested with five concentration standards respectively, and each concentration was repeated ten times. Read the result by comparing the color reactions of the color blocks.

#### Result

Table: Repeatability Study Results

lot	Specimen	Concentration range(mg/dL)	Is it within the range										
			Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8	Test 9	Test10	
ATTCH25020001	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
ATTCH25020002	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
ATTCH25020003	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes

**Conclusion:**

All the test results on the total cholesterol test card show the correct results. The results show that the total cholesterol test cards have consistent performance and good repeatability.

**2.3 Clinical test****Method**

The total cholesterol test card was compared with the Mindray biochemical analyzer. Fifty-six clinical samples collected from the subjects present were tested. Compare the reagent area with the corresponding color block on the color card at the specified time. Rotate the color card and match carefully. The test results are shown in the following table.

**Results:**

Table: Clinical Study Results

Number of Samples	Concentration range	Alltest strips	the Mindray biochemical analyzer	Whether it is consistent
56	0-99	0	0	yes
	100-149	14	14	yes
	150-199	39	39	yes
	200-259	3	3	yes
	Above 250	0	0	yes

**Conclusion:** A clinical trial was conducted to compare the total cholesterol test card of Hangzhou Alltest Biotechnology Co., Ltd. with the Mindray Biochemical analyzer. 56 samples were analyzed as follows: The test results of the total cholesterol test card of Hangzhou Alltest Biotechnology Co., Ltd. and the test results of Mindray Biochemical analyzer have a 100% coincidence rate, indicating that the two have a high coincidence rate in performance testing.

**2.4 Interfering Substance Study****Method:**

Detect interfering components in whole blood standards. A certain possible interfering substance was added to the whole blood standards with concentrations of 125mg/dL and 225mg/dL respectively, one at a time. The concentrations of the interfering substances are listed in the table below. Each blood sample was tested using five repeated total cholesterol test cards. According to the instructions on the packaging manual, compare the color reaction with the color blocks on the color card and read the result.

**Interfering Substances:**

The following potentially interfering substances at concentrations indicated were added to the Whole blood standard product:

Interfering Substances Tested	Concentration Level
Ascorbic acid	3 mg/dL
Bilirubin	20 mg/dL

Creatinine	30 mg/dL
Hemoglobin	400 mg/dL
Urea	500 mg/dL
EDTA	640 mg/dL
Heparin-Lithium	100 mg/dL
Hematocrit	30~55%

**Results:**

Table: Interfering Substance Study Results

Interference Substance	Interference substances Conc. (mg/dl)	Testing Results			
		125mg/dL Whole blood standard product without spiked interference substance	125mg/dL Whole blood standard product with spiked interference substance	225mg/dL Whole blood standard product without spiked interference substance	225mg/dL Whole blood standard product with spiked interference substance
Ascorbic acid	3 mg/dL	100-149mg/dL	100-149mg/dL	200-249mg/dL	200-249mg/dL
Bilirubin	20 mg/dL	100-149mg/dL	100-149mg/dL	200-249mg/dL	200-249mg/dL
Creatinine	30 mg/dL	100-149mg/dL	100-149mg/dL	200-249mg/dL	200-249mg/dL
Hemoglobin	400 mg/dL	100-149mg/dL	100-149mg/dL	200-249mg/dL	200-249mg/dL
Urea	500 mg/dL	100-149mg/dL	100-149mg/dL	200-249mg/dL	200-249mg/dL
EDTA	640 mg/dL	100-149mg/dL	100-149mg/dL	200-249mg/dL	200-249mg/dL
Heparin-Lithium	100 mg/dL	100-149mg/dL	100-149mg/dL	200-249mg/dL	200-249mg/dL
Hematocrit	30~55%	100-149mg/dL	100-149mg/dL	200-249mg/dL	200-249mg/dL

**Conclusion:**

From the above data, none of the substances at the concentration levels tested interfered with the ability for the Total Cholesterol Test Card to obtain correct results.

**2.5 Accuracy****Method:**

The accuracy of the total cholesterol test card (whole blood) was tested using samples from three different batches. For each batch, five different concentrations of whole blood standard samples were tested respectively, and the process was repeated five times. Compare the test results of the total cholesterol detection card with those of the Mindray biochemical analyzer. The test was conducted in accordance with the operation procedures stated in the instructions. The results are listed in the table below.

**Results:**

Table: Accuracy Study Results

lot	Specimen	Alltest strips					the Mindray biochemical analyzer	Whether it is consistent
		Test1	Test2	Test3	Test4	Test5		
ATTCH25020001	50mg/dL	0-99	0-99	0-99	0-99	0-99	53.2	yes
	125mg/dL	100-149	100-149	100-149	100-149	100-149	127.5	yes
	175mg/dL	150-199	150-199	150-199	150-199	150-199	178.2	yes
	225mg/dL	200-259	200-259	200-259	200-259	200-259	226.7	yes
	275mg/dL	Above 250	Above 250	Above 250	Above 250	Above 250	271.4	yes
ATTCH25020001	50mg/dL	0-99	0-99	0-99	0-99	0-99	53.2	yes
	125mg/dL	100-149	100-149	100-149	100-149	100-149	127.5	yes
	175mg/dL	150-199	150-199	150-199	150-199	150-199	178.2	yes
	225mg/dL	200-259	200-259	200-259	200-259	200-259	226.7	yes
	275mg/dL	Above 250	Above 250	Above 250	Above 250	Above 250	271.4	yes
ATTCH25020001	50mg/dL	0-99	0-99	0-99	0-99	0-99	53.2	yes
	125mg/dL	100-149	100-149	100-149	100-149	100-149	127.5	yes
	175mg/dL	150-199	150-199	150-199	150-199	150-199	178.2	yes
	225mg/dL	200-259	200-259	200-259	200-259	200-259	226.7	yes
	275mg/dL	Above 250	Above 250	Above 250	Above 250	Above 250	271.4	yes

**Conclusion:**

A comparison was made between the total cholesterol test card of Hangzhou AllTest Biotechnology Co., Ltd. and the Mindray Biochemical Analyzer. The test results of the total cholesterol test card of Hangzhou AllTest Biotechnology Co., Ltd. are relatively consistent with those of Mindray Biochemical Analyzer, indicating that the accuracy of the total cholesterol test card of Hangzhou AllTest Biotechnology Co., Ltd. is relatively high.

**2.6 Time flex****Method**

Test the optimal reading time of the total cholesterol test card. According to the operation steps in the manual, select a batch of total cholesterol test cards and conduct tests with five different

concentrations of whole blood standards. Repeat each test three times. The results were read at 1.5 minutes, 2 minutes, 2.5 minutes and 3 minutes after sample addition respectively. The results are shown in the following table.

**Result:**

Table: Time flex Study Results

Lot	Time(minutes)	Specimen	Concentration range(mg/dL)	Is it within the range		
				Test1	Test2	Test3
ATTCH25020001	1.5	50mg/dL	0-99	no	no	no
		125mg/dL	100-149	no	no	no
		175mg/dL	150-199	no	no	no
		225mg/dL	200-249	no	no	no
		275mg/dL	Above 250	no	no	no
	2	50mg/dL	0-99	yes	yes	yes
		125mg/dL	100-149	yes	yes	yes
		175mg/dL	150-199	yes	yes	yes
		225mg/dL	200-249	yes	yes	yes
		275mg/dL	Above 250	yes	yes	yes
	2.5	50mg/dL	0-99	yes	yes	yes
		125mg/dL	100-149	yes	yes	yes
		175mg/dL	150-199	yes	yes	yes
		225mg/dL	200-249	yes	yes	yes
		275mg/dL	Above 250	yes	yes	yes
	3	50mg/dL	0-99	no	no	no
		125mg/dL	100-149	no	no	no
		175mg/dL	150-199	no	no	no
		225mg/dL	200-249	no	no	no
		275mg/dL	Above 250	no	no	no

**Conclusion:**

The above data shows that the total cholesterol test card displays the correct result within 2 to 2.5 minutes after sample addition. Therefore, we recommend reading the result within 2 to 2.5 minutes and not reading it after 2.5 minutes.

**2.7 Open Pouch Stability**

**Method:**

The Open Pouch stability of the total cholesterol test card (whole blood) was evaluated using samples from three different batches. At room temperature, five concentrations of whole blood standard samples were tested respectively with total cholesterol test cards after 0, 15, 30, 45, 60, 75 and 90 minutes, in triplicate. The test was carried out in accordance with the packaging instructions. The results are listed in the table below.

Table: Time line for Open Pouch Stability Study

Time Temp.	0 minute	15 minutes	30 minutes	45 minutes	60 minutes	75 minutes	90 minutes

25°C	√	√	√	√	√	√	√
------	---	---	---	---	---	---	---

**Results:**

Table: Open Pouch Stability Study Results

Time(minutes)	Specimen	Concentration range(mg/dL)	Is it within the range								
			ATTCH25020001			ATTCH25020002			ATTCH25020003		
0	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
15	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
30	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
45	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
60	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
75	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
90	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes

**Conclusion:** The rapid total cholesterol test card remains stable at 0, 15, 30, 45, 60, 75, and 90 minutes after opening the pouch. It is determined that the shelf life of the product after opening is within 60 minutes after opening.

## 2.8 Accelerate Stability

### Method

Accelerated Stability of the Total Cholesterol Test Card (Whole Blood) was evaluated using samples from three different batches. These were placed in an incubator with the temperature calibrated at 45 °C and 55 °C, and relative humidity (RH) calibrated at 60%. A series of stability tests were performed at 0, 7, 14, 21, 28, 35, 42, 56 days. Tests were conducted using specimens of different concentrations. Testing at each specific time interval consisted of triplicates for each specimen. The tests were performed according to the package insert. Results are presented in tables below.

Arrhenius Formula:

$$\ln K = -E_a/RT + \ln A$$

“K” mean Rate constant

“A” mean Arrhenius constant

“E<sub>a</sub>” mean Activation energy

“R” mean Gas constant

“T” mean Temperature in Kelvin

Table: Time line for Accelerated Stability Study

Day Temp.	0day	7days	14 days	21 days	28 days	35 days	42 days	56 days
45 °C	√	√	√	√	√	√	√	√
55 °C	√	√	√	√	√	×	×	×

### Results:

Table: 45 °C Accelerated Stability Summary

Day	Specimen	Concentration range(mg/dL)	Is it within the range								
			ATTCH25020001			ATTCH25020002			ATTCH25020003		
0	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
7	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
14	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
21	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes

	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
28	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
		50mg/dL	0-99	yes							
35	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
		50mg/dL	0-99	yes							
42	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
		50mg/dL	0-99	yes							
56	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
		50mg/dL	0-99	yes							

Table: 55°C Accelerated Stability Summary

Day	Specimen	Concentration range(mg/dL)	Is it within the range								
			ATTCH25020001			ATTCH25020002			ATTCH25020003		
0	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
7	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
14	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
21	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes

28	50mg/dL	0-99	yes								
	125mg/dL	100-149	yes								
	175mg/dL	150-199	yes								
	225mg/dL	200-249	yes								
	275mg/dL	Above 250	yes								

**Conclusion:** The Total Cholesterol Test Card (Whole Blood) was stable at 45 °C for 56 days and at 55 °C for 28 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to be at least 18 months from the data of manufacture.

## 2.9 Real Time stability

### Method

A real time stability study of transfer lots will be run at the recommended storage temperatures to verify product stability over length of storage time. At the specified time points, five whole blood standards with concentrations of 50, 125, 175, 225 and 275mg/dl respectively were analyzed and tested using total cholesterol test cards in accordance with the quality control test procedure. Each test is repeated five times. The test results are compared with the color card and the results are read.

The following table lists the designated time points for conducting stability tests.

Table: Time line for Real Time Stability Study

Storage Temp	Day	Month						
	0	3	6	9	12	15	18	21
2~30°C	X	X	X	X	X	X	X	X

### Results:

Table: Real Time Stability Summary

Month	Specimen	Concentration range(mg/dL)	Is it within the range								
			ATTCH25020001			ATTCH25020002			ATTCH25020003		
0	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
3	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
6	50mg/dL	0-99	yes	yes	yes	yes	yes	yes	yes	yes	yes
	125mg/dL	100-149	yes	yes	yes	yes	yes	yes	yes	yes	yes
	175mg/dL	150-199	yes	yes	yes	yes	yes	yes	yes	yes	yes
	225mg/dL	200-249	yes	yes	yes	yes	yes	yes	yes	yes	yes
	275mg/dL	Above 250	yes	yes	yes	yes	yes	yes	yes	yes	yes
9	50mg/dL	0-99									
	125mg/dL	100-149									
	175mg/dL	150-199									

	225mg/dL	200-249									
	275mg/dL	Above 250									
12	50mg/dL	0-99									
	125mg/dL	100-149									
	175mg/dL	150-199									
	225mg/dL	200-249									
	275mg/dL	Above 250									
15	50mg/dL	0-99									
	125mg/dL	100-149									
	175mg/dL	150-199									
	225mg/dL	200-249									
	275mg/dL	Above 250									
18	50mg/dL	0-99									
	125mg/dL	100-149									
	175mg/dL	150-199									
	225mg/dL	200-249									
	275mg/dL	Above 250									
21	50mg/dL	0-99									
	125mg/dL	100-149									
	175mg/dL	150-199									
	225mg/dL	200-249									
	275mg/dL	Above 250									

**Conclusion:** The data results show that the total cholesterol test card (whole blood) can be stably stored for 6 months at 25°C, which can confirm that the shelf life of this product is at least 3 months from the production data.

## 2.10 Sample size test

### Methods:

Test the amount of sample (whole blood) required for the total cholesterol test card (whole blood). Five concentrations of whole blood standard samples were tested respectively. Each standard sample was added in three different volumes of 5µL, 10µL, and 15µL respectively. A batch of products was tested in three batches. The test was conducted in accordance with the packaging instructions. The results are listed in the table below.

### Results:

Table: Sample size test Results

lot	Specimen	Concentration range(mg/dL)	Is it within the range								
			Sample addition volume								
			5µL			10µL			15µL		
ATTCH25020001	50mg/dL	0-99	no	no	no	yes	yes	yes	no	no	no
	125mg/dL	100-149	no	no	no	yes	yes	yes	no	no	no
	175mg/dL	150-199	no	no	no	yes	yes	yes	no	no	no
	225mg/dL	200-249	no	no	no	yes	yes	yes	no	no	no
	275mg/dL	Above 250	no	no	no	yes	yes	yes	no	no	no

**Conclusion:** There are differences among the test results of the three sample dosages of 5 $\mu$ L, 10 $\mu$ L and 15 $\mu$ L. To reduce errors, 10 $\mu$ L is the best result.

### Document History Summary

Version No.	Date	Description	Remark
01	2025.08.20	New document	N/A



**Self test del colesterolo totale  
(Sangue intero)  
Foglioletto illustrativo**

REF OTCH-404H Italiano

Un test per la determinazione semiquantitativa del colesterolo totale nel sangue prelevato da un dito umano.

Solo per uso diagnostico *in vitro* e per autotest.

**【USO PREVISTO】**

La self test del colesterolo totale è destinata all'uso diagnostico *in vitro* per la determinazione semiquantitativa del colesterolo nel sangue prelevato da un dito umano. È adatta all'autodiagnosi.

**【RIEPILOGO】**

Il colesterolo è un lipide che svolge un ruolo importante nelle membrane cellulari, negli ormoni e nella vitamina D, ed è un fattore di rischio per le malattie cardiovascolari. Attraverso gli esami del sangue, possiamo conoscere il livello di colesterolo totale di una persona, in modo da poter gestire al meglio la nostra salute.

**【PRINCIPIO】**

Il campione analizzato viene aggiunto all'area di aggiunta del campione sulla scheda di prova e si infila in modo uniforme e rapido. Durante il processo di infiltrazione, le cellule del sangue vengono filtrate e il plasma si diffonde nella zona di reazione, dove si trovano enzimi e sostanze chimiche. Il prodotto reagisce e sviluppa un colore, che può essere confrontato con la scala cromatica, per il giudizio visivo.

**【REAGENTI】**

In base al peso secco al momento dell'impregnazione, le concentrazioni indicate possono variare entro le tolleranze di fabbricazione.

Reagente	Composizione
Colesterolo totale (TC)	Colesterolo esterasi > 0,3U
	Colesterolo ossidasi > 0,16U
	4-Aminoantipirina > 0,06 mg

**【PRECAUZIONI】**

- Solo per uso diagnostico *in vitro* autodiagnostico.
- La carta deve rimanere nella confezione chiusa fino al momento dell'utilizzo.
- Non utilizzare dopo la data di scadenza.
- Non toccare l'area campione della carta.
- Gettare via qualsiasi carta scolorita o danneggiata.
- La carta utilizzata deve essere smaltita secondo le normative locali dopo il test.

**【CONSERVAZIONE E STABILITÀ】**

Conservare nella confezione originale chiusa, a temperatura ambiente o in frigorifero (2-30 °C). Tenere al riparo dalla luce solare diretta. Le scheda sono stabili fino alla data di scadenza stampata sulla confezione. **NON CONGELARE.** Non utilizzare oltre la data di scadenza.

Nota: la stabilità potrebbe essere ridotta in condizioni di elevata umidità.

**【RACCOLTA E PREPARAZIONE DEI CAMPIONI】**

1. I campioni accettabili includono sangue intero capillare prelevato dal polpastrello.
2. I campioni di sangue intero devono essere analizzati subito dopo il prelievo.
3. Il campione dal polpastrello deve essere ottenuto da un flusso sanguigno spontaneo libero dopo la puntura.
4. **Non raccogliere il sangue capillare premendo o stringendo il dito troppo forte**, poiché ciò spingerebbe il fluido dai tessuti nel sangue e potrebbe causare falsi risultati.

**【MATERIALI】**

- Scheda di prova
- Contagocce
- Foglietto illustrativo
- Lancetta
- Tampone imbevuto di alcol

**Materiali richiesti ma non forniti**

- Timer

**【PROCEDURA DI TEST】**

Lavarsi le mani con il sapone e risciacquare con acqua tiepida pulita.

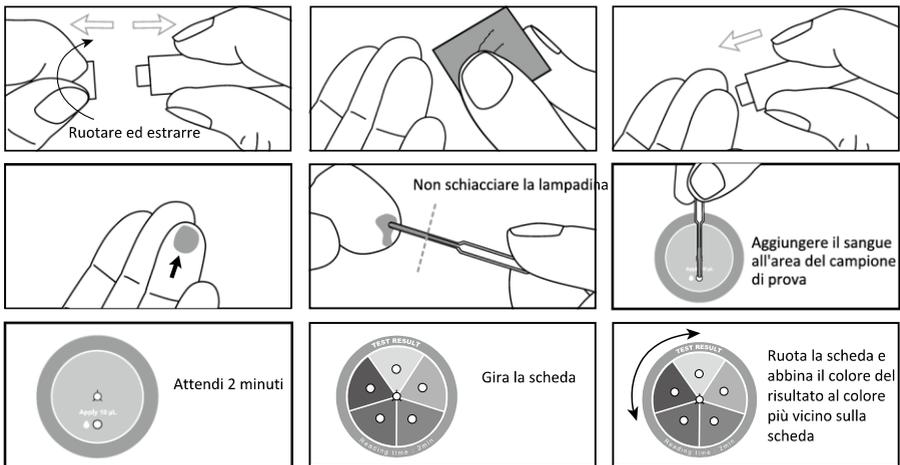
Portare la busta a temperatura ambiente prima di aprirla. Aprire la busta, estrarre la scheda di test e posizionarla su una superficie pulita e piana. Eseguire il test entro un'ora; i risultati migliori si otterranno se il test viene eseguito subito dopo l'apertura della busta di alluminio.

Rimuovere il contagocce, la lancetta e la compressa imbevuta di alcol e posizionarli vicino alla scheda di test.

1. Estrarre con cautela e gettare il cappuccio rilasciato della lancetta.
2. Utilizzare il tampone imbevuto di alcol in dotazione per pulire la punta del dito medio o anulare, come punto di puntura. Lasciare asciugare all'aria.
3. Premere la lancetta dal lato da cui è stato estratto il cappuccio; la punta si ritrae automaticamente e in modo sicuro dopo l'uso. Massaggiare la mano senza toccare il sito della puntura, massaggiando la mano verso la punta del dito medio o anulare da pungere.
4. Tenendo la mano rivolta verso il basso, massaggiare l'estremità punta per ottenere una goccia di sangue.
5. **Senza premere il contagocce**, metterlo a contatto con il sangue. Il sangue migra fino alla linea indicata sul contagocce capillare. Se il sangue non raggiunge la linea indicata, è possibile massaggiare nuovamente il dito per ottenere altro sangue. Evitare la formazione di bolle d'aria.
6. Rilasciare il sangue raccolto nell'area campione della scheda premendo il contagocce.
7. Attendere che il sangue sia completamente distribuito nel pozzetto e attendere 2 minuti prima di girare la scheda.

**NON girare la scheda prima che siano trascorsi 2 minuti.**

8. Girare la scheda dopo 2 minuti.
9. Leggi i risultati ruotando la carta e abbinando il colore più simile entro 30 secondi. Non leggere il risultato **dopo 2 minuti e 30 secondi** dall'applicazione del campione di sangue.



**【INTERPRETAZIONE DEI RISULTATI DEL TEST】**

Allineare		INTERPRETAZIONE
<b>Normale</b>	0-99 mg/dL(0-2,6 mmol/L) 100-149 mg/dL(2,6-3,9 mmol/L) 150-199 mg/dL(3,9-5,2 mmol/L)	Questi intervalli sono considerati ottimali per il colesterolo totale. Mantieni uno stile di vita sano per mantenere i tuoi livelli entro questo intervallo favorevole.
<b>Al limite dell'alto</b>	200-249 mg/dL(5,2-6,5 mmol/L)	Questo valore è classificato come borderline alto. Si consiglia di monitorare attentamente la propria dieta e l'attività fisica. Una valutazione completa del rischio dovrebbe includere la valutazione di altri indicatori lipidici nel sangue (come LDL-C, HDL-C e trigliceridi). Si raccomandano modifiche dello stile di vita e, in base al rischio complessivo, si può prendere in considerazione un intervento medico.
<b>Alto</b>	> 250 mg/dL(> 6,5 mmol/L)	Questo livello è considerato elevato ed è associato a un aumento del rischio cardiovascolare. Si raccomanda di consultare tempestivamente il proprio medico per una valutazione completa e per discutere le strategie terapeutiche più appropriate.

**【SOSTANZE INTERFERENTI】**

Non è stato osservato alcun effetto significativo alle seguenti concentrazioni per ciascuna sostanza.

Acido ascorbico: 3 mg/dL	Bilirubina 20 mg/dL	Creatinina: 30 mg/dL	Emoglobina: 400 mg/dL
Urea: 500 mg/dL	EDTA: 640 mg/dL	Eparina-Litio: 100 mg/dL	Ematocrito: tra il 30 e il 55% non ha alcun effetto sui risultati dei test.

**Indice dei simboli**

	Consultare le istruzioni per l'uso o consultare le istruzioni per l'uso elettroniche		Contiene sufficiente per <n> test		Limite di temperatura
	Dispositivo medico diagnostico <i>in vitro</i>		Codice batch		Catalogare numero
	Attenzione		Data di scadenza		Non riutilizzare
	Non utilizzare se la confezione è danneggiata e consultare le istruzioni per l'uso		Produttore		



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Numero: 14603513000  
Data di revisione: 2026-01-09



# Total Cholesterol Test Card (Whole Blood) Package Insert

REF OTCH-404H	English
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A test for the semi-quantitative determination of Total Cholesterol in human finger prick blood.  
For self-testing *in vitro* diagnostic use only.

**【INTENDED USE】**

The Total Cholesterol Test Card is intended for *in-vitro* diagnostic use for the semi-quantitative determination of cholesterol in human finger prick blood. It is suitable for self-testing use.

**【SUMMARY】**

Cholesterol is a lipid that is an important component of cell membranes, hormones, and vitamin D, and is a risk factor for cardiovascular disease. Through blood tests, we can know a person's total cholesterol level so that we can manage our health.

**【PRINCIPLE】**

The tested sample is added to the sample adding area of the test card, and it infiltrates evenly and rapidly. During the infiltration process, the blood cells are filtered, and the plasma diffuses to the reaction later and the enzymes and chemicals in the reaction layer. The product reacts and develops color, and compare with the color chart for eye reading judgment.

**【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-Aminoantipyrene >0.06mg

**【PRECAUTIONS】**

- For self-testing *in vitro* diagnostic use only.
- The card should remain in the closed packaging bag until use.
- Do not use after the expiration date.
- Do not touch the sample area of the card.
- Discard any discolored or damaged card.
- The used card should be discarded according to local regulations after testing.

**【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. Cards 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】**

1. Acceptable specimens include capillary whole blood from the fingertip.
2. Whole blood specimens should be tested immediately after lancing.
3. Fingertip sample must be obtained from a free spontaneous blood flow after the puncture.
4. **Do not collect capillary blood by pressing or squeezing the finger too hard** as this will push fluid from the tissue into the blood and may cause false results.

**【MATERIALS】**

- |             |           |  |               |
|-------------|-----------|--|---------------|
| • Test Card | • Dropper | <b>Materials Provided</b>                  |               |
|             |           | • Package Insert                           | • Lancet      |
|             |           | <b>Materials Required But Not Provided</b> |               |
|             |           |  | • Alcohol Pad |

- Timer

**【TEST PROCEDURE】**

Wash your hands with soap and rinse with clear warm water.

Bring the pouch to room temperature before opening it. Open the pouch, remove the test card and place it on a clean and level surface. Run the test within one hour and best results will be obtained if the test is performed immediately after opening the foil pouch.

Remove the dropper, lancet and alcohol pad, place them close to the test card.

1. Carefully pull off and dispose the released cap of the lancet.
2. Use the provided alcohol pad to clean the fingertip of the middle or ring finger as the puncture site. Allow to air dry.
3. Press the lancet, on the side from where the cap was extracted; the tip retracts automatically and safely after use. Massage the hand without touching the puncture site by massaging the hand towards the fingertip of the middle or ring finger to be punctured.
4. Keeping the hand down massage the end that was pricked to obtain a blood drop.
5. **Without squeezing the dropper bulb**, put it in contact with the blood. The blood migrates into the line indicated on the capillary dropper.

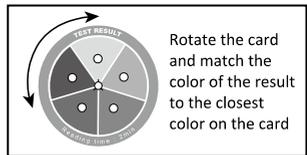
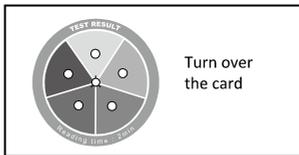
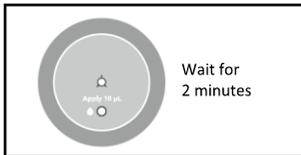
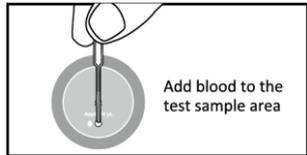
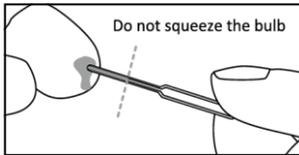
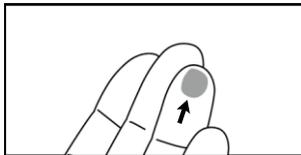
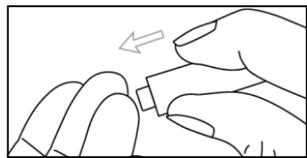
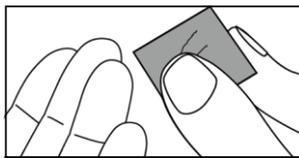
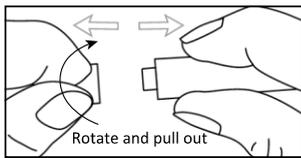
You may massage again your finger to obtain more blood if the blood does not reach the indicated line. Avoid of air bubbles.

6. Release the blood collected into the sample area of the card by squeezing the dropper bulb.
7. Wait for the blood to be totally dispensed in the well and wait 2 minutes before turning the test card over.

**DO NOT turn over the test card before 2 minutes.**

8. Turn over the test card after 2 minutes.
9. Read the results by rotating the card and matching the closest matching color within 30 seconds.

Do not read the result **after 2 minutes 30 seconds** of applying the blood sample.



### 【TEST RESULT INTERPRETATION】

Range		INTERPRETATION
<b>Normal</b>	0-99 mg/dL (0-2.6 mmol/L) 100-149 mg/dL (2.6-3.9 mmol/L) 150-199 mg/dL(3.9-5.2 mmol/L)	These ranges are considered optimal for total cholesterol. Maintain a healthy lifestyle to keep your levels within this favorable range.
<b>Borderline High</b>	200-249 mg/dL(5.2-6.5 mmol/L)	This is classified as borderline high. It is advisable to monitor your diet and physical activity closely. A comprehensive risk assessment should include evaluation of other blood lipid indicators (such as LDL-C, HDL-C, and triglycerides). Lifestyle modifications are recommended, and medical intervention may be considered based on overall risk.
<b>High</b>	>250 mg/dL(>6.5 mmol/L)	This level is considered high and is associated with increased cardiovascular risk. It is recommended to consult your healthcare provider promptly for a comprehensive evaluation and to discuss appropriate treatment strategies.

### 【INTERFERING SUBSTANCES】

No significant effect was observed at the following concentration for each substance.

Ascorbic acid: 3 mg/dL	Bilirubin 20 mg/dL	Creatinine: 30 mg/dL	Hemoglobin: 400 mg/dL
Urea: 500 mg/dL	EDTA: 640 mg/dL	Heparin-Lithium: 100 mg/dL	Hematocrit: Between 30~55% has no effect on test results.

### Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	In vitro diagnostic medical device		Batch code		Catalogue number
	Caution		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		



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# Gesamtcholesterin-Testkarte (Vollblut)

## Packungsbeilage

**REF OTCH-404H | Deutsch**

Ein Test für die semiquantitative Bestimmung des Gesamtcholesterins im menschlichen Fingerblut.

Nur zur Selbsttestung und In-vitro-Diagnostik.

### 【BEWAHRTLICHER VERWENDUNGSZWECK】

Die Gesamtcholesterin-Testkarte ist für *In-vitro-Tests* vorgesehen. diagnostische Anwendung zur semiquantitativen Bestimmung von Cholesterin im menschlichen Fingerblut. Es eignet sich für Selbsttests.

### 【ZUSAMMENFASSUNG】

Cholesterin ist ein Lipid und wichtiger Bestandteil von Zellmembranen, Hormonen und Vitamin D. Es stellt einen Risikofaktor für Herz-Kreislauf-Erkrankungen dar. Mithilfe von Bluttests lässt sich der Gesamtcholesterinspiegel bestimmen, um die Gesundheit zu schützen.

### 【PRINZIP】

Die zu testende Probe wird auf das Probenauftragsfeld der Testkarte aufgetragen und dringt gleichmäßig und schnell ein. Während des Infiltrationsprozesses werden die Blutzellen herausgefiltert, und das Plasma diffundiert später zu den Enzymen und Chemikalien in der Reaktionsschicht. Das Produkt reagiert und färbt sich; vergleichen Sie die Farbe mit der Farbskala. für die Beurteilung der Augenlesefähigkeit.

### 【REAGENZIEN】

Die angegebenen Konzentrationen können, basierend auf dem Trockengewicht zum Zeitpunkt der Imprägnierung, innerhalb der Fertigungstoleranzen variieren.

Reagens	Zusammensetzung
Gesamtcholesterin (TC)	Cholesterinesterase > 0,3 U
	Cholesterinoxidase > 0,16 U
	4-Aminoantipyrin > 0,06 mg

### 【VORSICHTSMASSNAHMEN】

- Nur zur Selbsttestung und *In-vitro*-Diagnostik.
- Die Karte sollte bis zur Verwendung im geschlossenen Verpackungsbeutel bleiben.
- Nach Ablauf des Verfallsdatums nicht mehr verwenden.
- Berühren Sie nicht den Probenbereich der Karte.
- Verfärbte oder beschädigte Karten bitte entsorgen.
- Die gebrauchte Karte sollte nach der Prüfung gemäß den örtlichen Vorschriften entsorgt werden.

### 【LAGERUNG UND STABILITÄT】

In der verschlossenen Verpackung bei Raumtemperatur oder gekühlt (2-30 °C) lagern. Vor direkter Sonneneinstrahlung schützen. Die Karten sind bis zum auf der Verpackung aufgedruckten Verfallsdatum haltbar. **Nicht einfrieren.** Nach Ablauf des Verfallsdatums nicht mehr verwenden.

Hinweis: Die Stabilität kann bei hoher Luftfeuchtigkeit beeinträchtigt sein.

### 【Probenentnahme und-vorbereitung】

1. Als Probenmaterial eignen sich kapillare Vollblutproben aus der Fingerbeere.
2. Vollblutproben sollten unmittelbar nach der Entnahme untersucht werden.
3. Die Blutprobe aus der Fingerbeere muss aus dem freien, spontanen Blutfluss nach der Punktion gewonnen werden.
4. **Kapillarblut sollte nicht durch zu starkes Drücken oder Quetschen des Fingers entnommen werden**, da dadurch Flüssigkeit aus dem Gewebe in das Blut gedrückt wird und falsche Ergebnisse entstehen können.

### 【MATERIALIEN】

- Testkarte
- Tropfer
- **Beigestellte Materialien**
- Packungsbeilage
- Lanzette
- Alkoholtupfer

**Benötigte, aber nicht bereitgestellte Materialien**

• Timer

### 【TESTVERFAHREN】

Waschen Sie Ihre Hände mit Seife und spülen Sie sie mit klarem, warmem Wasser ab.

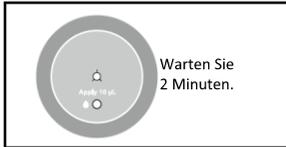
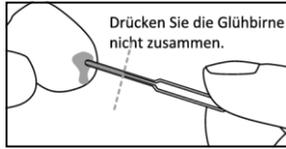
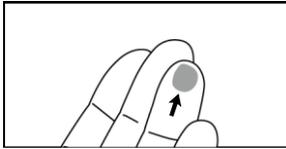
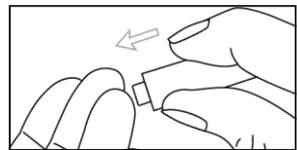
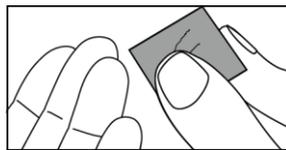
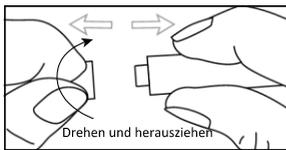
Den Beutel vor dem Öffnen auf Zimmertemperatur bringen. Beutel öffnen, Testkarte entnehmen und auf eine saubere, ebene Fläche legen. Den Test innerhalb einer Stunde durchführen. Die besten Ergebnisse erzielen Sie, wenn der Test unmittelbar nach dem Öffnen des Folienbeutels erfolgt.

Nehmen Sie die Pipette, die Lanzette und ein Alkoholtupfer heraus und legen Sie diese in die Nähe der Testkarte.

1. Die gelöste Schutzkappe der Lanzette vorsichtig abziehen und entsorgen.
2. Reinigen Sie die Fingerkuppe des Mittel- oder Ringfingers an der Einstichstelle mit dem beiliegenden Alkoholtupfer. Lassen Sie sie an der Luft trocknen.
3. Drücken Sie die Lanzette auf die Seite, von der die Kappe abgezogen wurde; die Spitze zieht sich nach Gebrauch automatisch und sicher zurück. Massieren Sie die Hand, ohne die Einstichstelle zu berühren, indem Sie die Hand in Richtung der Fingerspitze des zu punktierenden Mittel- oder Ringfingers massieren.
4. Während die Hand unten bleibt, massieren Sie das Ende, das angestochen wurde, um einen Blutstropfen zu gewinnen.
5. **Drücken Sie den Pipettenballon nicht zusammen** und bringen Sie ihn mit dem Blut in Kontakt. Das Blut fließt in die auf der Kapillarpipette markierte Linie.  
Sie können Ihren Finger erneut massieren, um mehr Blut zu gewinnen, falls das Blut die angegebene Linie nicht erreicht. Vermeiden Sie Luftblasen.
6. Geben Sie das gesammelte Blut in die Probe. Fläche der Karte durch Zusammendrücken des Pipettenballons.
7. Warten Sie, bis das Blut vollständig in die Vertiefung geflossen ist, und warten Sie 2 Minuten, bevor Sie die Testkarte umdrehen.

**Testkarte darf nicht vor Ablauf von 2 Minuten umgedreht werden.**

8. Testkarte nach 2 Minuten umdrehen.
9. Das Ergebnis lässt sich ablesen, indem man die Karte dreht und innerhalb von 30 Sekunden die am besten passende Farbe auswählt.  
Das Ergebnis sollte nicht **nach 2 Minuten und 30 Sekunden** nach dem Auftragen der Blutprobe abgelesen werden.



### 【INTERPRETATION DER TESTERGEBNISSE】

Reichweite		INTERPRETATION
<b>Normal</b>	0-99 mg/dL (0-2,6 mmol/L) 100-149 mg/dL (2,6-3,9 mmol/L) 150-199 mg/dL (3,9-5,2 mmol/L)	Diese Bereiche gelten als optimal für den Gesamtcholesterinspiegel. Pflegen Sie einen gesunden Lebensstil, um Ihre Werte in diesem günstigen Bereich zu halten.
<b>Grenzbereich hoch</b>	200-249 mg/dL (5,2-6,5 mmol/L)	Dies wird als grenzwertig hoch eingestuft. Es ist ratsam, Ihre Ernährung und körperliche Aktivität genau zu überwachen. Eine umfassende Risikobewertung sollte auch die Beurteilung anderer Blutfettindikatoren (wie LDL-C, HDL-C und Triglyceride) umfassen. Es werden Änderungen des Lebensstils empfohlen, und je nach Gesamtrisiko kann eine medizinische Intervention in Betracht gezogen werden.
<b>Hoch</b>	> 250 mg/dL (> 6,5 mmol/L)	Dieser Wert gilt als hoch und ist mit einem erhöhten kardiovaskulären Risiko verbunden. Es wird empfohlen, sich umgehend an Ihren Arzt zu wenden, um eine umfassende Untersuchung durchführen zu lassen und geeignete Behandlungsstrategien zu besprechen.

### 【STÖRSTOFFE】

Bei den folgenden Konzentrationen wurde für jede Substanz kein signifikanter Effekt beobachtet.

Ascorbinsäure: 3 mg/dL	Bilirubin 20 mg/dL	Kreatinin: 30 mg/dL	Hämoglobin: 400 mg/dL
Harnstoff: 500 mg/dL	EDTA: 640 mg/dL	Heparin-Lithium: 100 mg/dL	Hämatokrit: Ein Wert zwischen 30 und 55 % hat keinen Einfluss auf die Testergebnisse.

### Symbolverzeichnis

	Beachten Sie die Gebrauchsanweisung oder die elektronische Gebrauchsanweisung.		Enthält ausreichend für <n> Tests		Temperaturgrenze
	In-vitro-Diagnostikum		Batch-Code		Katalog Nummer
	Vorsicht		Mindesthaltbarkeitsdatum		Nicht wiederverwenden
	Nicht verwenden, wenn die Verpackung beschädigt ist. Gebrauchsanweisung beachten.		Hersteller		



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