pts panels®

Cholesterol

Test Strips

For professional use with CardioChek® brand analyzers

INTENDED USE

PTS Panels® cholesterol test strips are for the quantitative determination of total cholesterol in venous whole blood and capillary whole blood from the fingertip. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. This system is intended for professional use.

SUMMARY

Cholesterol is an important substance used by the body in the manufacture of certain hormones and in cell walls. Elevated cholesterol is a risk factor for coronary artery disease.

A MEMo Chip® is provided with each package of test strips and must be properly inserted into the analyzer before any test can be run. The MEMo Chip contains the test name, calibration curve, lot number and test strip expiration date. After the test strip is inserted into the analyzer and blood applied to the test strip, test results are displayed in as little as 45 seconds.

PRINCIPLES OF THE TEST

Cholesterol test results are based on a reading of light reflected off a test strip that has changed color after blood is applied. The deeper the color is, the higher the cholesterol level. The analyzer converts this reading into a cholesterol result and displays it. This procedure is based on the "Trinder Method" for the determination of total cholesterol.

Cholesterol

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{cholesterol esterase}} \text{Cholesterol} + \text{fatty acid}$$

$$\text{Cholesterol} + H_2O + O_2 \xrightarrow{\text{cholesterol oxidase}} \text{Cholesterol-4-en-3-one} + H_2O_2$$

$$2H_2O_2 + \text{4-AAP} + \text{Disubstituted Aniline} \xrightarrow{\text{peroxidase}} \text{Quinoneimine dye} + 4H_2O$$

MATERIALS PROVIDED

- PTS Panels cholesterol test strips
- MEMo Chip (contains lot-specific test strip information)
- Instructions for use

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek PA or CardioChek Plus professional analyzer
- Quality control materials
- Lancets for fingerstick (or venous blood collection supplies)
- Alcohol wipes and gauze
- Capillary blood collector or other precision pipet for blood collection and application

CHEMICAL COMPOSITION

Each cholesterol test strip contains the following active ingredients:

Cholesterol Esterase (Microorganism)	≥ 0.75 I.U.
Cholesterol Oxidase (Microorganism)	≥ 0.5 I.U.
4-aminoantipyrine	≥ 12 µg
Peroxidase (Horseradish)	≥ 1 I.U.
Substituted aniline derivatives	≥ 30 µg

Test strips are contained in a desiccated vial to control moisture. Molecular sieve is integrated into the vial.

STORAGE AND HANDLING

- Store test strip package in a cool, dry place at room temperature 68-86°F (20-30°C) or refrigerated at 35-46°F (2-8°C). Test strips must be brought to room temperature 68-86°F (20-30°C) before using. Do not freeze.
- Keep away from heat and direct sunlight.
- If a desiccant packet is included in the vial, do not remove or discard it.
- Always replace vial cap immediately after removing a test strip.
- Use test strip as soon as you have removed it from the vial.
- Keep the MEMo Chip in the original box that held the test strips.
- Store the test strips in the original vial. Do not combine with other test strips and do not store the MEMo Chip in the test strip vial.
- After opening, the test strips are stable until expiration date if vial is properly stored and always capped.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- PTS Panels cholesterol test strips can only be used in CardioChek brand analyzers.
- Make sure the MEMo Chip and test strip lot numbers match. Never use a MEMo Chip from a different lot than the test strip.
- Do not use if vial/cap is open or damaged.
- Out-of-date or expired test strips cannot be used in your test system. Check vial for expiration date before use.
- Add all of the blood to the test strip at one time. If you do not get all of the blood on the test strip, do not add additional blood to the same test strip. Test again with a new, unused test strip and a fresh blood sample.
- Discard test strip after using. Test strips are to be read once. Never insert or read a used test strip.
- If you get an unexpected result, test again.
- Do not ingest.
- Users should adhere to Standard Precautions when handling or using this device. All parts of the system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.
- The analyzer should be cleaned and disinfected after use on each patient. This test system may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.
- Please refer to the analyzer User Guide for cleaning and disinfection instructions. This procedure is important to prevent the potential transmission of infectious diseases.
- Only auto-disabling, single-use lancing devices may be used with this device

SPECIMEN COLLECTION AND PREPARATION

PTS Panels test strips are designed for use with fresh capillary (fingerstick) whole blood or fresh venous whole blood collected in EDTA or heparin tubes. To obtain a drop of blood from a fingerstick, follow the steps below:

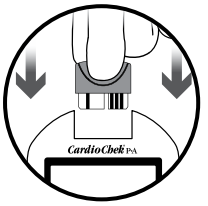
- **Use of lotions and handcreams should be avoided before testing.**
- Hands should be washed in warm water with antibacterial soap, rinsed and dried thoroughly.
- Clean the fingertip with alcohol. Be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, auto-disabling, single-use lancet to puncture the side of the fingertip.
- Wipe away the first drop of blood with a clean piece of gauze.
- Gently, without force, apply pressure to the fingertip to accumulate a drop of blood.
- Excessive squeezing of the finger may alter test results.
- See the "DIRECTIONS FOR USE - TESTING" section for information on how to apply the blood to the test strip.
- Discard used materials properly.

Caution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.

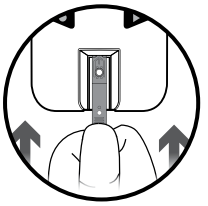
DIRECTIONS FOR USE - TESTING

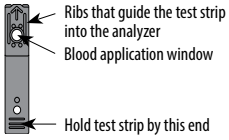
IMPORTANT: Read all instructions carefully before testing.

1. Insert the MEMo Chip that matches the lot number on the test strip vial and press one of the buttons to turn on the analyzer.

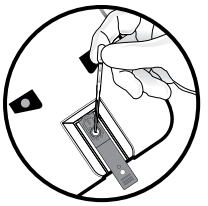


2. Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the test strip into the analyzer. Push the test strip in as far as it will go.*

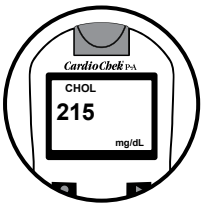




3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 15 µL of whole blood to the test strip blood application window.



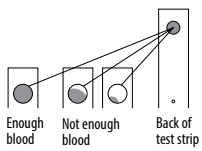
4. In as little as 45 seconds, the result will appear on the display. Remove and discard test strip. Do not add more blood to a test strip that has been used.



* As an alternative, the test strip may be inserted into the analyzer within 10 seconds AFTER blood is applied to the test strip, when blood is applied to the test strip directly from a finger. Touch a drop of blood hanging from the finger to the blood application window of the test strip. The blood drop must fill the entire window. Insert the test strip into the analyzer. In as little as 45 seconds, the result will appear on the display.

ADDITIONAL CONSIDERATIONS

- If no result is displayed, make sure:
  - Enough blood was added to the test strip to completely fill the blood application window.
  - Analyzer is on. (If it won't turn on, refer to analyzer user guide section on changing batteries.)
  - MEMo Chip is properly installed in port.
- If you get a reading of "LOW", "<___", "HIGH", ">___" or any unexpected result, **test again.**
- See analyzer user guide Troubleshooting section for additional help.
- To verify enough blood has been applied to the test strip, remove test strip after testing and check back side of reaction area. Reaction area should be completely and evenly colored. If the area is not completely and evenly colored, discard the used test strip and test again.



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TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL) or in millimoles per liter (mmol/L). The analyzer is preset to mg/dL, which is the appropriate unit in the United States and many other countries. Other countries use mmol/L. Select the units that are correct for your country. For instructions on how to change the units, please see the analyzer user guide. No calculation of results is necessary.

QUALITY CONTROL

Quality control tests are used to ensure that the total system (analyzer, test strips, MEMo Chip) is working properly. Users should run controls when results are questionable or to comply with their own facility's quality control requirements. See instructions for use provided with the quality control materials for information on how to run controls. The CardioChek PA and CardioChek Plus professional analyzers are factory calibrated before they are packaged. Use the gray check strip supplied with the analyzer to verify that the analyzer's electronics and optics are working properly. The check strip is NOT a quality control test.

CAUTION: If your quality control test result falls outside the control range shown on the control range card, DO NOT use the system to test blood. The system may not be working properly. If you cannot correct the problem, contact Customer Service for help.

EXPECTED VALUES

Blood cholesterol levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise.

The expected or reference ranges recommended are as follows from the US National Cholesterol Education Program (NCEP) 2001 Guidelines:[7]

Cholesterol (Total) Expected Values

- Below 200 mg/dL (5.18 mmol/L) – desirable
- 200-239 mg/dL (5.18-6.20 mmol/L) – borderline high
- 240 mg/dL (6.21 mmol/L) and above – high

A healthcare professional will discuss values that are specifically appropriate for each patient. At least two measurements of cholesterol on separate occasions should be made before a medical decision is made, since a single reading may not be representative of 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.

MEASURING RANGE

This test system will detect cholesterol levels from 100-400 mg/dL (2.59-10.36 mmol/L) and will display a number value for results in this range.
Results below this range will read, "LOW" or "<100 mg/dL (2.59 mmol/L)."
Results above this range will read, "HIGH" or ">400 mg/dL (10.36 mmol/L)."
IMPORTANT: If you get one of these results, or an unexpected result for any test, test again with a new unused test strip.

LIMITATIONS OF THE PROCEDURE

1. **PRESERVATIVES:** Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system. EDTA and Heparin do not interfere with the test.
2. **NEONATAL USE:** This product has not been tested using neonatal blood. This test system should not be used with these samples.
3. **METABOLITES:** Reducing substances such as Vitamin C may falsely decrease the test result.
4. **HEMATOCRIT:** Hematocrit values above 50% or lower than 30% may incorrectly lower the cholesterol result.
5. **BILIRUBIN AND HEMOGLOBIN:** Bilirubin up to 20 mg/dL and hemoglobin up to 200 mg/dL do not interfere.

PERFORMANCE CHARACTERISTICS

1. **ACCURACY:** A clinical study was performed by healthcare professionals who measured cholesterol levels on fresh capillary blood specimens from 125 persons. The results below show that the cholesterol test strips compare well to a reference cholesterol method that is correlated to the "Abell-Kendall Method." The performance of the cholesterol test strips have been determined by a network laboratory (Cholesterol Reference Method Laboratory Network) to meet both accuracy and precision requirements recommended by the NCEP. This certification is issued through the Centers for Disease Control.

   PTS Panels Cholesterol Test Strips vs. Reference Method

   Number of patients = 125 slope = 1.01
   y-intercept = -1.83 r = 0.91

   Two hundred three (203) persons stuck their own finger and tested their cholesterol. In these studies 4.4%, or 9 patients, obtained results that were incorrectly low (false negatives). About 23% of the patients obtained results that were incorrectly high (false positives).

2. **PRECISION:** Twenty replicates of various levels of whole blood were tested for cholesterol. The following results were obtained:

No. of Samples	20	20	20	20
Mean Cholesterol Conc. (mg/dL)	105	154	230	262
Std. Deviation (mg/dL)	2.54	3.72	6.61	7.67
Coefficient of Variation (%)	2.42	2.41	2.88	2.92

   This means that the variation between strips is less than 3%.

3. **INTERFERENCES:** See LIMITATIONS section.

CLIA INFORMATION (US ONLY)

Complexity Categorization: Waived

USA: RX ONLY

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1708	CardioChek PA professional analyzer
2700	CardioChek Plus professional analyzer
1711	PTS Panels cholesterol test strips – 25 tests
2863	PTS Collect™ capillary tubes, 15µL – 25 count
0721	PTS Panels multi-chemistry controls – Level 1 & Level 2

REFERENCES

1. Data on file, Polymer Technology Systems, Inc., Whitestown, IN 46075.
2. Clinical Diagnosis and Management by Laboratory Methods, Eighteenth Edition, John Bernard Henry, Editor,. W.B. Saunders Company, Philadelphia, 1991.
3. NCCLS Proposed Guideline EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
4. NCCLS Tentative Guideline EP7-T. Interference Testing in Clinical Chemistry. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
5. National Cholesterol Education Program. Report of expert panel on detection, evaluation, and treatment of high blood cholesterol in adults. National Heart, Lung and Blood Institute, NIH, Bethesda, MD, Arch. Int. Med., 148:36-69 (1988).
6. NCCLS. User evaluation of precision performance of clinical chemistry devices: tentative guidelines. 1984:2(1):1-48.EP5-T.
7. 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.

CUSTOMER SERVICE

For assistance with PTS Diagnostics products, please contact PTS Diagnostics Customer Service (M-F, 6 a.m. - 9 p.m. US EST) or your local authorized dealer.

1-877-870-5610 (Toll-free inside the USA)
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E-mail: customerservice@ptsdiagnostics.com

PTS Panels test strips are manufactured in the United States by Polymer Technology Systems, Inc., Whitestown, IN 46075.

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CE

EXPLANATION OF SYMBOLS

	Use by		Manufacturer
LOT	Batch code		Temperature limitation
IVD	*In vitro* diagnostic medical device		Keep away from sunlight
REF	Catalog number		Keep dry
	Consult instructions for use		Caution
CE	This product fulfills the requirements of European Directive 98/79/EC on *in vitro* diagnostic medical devices	Σ	Contains sufficient for <n> tests
		EC REP	Authorized representative in the European Community