pts panels®

CHOL+GLU

Test Strips

For professional use with CardioChek® PA and CardioChek® Plus analyzers

INTENDED USE

The CardioChek PA and CardioChek Plus test systems (consisting of the CardioChek PA and CardioChek Plus professional analyzers and PTS Panels® CHOL+GLU test strips) is for the quantitative determination of total cholesterol and glucose in venous whole blood and capillary whole blood from the fingertip and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for *in vitro* diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

SUMMARY

PTS Panels CHOL+GLU test strips measure total cholesterol and glucose in whole blood with the CardioChek PA or the CardioChek Plus professional analyzers, and provide a quantitative result. 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 90 seconds.

PRINCIPLES OF THE TEST

When blood is applied to a test strip, the blood reacts to produce color that is read by the analyzer using reflectance photometry. The amount of color produced is proportional to the concentration. The enzymatic reactions that occur are listed below:

Cholesterol

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

$$\text{Cholesterol} + H_2O + O_2 \xrightarrow{\text{cholesterol oxidase}} \text{Cholestenone} + H_2O_2$$

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

Glucose

$$\beta\text{-D-Glucose} + O_2 \xrightarrow{\text{glucose oxidase}} \text{D-Gluco-1,5-Lactone} + H_2O_2$$

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

MATERIALS PROVIDED

- PTS Panels CHOL+GLU 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/or gauze
- Capillary blood collectors or other precision pipet for blood collection and application

CHEMICAL COMPOSITION

Each CHOL+GLU test strip contains the following active ingredients:

Cholesterol Esterase (Microorganism)	≥ 0.6 I.U.
Cholesterol Oxidase (Microorganism)	≥ 0.4 I.U.
Peroxidase (Horseradish)	≥ 1 I.U.
4-aminoantipyrine	≥ 15 µg
Substituted aniline derivatives	≥ 20 µg
Glucose oxidase (Aspergillus niger)	≥ 0.2 I.U.
N, N-disubstituted aniline	≥ 15 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 68-82°F (20-28°C) or refrigerated at 35-46°F (2-8°C). Test strips must be brought to room temperature 68-82°F (20-28°C) before using. Do not freeze.
- Keep away from heat and direct sunlight.
- 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 CHOL+GLU test strips can only be used in CardioChek PA and CardioChek Plus professional 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.

Caution: This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

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:

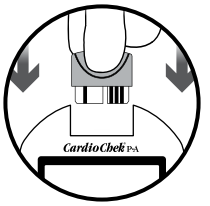
- **Use of lotions and handcreams should be avoided before testing.**
- Hands should be washed in warm water with antibacterial soap and rinsed and dried thoroughly.
- Clean the fingertip with alcohol. Be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, auto-disabling, 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 "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.

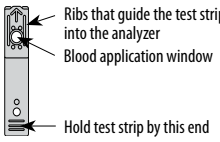
DIRECTIONS FOR USE - TESTING

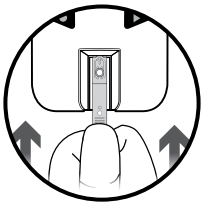
IMPORTANT: Read all instructions carefully before testing.

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

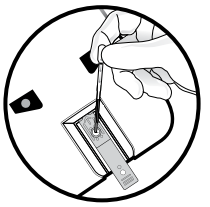


2. Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the test strip into analyzer. Push the test strip in as far as it will go.

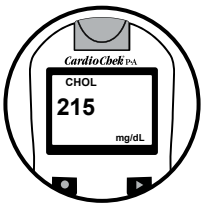




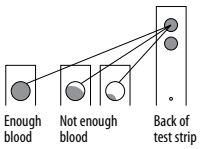
3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 25-30 µL of whole blood to the test strip blood application window.



4. In as little as 90 seconds, the result will appear on the display. As necessary, press Next to view aditional results. Remove and discard test strip. Do not add more blood to a test strip that has been used.



To verify that enough blood has been applied to the test strip, after testing is completed, remove test strip and check back of test strip. If areas are not completely and evenly colored, discard test strip and test again. See diagram.



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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 and that the test results are accurate and reliable within the limits of the system. 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

The expected or reference ranges recommended are from the US National Cholesterol Education Program (NCEP) 2001 Guidelines[9] and are:

Cholesterol (Total) Expected Values

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

The frequency of home cholesterol testing should be determined in consultation with your physician.

Glucose Expected Values

Blood glucose levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise. Your physician or healthcare professional will discuss "target values" (that is, highs and lows) specifically appropriate for you. A glucose level below 50 mg/dL (2.78 mmol/L) or above 240 mg/dL (13.32 mmol/L) may indicate a serious medical condition. If your test result should fall below 50 mg/dL (2.78 mmol/L) or exceed 240 mg/dL (13.32 mmol/L), you should contact your physician or healthcare professional as soon as possible. The expected fasting blood glucose value in a person without diabetes is ≤99 mg/dL (5.5 mmol/L) and the expected 2-hour postprandial blood glucose is ≤139 mg/dL (7.7 mmol/L).[6]

MEASURING RANGE

This test system will provide numeric results in the following ranges:

Cholesterol: 100-400 mg/dL (2.59-10.36 mmol/L)

Glucose: 20-600 mg/dL (1.11-33.3 mmol/L)

Results below these ranges will read, "LOW", "<100 mg/dL (2.59 mmol/L)" (cholesterol), or "<20 mg/dL (1.11 mmol/L)" (glucose).

Results above these ranges will read, "HIGH", ">400 mg/dL (10.36 mmol/L)" (cholesterol), or ">600 mg/dL (33.3 mmol/L)" (glucose).

IMPORTANT: If you get a result of one of these results, or an unexpected result for any test, test again with a new unused test strip.

LIMITATIONS OF THE PROCEDURE

Studies were performed to test for substances that may interfere with these tests. The results are below.

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** and **ARTERIAL BLOOD:** This product has not been tested using neonatal or arterial blood. This test system should not be used with these blood samples.
3. **METABOLITES:** Normal concentrations of Vitamin C did not effect the glucose results.
4. **HEMATOCRIT:** Hematocrit values above 55% and below 30% may incorrectly lower the glucose results. Hematocrits above 50% for lower than 30% may incorrectly lower the cholesterol results.
5. **BILIRUBIN AND HEMOGLOBIN:** Bilirubin up to 20 mg/dL and hemoglobin up to 200 mg/dL do not interfere.
6. **ALTITUDE:** Testing at altitudes up to 10,000 feet has no effect on glucose results.
7. **DEHYDRATION:** Severe dehydration and excessive water loss may produce falsely low glucose results.
8. The analyzer should not be used to test critically ill patients.
9. Blood samples from patients in shock, patients with severe dehydration, or patients in a hyperosmolar state (with or without ketosis) have not been tested. It is not recommended to test those samples with this system.
10. Not for use on patients who are severely hypotensive.

PERFORMANCE CHARACTERISTICS

1. **ACCURACY:**

Cholesterol

Results from clinical studies comparing the PTS Panels test strips to the Cholesterol Reference Method Laboratory Network (CRMLN) serum methods are listed below:

PTS Panels Cholesterol Test Strips vs. Abell-Kendall Traceable Method

n = 125 samples
range of samples tested: 125 to >400 mg/dL
y = 1.01x - 1.83 r = 0.91

PTS Panels Glucose Test Strips vs. Commercially Available Glucose System

Number of patients = 120 slope = 0.951
y-intercept = 5.36 r = 0.99

CHOL+GLU

The PTS Panels CHOL+GLU test strips were run by professionals using a CardioChek analyzer and the results were compared to results from PTS Panels single-analyte cholesterol and glucose test strips. The results were as follows:

Cholesterol Comparison

n = 112 samples
y = 0.895x + 21.4 r = 0.905
Bias at 200 mg/dL = +0.20%
Bias at 240 mg/dL = -1.58%

Glucose Comparison

n = 113 samples
y = 1.017x - 5.3 r = 0.986
Bias at 80 mg/dL = -4.93%
Bias at 126 mg/dL = -2.51%

The CHOL+GLU test strips compare well to the PTS Panels cholesterol and glucose test strips.

2. **PRECISION:** Laboratory professionals tested two levels of whole blood for cholesterol and glucose using CHOL+GLU test strips. The following results were obtained:

Cholesterol			
No. of Observations (n)	20	20	20
Mean Chol Conc. (mg/dL)	158.1	196.7	217.4
Std. Deviation (mg/dL)	9.1	11.7	8.1
Coefficient of Variation (%)	5.76	5.95	3.73
Glucose			
No. of Observations (n)	20	20	20
Mean Glu Conc. (mg/dL)	44.8	59.0	249.5
Std. Deviation (mg/dL)	3.9	3.2	8.2
Coefficient of Variation (%)	8.71	5.42	3.29

3. **INTERFERENCE:** 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
1765	PTS Panels CHOL+GLU test strips, 25 count
2865	PTS Collect™ capillary tubes, 30µL - 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.
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6. American Diabetes Association Standards of Medical Care in Diabetes - 2015. Diabetes Care 2015; 38 (Suppl. 1): S10.
7. Young, DL, et. Al., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Wash., D.C., 1990.
8. National Cholesterol Education Program 2001 Guidelines, National Institutes of Health, National Heart, Lung and Blood Institute, May, 2001.
9. ATP III NCEP Guidelines for CHD Risk. JAMA. 2001. 285:2486-2509.
10. Castelli, WP, et al. Circulation 1983. 67(4): 730-734.

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)
+1-317- 870-5610 (Direct)
+1-317-870-5608 (Fax)
E-mail: customerservice@ptsdiagnostics.com

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

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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