# pts panels®

## Lipid Panel

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 analyzers and PTS Panels® lipid panel test strips) are for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol, and triglycerides in venous whole blood and capillary whole blood from the fingertip and are 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. HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders. A TC/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek PA and CardioChek Plus analyzers.

### SUMMARY

PTS Panels lipid panel test strips measure total cholesterol, HDL cholesterol, and triglycerides in whole blood with the CardioChek PA or the CardioChek Plus professional analyzer, and provide a quantitative result. 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. 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**

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

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

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

**HDL Cholesterol**

$$\text{VLDL, LDL, HDL plasma} \longrightarrow \text{VLDL, LDL, depleted plasma}$$

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

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

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

**Triglycerides**

$$\text{Triglyceride} + 3H_2O \xrightarrow{\text{lipoprotein lipase}} \text{Glycerol} + \text{3 fatty acid}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow[Mg]{\text{glycerol kinase}} \text{Glycerol-3-PO}_4 + \text{ADP}$$

$$\text{Glycerol-3-PO}_4 + O_2 \xrightarrow{\text{glycerophosphate oxidase}} \text{Dihydroxyacetone-PO}_4 + H_2O_2$$

$$2H_2O_2 + \text{4-AAP} + \text{N, N-disubstituted aniline} \xrightarrow{\text{peroxidase}} \text{Quinoneimine dye} + 4H_2O$$

### MATERIALS PROVIDED

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

### MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek PA or CardioChek Plus professional analyzers
- 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 PTS Panels lipid panel test strip contains the following active ingredients:

| | |
|---|---|
| Cholesterol Esterase (Microorganism) | ≥ 1.75 I.U. |
| Cholesterol Oxidase (Microorganism) | ≥ 1 I.U. |
| Peroxidase (Horseradish) | ≥ 10 I.U. |
| 4-aminoantipyrine | ≥ 64 µg |
| Substituted aniline derivatives | ≥ 60 µg |
| Phosphotungstic acid | ≥ 0.3 mg |
| N, N-disubstituted aniline | ≥ 50 µg |
| Glycerol-3-Phosphate Oxidase (Microorganism) | ≥ 1.5 I.U. |
| Glycerol Kinase (Microorganism) | ≥ 2.0 I.U. |
| ATP (Microorganism) | ≥ 50 µg |
| Lipoprotein lipase (Microorganism) | ≥ 4.5 I.U. |

Test strips are contained in a desiccated vial to control moisture. Silica gel (not more than 5g) and molecular sieve are either in a desiccant packet or 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 lipid panel test strips can only be used in the CardioChek 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.
- Out-of-date or expired 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 strip, do not add 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 analyzer. 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 analyzer.

### SPECIMEN COLLECTION AND PREPARATION

PTS Panels lipid panel 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.
- If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, disposable 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.

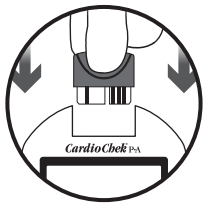
**Caution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.**

### DIRECTIONS FOR USE - TESTING

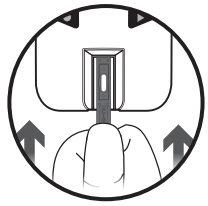
**IMPORTANT: Read all instructions carefully before testing.**

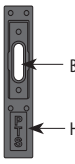
**For best results, test patient in a fasting state (no food or drink, except water, for at least 12 hours).**

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.

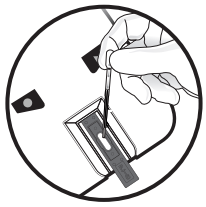



2. Hold the test strip by the end marked "PTS". Insert the opposite end of the test strip into analyzer. Push the test strip in as far as it will go.

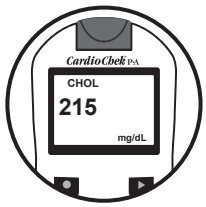




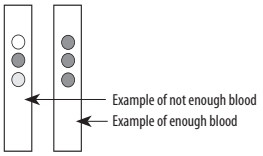

3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 35-40 µL of whole blood to the test strip blood application window.



4. In as little as 90 seconds, the results will appear on the display automatically on the analyzer. 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 and are:[9]

**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

**HDL Cholesterol Expected Values**

- Below 40 mg/dL (1.04 mmol/L) – low HDL (High risk for CHD*)
- 60 mg/dL (1.55 mmol/L) and above – high HDL (Low risk for CHD*)

*CHD - Coronary Heart Disease

**Triglycerides Expected Values**

- Below 150 mg/dL (1.70 mmol/L) – normal
- 150-199 mg/dL (1.70-2.25 mmol/L) – borderline high
- 200-499 mg/dL (2.26-5.64 mmol/L) – high
- 500 mg/dL and above (5.65 mmol/L) – very high

**LDL Cholesterol Expected Values**

- Below 100 mg/dL (2.59 mmol/L) – optimal
- 100-129 mg/dL (2.59- 3.35 mmol/L) – near optimal
- 130-159 mg/dL (3.36- 4.12 mmol/L) – borderline high
- 160-189 mg/dL (4.13- 4.90 mmol/L) – high
- 190 mg/dL and above (4.91 mmol/L) – very high

LDL can be calculated using the equation below.
Calculated LDL is an estimation of LDL and valid only if triglyceride level is 400 mg/dL or below.[10]
LDL (calculated) = cholesterol – HDL – (triglycerides/5)
A total cholesterol/HDL ratio (TC/HDL ratio) can also be calculated.[11]

## MEASURING RANGE

This test system will display numeric results in the following ranges:
**Cholesterol:** 100-400 mg/dL (2.59-10.36 mmol/L)
**HDL Cholesterol:** 20-120 mg/dL (0.52-3.11 mmol/L)
**Triglycerides:** 50-500 mg/dL (0.57-5.65 mmol/L)
Results below the range will read, "LOW" or "<100 mg/dL (2.59 mmol/L)" (cholesterol), "<20 mg/dL (0.52 mmol/L)" (HDL cholesterol), or "<50 mg/dL (0.57 mmol/L)" (triglycerides).
Results above this range will read, "HIGH" or ">400 mg/dL (10.36 mmol/L)" (cholesterol), ">120 mg/dL (3.11 mmol/L)" (HDL cholesterol), or ">500 mg/dL (5.65 mmol/L)" (triglycerides).
**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

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

1. **PRESERVATIVES:** EDTA and heparin in venous blood collection tubes had no effect on the results of the test strip.
2. **DRUGS:** Dopamine and methyldopa decreased the results of all the lipids.
3. **METABOLITES:** Extremely high doses of ascorbic acid (Vitamin C) decreased the results of all the lipids.
4. **HEMATOCRIT:** No hematocrit effect was observed for samples between 30 and 45% HCT.
5. **NEONATAL USE:** This product has not been tested using neonatal blood. This test system should not be used with these samples.
6. **HAND LOTIONS/COSMETICS:** Cosmetics such as handcreams or lotions often contain glycerol. Use of these products may cause inaccurate results.
7. Displayed results are rounded.

## PERFORMANCE CHARACTERISTICS

1. **ACCURACY:** Results from clinical studies comparing the PTS Panels professional 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 HDL Cholesterol Test Strips vs. Abell-Kendall Method run by a CRMLN Laboratory**
n = 87 samples
range of samples tested: <25 to 80 mg/dL
y = 1.10x -4.1 r = 0.89

**PTS Panels Triglycerides Test Strips vs. CRMLN Reference Method**
n = 111 samples
range of samples tested: 68 to 481 mg/dL
y = 0.97x +2.8 r = 0.97

The PTS Panels lipid panel test strips were run by professionals on a CardioChek Plus professional analyzer and the results were compared to results from PTS Panels single test strips. The results are listed by test as follows:

**Cholesterol Comparison**
n = 110 samples
range of samples tested: 134 to 315 mg/dL
y = 0.94x +14.5 r = 0.92

**Triglycerides Comparison**
n = 105 samples
range of samples tested: 62 to 464 mg/dL
y = 0.97x -6.0 r = 0.98

The PTS Panels lipid panel test strips compare well to the single-analyte PTS Panels cholesterol, HDL cholesterol, and triglycerides professional test strips.

**HDL Cholesterol Comparison**
(Extended HDL cholesterol range): Results of an accuracy study comparing whole blood HDL cholesterol on PTS Panels lipid panel test strips on the CardioChek PA and the CardioChek Plus analyzers to the Roche Cobas Integra 400 plus HDL Cholesterol (reference) are summarized below. The lipid panel HDL cholesterol compares well to the reference.

**PTS Panels Lipid Panel HDL cholesterol vs. Reference**

| CardioChek PA | CardioChek Plus |
|---|---|
| n = 80 samples | n = 80 samples |
| y = 0.93x +0.98 | y = 0.99x +0.55 |
| r = 0.98 | r = 0.98 |

Range of samples tested: 21 to 112 mg/dL HDL cholesterol.

2. **PRECISION:** Laboratory professionals tested two levels of whole blood for cholesterol, HDL cholesterol, and triglycerides using PTS Panels lipid panel test strips. The following results were obtained:

**Cholesterol**

| | | |
|---|---|---|
| No. of Observations (n) | 20 | 20 |
| Mean Chol Conc. (mg/dL) | 197.2 | 251.3 |
| Std. Deviation (mg/dL) | 8.4 | 10.0 |
| Coefficient of Variation (%) | 4.3 | 4.0 |

**Triglycerides**

| | | |
|---|---|---|
| No. of Observations (n) | 20 | 20 |
| Mean Trig Conc. (mg/dL) | 157.0 | 284.0 |
| Std. Deviation (mg/dL) | 6.1 | 16.8 |
| Coefficient of Variation (%) | 3.9 | 5.9 |

**HDL Cholesterol** (Multiple operators, analyzers, time periods)
Using a lot of lipid panel test strips with an extended HDL dynamic range, three operators tested three levels of whole blood samples on five analyzers (both CardioChek PA and CardioChek Plus) for HDL cholesterol over three time periods with the results that follow.

| **CardioChek PA** | **HDL Level 1** | **HDL Level 2** | **HDL Level 3** |
|---|---|---|---|
| No. of Observations (n) | 80 | 80 | 80 |
| Mean HDL Conc. (mg/dL) | 38.3 | 62.4 | 106.0 |
| Std. Deviation (mg/dL) | 1.65 | 2.26 | 4.2 |
| Coefficient of Variation (%) | 4.3 | 3.6 | 4.0 |
| **CardioChek Plus** | **HDL Level 1** | **HDL Level 2** | **HDL Level 3** |
| No. of Observations (n) | 80 | 80 | 78 |
| Mean HDL Conc. (mg/dL) | 39.5 | 63.3 | 108.3 |
| Std. Deviation (mg/dL) | 1.63 | 2.66 | 5.24 |
| Coefficient of Variation (%) | 4.1 | 4.2 | 4.8 |

3. **INTERFERENCE:** See Limitations Section.

## AVAILABILITY

| REF/CAT NO. | DESCRIPTION |
|---|---|
| 1708 | CardioChek PA professional analyzer |
| 2700 | CardioChek Plus professional analyzer |
| 1710 | PTS Panels lipid panel test strips – 15 count |
| 2866 | PTS Collect™ capillary tubes, 40µL – 16 count |
| 0721 | PTS Panels multi-chemistry controls – Level 1 & Level 2 |
| 0722 | PTS Panels HDL cholesterol controls – Level 1 & Level 2 |

## REFERENCES


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10. Friedewald et al. Clin Chem. 1972. 18(6):499-502.
11. Castelli, WP, et al. Circulation 1983. 67(4): 730-734.


## CUSTOMER SERVICE

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


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PTS Panels test strips are manufactured in the United States by Polymer Technology Systems, Inc., Indianapolis, IN 46268 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. | | Contains sufficient for <n> tests |
| | | EC REP | Authorized representative in the European Community |