PS-002575 E Rev. 5 07/14

PTS PANELS Lipid Panel Test Strips

for use with CardioChek® P•A and CardioChek Plus Analyzers

INTENDED USE

PTS PANELS Lipid Panel Test Strips measure total cholesterol, HDL cholesterol and triglycerides in whole blood. Lipid measurements are used in the diagnosis and treatment of lipoprotein metabolism and lipid disorders (such as diabetes mellitus), atherosclerosis, and various renal and liver diseases.

SUMMARY

Lipid Panel Test Strips measure total cholesterol, HDL cholesterol and triglycerides in whole blood with the CardioChek P•A or CardioChek Plus analyzers. 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 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 strip, test results are displayed in about two minutes.

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

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

$$\text{Glycerol} + ATP \xrightarrow[Mg]{\text{glycerol kinase}} \text{Glycerol - 3-}PO_4 + ADP$$

$$\text{Glycerol - 3-}PO_4 + O_2 \xrightarrow{\text{glycerophosphate oxidase}} \text{Dihydroxyacetone - }PO_4 + H_2O_2$$

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

MATERIALS PROVIDED

- Vial of test strips and desiccant
- MEMo Chip (contains lot-specific test strip information)
- Instructions

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek P•A or CardioChek Plus analyzer
- Quality Control Materials
- Lancets for fingerstick (or venous blood collection supplies)
- Alcohol wipes and/or gauze
- Capillary Blood Collector or other precision pipet for blood collection and application

CHEMICAL COMPOSITION

Each 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.

Each vial contains not more than 5g silica gel desiccant.

STORAGE AND HANDLING

- Store test strip package in a cool, dry place at room temperature of 68-86°F (20-30°C). Strips may be stored in a refrigerator at 35-46°F (2-8°C), but must be brought to room temperature before using. Do not freeze.
- Keep away from heat and direct sunlight.
- Do not remove or discard the desiccant packet in the vial.
- 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 either in the analyzer or stored with the original lot of strips.
- Store the test strips in the original vial. Do not combine with other 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.

PRECAUTIONS

- For *in vitro* diagnostic use.
- Lipid Panel Test Strips can only be used in the CardioChek P•A or CardioChek Plus 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.
- 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 strip. Test again with a new unused test strip and fresh blood sample.
- Discard test strip after using. Strips are to be read once. Never insert or read a used test strip.
- **Do not ingest.**

SPECIMEN COLLECTION AND PREPARATION

PTS PANELS Test Strips are designed for use with fresh capillary (fingerstick) whole blood. Fresh venous whole blood collected in EDTA or heparin tubes is also an acceptable sample. To obtain a drop of blood from a fingerstick, follow the steps listed 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.
- 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 "TESTING" section for information on how to apply the blood to the test strip.
- Discard used materials properly.

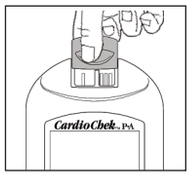
Caution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.

TESTING

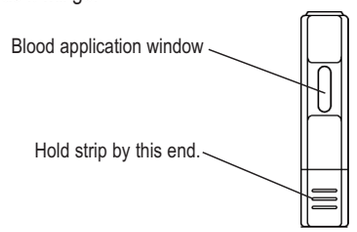
IMPORTANT: Read all instructions carefully before testing.

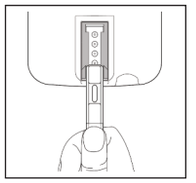
Test patient in a fasting state*.

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.

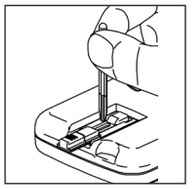


2. Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the strip into analyzer. Push the strip in as far as it will go.





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.

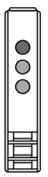


4. In about two minutes, the result will appear on the display. (To display additional results, press the (NEXT) button.) Remove and discard strip. DO NOT add more blood to a test strip that has been used.

*For best results (Fasting State - No food or drink, only water, for at least 12 hours.)

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

Example of not enough blood



Example of enough blood

TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL) or in millimoles per liter (mmol/L). The mg/dL measurement is a US version, while mmol/L is used in many countries around the world. The CardioChek P•A and CardioChek Plus are preset to US units by the manufacturer. No calculation of results is necessary. To change to INTL (mmol/L) units, please see CardioChek P•A or CardioChek Plus User Guide.

Manufactured by
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CALIBRATION AND QUALITY CONTROL
Quality Control tests are used to ensure that the total system (analyzer, 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 the CardioChek P•A or CardioChek Plus User Guide for instructions on how to run controls.
The CardioChek P•A and CardioChek Plus are factory calibrated before they are packaged. Use the Check Strip supplied to verify that the analyzer's electronics and optics are working properly. The Check Strip is NOT a Quality Control test. Please refer to the CardioChek P•A or CardioChek Plus User Guide for the proper procedure to be used to perform a Quality Control test.

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]

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.

Additional Considerations:
1. NEONATAL USE: There has been no data generated to validate the use of this system with neonatal blood specimens. Until such data become available, this test system should not be used on neonatal samples.
2. Cosmetics such as handcreams or lotions often contain glycerol. Use of these products may cause inaccurate results.
3. Displayed results are rounded.

MEASURING RANGE
Lipid Panel Test Strips will display numeric results in the following ranges:
Cholesterol: 100-400 mg/dL (2.59- 10.36 mmol/L)
HDL Cholesterol: 15-100 mg/dL (0.39- 2.59 mmol/L)
Triglycerides: 50-500 mg/dL (0.57- 5.65 mmol/L)
Results below the range will read, "LOW" or "<___" (less than the measuring range). Results above this range will read, "HIGH" or ">___" (greater than the measuring range).
IMPORTANT: If you get a result of "LOW", "<___" (less than), "HIGH", ">___" (greater than) or an unexpected result for any test, test again with a new unused test strip.

PERFORMANCE CHARACTERISTICS
1. ACCURACY: 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** 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** 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** 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 Lipid Panel Test Strips were run by professionals on a CardioChek P•A 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
   HDL Cholesterol Comparison
   n = 109 samples
   range of samples tested: 30 to 83 mg/dL
   y = 0.92x +15.4
   r = 0.94
   Triglycerides Comparison
   n = 105 samples
   range of samples tested: 62 to 464 mg/dL
   y = 0.97x -6.0
   r = 0.98

   The Lipid Panel Test Strips compare well to the PTS PANELS Cholesterol, HDL Cholesterol and Triglycerides Test Strips.
2. PRECISION: Laboratory professionals tested two levels of whole blood for cholesterol, HDL cholesterol and triglycerides using 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
HDL Cholesterol		
No. of Observations (n)	20	20
Mean HDL Conc. (mg/dL)	39.2	61.5
Std. Deviation (mg/dL)	2.5	2.8
Coefficient of Variation (%)	6.4	4.6
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

3. INTERFERENCE: See Limitations Section.

CLIA INFORMATION (US only)
Complexity Categorization: Waived

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1708	CardioChek P•A Analyzer
2700	CardioChek Plus Analyzer
1710	Lipid Panel Test Strips, 15 count
0739	Capillary Blood Collector (Pipet) Kit-40 µL, 16 count
0721	PTS PANELS Multi-Chemistry Controls – Level 1 & Level 2
0722	PTS PANELS HDL Cholesterol Controls – Level 1 & Level 2

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11. Castelli, WP, et al. Circulation 1983. 67(4): 730-734.

CUSTOMER SERVICE
PTS Customer Service is available to answer questions. Outside Customer Service hours, please contact your healthcare professional.

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The CardioChek P•A, CardioChek Plus, and PTS PANELS Lipid Panel Test Strips are manufactured in the US by Polymer Technology Systems, Inc., Indianapolis, IN 46268.

CE 0197

AUTHORIZED EUROPEAN REPRESENTATIVE
per IVDD 98/79/EC
MDSS GmbH
30175 Hannover
Germany

Explanation of Symbols

	Use By/ Expiration date	REF	Catalog number
			Consult instructions for use
LOT	Batch Code/ Lot number		
IVD	For in vitro diagnostic use		Manufacturer
CE 0197	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.		Store at/Temperature limitation