Procedure: CardioChek® PA Test System/ PTS Panels® Lipid Panel Test Strips

Approved

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I. Purpose

PTS Panels® lipid panel test strips measure total cholesterol, HDL 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. Lipid measurements are used in the diagnosis and treatment of lipoprotein metabolism and lipid disorders, atherosclerosis, and various renal and liver diseases.

The CardioChek® PA analyzer is intended for *in vitro* diagnostic use, using whole blood samples. This Point-of-Care (POC) test system is designed for professional use. This analyzer is a component of a test system that includes PTS Panels test strips.

II. Principle

The CardioChek PA test system consists of three main parts, including the analyzer, the PTS Panels test strips, and the MEMo Chip®.

A. The CardioChek PA Test System

The analyzer employs light reflectance to measure an end-point enzymatic chemical reaction. The test strips are impregnated with enzymes which are specific for the analyte to be measured. When blood is applied to the test strip, a sequence of chemical reactions occurs which results in a color change on the test strip. The intensity of this colorimetric reaction is measured by light reflectance and is directly proportional to the amount of analyte in the blood. Using a stored standard calibration curve, the analyzer calculates and displays the result on the screen.

B. PTS Panels Test Strips

Test strips are designed for specific analytes. A test strip is inserted into the analyzer and blood is then applied to the blood application window. The ensuing chemical reaction produces a color change, which the analyzer measures and compares to the calibration curve stored in the MEMo Chip. The analyzer converts this color reading into a test result displayed on the screen. Each PTS Panels test strip box contains a package insert that provides instructions for use and information specific for each test.

C. MEMo Chip

Each package of PTS Panels test strips contains a color-coded MEMo Chip. The color-coded MEMo Chip contains the settings for each test. The top of the MEMo Chip has a finger notch. The bottom has a label with the test name and lot number. Always make sure you insert the MEMo Chip into the port with the finger notch facing up. The MEMo Chip reads the test strip expiration date, tells the analyzer which test(s) to run, contains the calibration curve and the lot number for the specific test strip lot, controls test sequences and timing,

and establishes the measuring range for the test. The MEMo Chip contains proper settings for the test strip lot you are using.

Guidelines for Using the MEMo Chip®:

- The MEMo Chip must be in place to run a test.
- Use only the MEMo Chip that is included with each package of test strips. The lot number code on the test strip vial, MEMo Chip, and analyzer display must match.
- If the expiration date in the MEMo Chip has passed, the analyzer will display EXPIRED LOT.
- If your MEMo Chip is lost or missing, please call PTS, Inc. Customer Service for a replacement.

The MEMo Chip port is located at the top center of the analyzer. The MEMo Chip is inserted into this port with the finger notch facing up. Push firmly, but gently, until the MEMo Chip is fully inserted.

III. Specimen Collection

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. For best results, samples should be obtained from patients in a fasting state (no food or drink, except water, for at least 12 hours).

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

A. Fingerstick (Capillary) Whole Blood Samples

1. Warm the fingers to increase blood flow.
2. Let the arm hang down at the person's side briefly to allow blood flow to the finger tips.
3. Hands should be washed in warm water with soap, rinsed and dried thoroughly. If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
4. Use a new sterile, disposable lancet to puncture the side of the fingertip.
5. Wipe away the first drop of blood with a clean piece of gauze.
6. Use the second blood drop to begin the capillary tube collection of 40µL of blood to dose the Lipid Panel test strip. Gently, without force, apply pressure to the fingertip to accumulate a drop of blood. Touch the tip of the capillary blood collector or calibrated pipette to the drop. Allow the horizontal fill of the capillary tube without the introduction of bubbles or air spaces.

7. In order to prevent air bubbles or gaps, hold the capillary tube at a slight upward angle and draw the blood to the first black line.
8. See section VI to perform the test.

B. Venous Whole Blood Samples

1. Collect the venous sample in a green top (Lithium heparin) tube or lavender top (EDTA) tube.
2. Gently mix the tube by inversion 10 times.
3. Carefully open the tube and remove a 40µL sample using either a capillary blood collector or calibrated pipette.
4. See section VI to perform the test.

C. Limitations and Interfering Substances:

1. Studies were performed to test for substances that may interfere with these tests. The results are below.
    a. PRESERVATIVES: EDTA and heparin in venous blood collection tubes had no effect on the results of the test strip.
    b. DRUGS: Dopamine and methyldopa decreased the results of all the lipids.
    c. METABOLITES: Extremely high doses of ascorbic acid (Vitamin C) decreased the results of all the lipids.
    d. HEMATOCRIT: No hematocrit effect was observed for samples between 30 and 45% HCT.
    e. NEONATAL USE: This product has not been tested using neonatal blood. This test system should not be used with these samples.
    f. HAND LOTIONS/COSMETICS: Cosmetics such as handcreams or lotions often contain glycerol. Use of these products may cause inaccurate results.
2. Displayed results are rounded.

IV. Equipment/Materials/Reagents

The PTS Panels® lipid panel test strip is a self-contained disposable test strip preloaded with the reagents necessary to measure total cholesterol, HDL cholesterol, and triglycerides. Calculated LDL results are available for samples with total cholesterol, HDL cholesterol, and triglycerides within the measuring range of the analyzer. For individuals with triglycerides levels above 400 mg/dL, LDL will not be displayed on the analyzer.

A. Equipment:

1. CardioChek® PA analyzer

B. Materials:

1. Vial of PTS Panels lipid panel test strips
2. MEMo Chip® (contains lot-specific test strip information)
3. Lancets for fingerstick (or venous blood collection supplies)
4. Gauze
5. Capillary blood collector or other capillary pipette
6. Biohazard disposal receptacle

C. Reagent Preparation:

There is no preparation required for PTS Panels lipid panel test strips.

D. Storage and Handling Requirements:

1. The optimal storage conditions for a test strip package are in a cool, dry place at room temperature of 68-86°F (20-30°C). Test 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.
2. Keep away from heat and direct sunlight.
3. If a desiccant packet is included in the vial, do not remove or discard it.
4. Always replace vial cap immediately after removing a test strip.
5. Use test strip as soon as you have removed it from the vial.
6. Keep the MEMo Chip in the original box that held the test strips and do not store the MEMo Chip in the test strip vial.
7. Store the test strips in the original vial. Do not combine with other test strips.
8. After opening, the test strips are stable until expiration date if vial is properly stored and always capped.

V. System Checks

Several 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 these tests whenever a new lot of PTS Panels test strips are received, with each new lot number, when there are unexpected results, and to comply with their state or facility's requirements.

A. Use of the Check Strip

The gray check strips (included in the analyzer carrying case) verify that the CardioChek PA analyzer's electronic and optical systems are functioning properly. Each check strip is calibrated to read a specific reflectance. The check strip does not replace liquid QC. It is recommended that the check strip verification be performed:

1. Daily
2. If the analyzer has been dropped
3. If there are unexpected patient or QC results

How to Use the Check Strip:

1. With the MEMo Chip out, turn the analyzer on by pressing either button.
2. When INSTALL MEMO CHIP is displayed, press Next until UTILITY is displayed. Press Enter.
3. When CHECK STRIP is displayed, press Enter.
4. When INSERT STRIP is displayed, insert the check strip with the ribbed side up.
5. Record the result (PASSED or FAILED). Remove the check strip and store it in the analyzer carrying case.
6. Press Next until EXIT is displayed. Press Enter.

Expected Results:

All results for the check strip should be PASSED. If test result is FAILED, clean the CardioChek PA analyzer reflectance test strip slot (Section IX) and retest. If the results remain outside the specified range, contact PTS, Inc. Customer Service at: +1-877-870-5610 (toll-free inside the U.S. and Canada) or +1-317-870-5610.

B. Quality Control of the PTS Panels® Lipid Panel Test Strips

Quality Control tests are used to ensure that the system (analyzer, test strips, and MEMo Chip) is working properly. Controls should be run with each new lot of test strips, each new shipment, and according to state and federal regulations as they apply to each state. Users should also run controls when results are questionable and in compliance with their facility's Quality Control policies.

Quality Control of the PTS Panels lipid panel test strips requires the use of both the PTS Panels multi-chemistry controls (for total cholesterol and triglycerides) and the PTS Panels HDL cholesterol controls (for HDL cholesterol).

How to Use PTS Panels Multi-Chemistry or HDL Cholesterol Controls:

1. With the MEMo Chip out, press any button to turn the CardioChek PA analyzer on. Press Next until the display reads UTILITY. Press Enter.
2. Press Next until the display reads RUN CONTROL. Press Enter.
3. INSERT MEMO CHIP appears on the screen. Insert the MEMo Chip for the matching lot of lipid panel test strips to be checked and press ENTER.
4. RUN CONTROL appears on the screen. Press ENTER. Perform a 3-point check to verify the lot number on the MEMo Chip, the vial of test strips, and the screen display match.
5. Insert the test strip into the analyzer. Immediately replace the vial cap, making sure the test strip vial is closed tightly. The CardioChek PA analyzer will display APPLY SAMPLE. This indicates the system is ready for a sample (control) to be applied.
6. Mix the control material well by gentle inversion.
7. Remove control vial cap and turn bottle upside down directly above test strip sample application window.
8. Carefully squeeze vial to deliver two hanging drops of control solution to the test strip and allow the drops to fall onto the center of the blood application window.
9. Replace control vial cap.
10. Results will be displayed in about two (2) minutes.

Expected Results:

All results for the controls should be in the ranges specified on the Quality Control Range Card. If test results are outside the specified range:

1. Check the expiration dates of the test strips and controls. If expired, retest with unexpired strips and controls.
2. If not expired, check that the MEMo Chip® matches the test strip lot.
3. Clean the CardioChek® PA analyzer test strip insert slot (Section IX) and retest.

If the results remain outside the specified range, contact PTS, Inc. Customer Service at: +1-877-870-5610 (toll-free inside the U.S. and Canada) or +1-317-870-5610.

VI. Step-by-Step Procedure to Run PTS Panels® Lipid Panel Tests

PTS Panels test strips are designed for use with fresh capillary (fingerstick) whole blood, or venous whole blood collected in EDTA or heparin tubes (See Section III).

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

1. Insert correct MEMo Chip for the lot of test strips in use with finger notch (top) side up, lot number code facing down.
2. Turn CardioChek PA analyzer on by pressing either button.
3. A short series of auto-checks will appear and a lot number will appear on the screen. Perform a 3-point check to ensure the lot number displayed on the screen matches the lot number of the vial of strips and the MEMo Chip inserted into the analyzer.
4. When INSERT STRIP is displayed, insert the test strip into the analyzer. Immediately replace the vial cap, making sure the test strip vial is capped tightly. The CardioChek PA analyzer will display APPLY SAMPLE with a blood drop icon over the lipid panel test strip. This indicates the system is ready for a sample to be applied to the lipid panel test strip.
5. Obtain a fingerstick blood sample (Section III). Wipe away the first drop of blood and use the second drop to begin the capillary tube collection of 40µL of blood.
6. Use the capillary tube or plastic blood collector to apply the entire 40µL sample of whole blood to the test strip blood application window while hovering. NOTE: Do NOT place the tip of the capillary tube on the testing area.
7. The results will be displayed in about two (2) minutes. Press the Next button to display each analyte of the test panel.
8. Remove test strip and discard.

The analyzer automatically shuts down after three minutes of idle time.

VII. Expected Results

Total Cholesterol[12] Expected Values:

	mg/dL	mmol/L
Lower risk	< 200	< 5.18
Borderline risk	200 – 239	5.18 – 6.20
Higher risk	≥ 240	≥ 6.21

HDL Cholesterol[12] Expected Values:

	mg/dL	mmol/L
At Risk (male)	< 40	< 1.04
At Risk (female)	< 50	< 1.29
Borderline to near optimal	40 – 59	1.04 – 1.54
Optimal	≥ 60	≥ 1.55

Triglycerides[12] Expected Values:

	mg/dL	mmol/L
Normal	< 150	< 1.70
Borderline high	155 – 199	1.70 – 2.25
High	200 – 499	2.26 – 5.64
Very high	≥ 500	≥ 5.65

LDL Cholesterol[12] Expected Values:

	mg/dL	mmol/L
Optimal	< 100	< 2.59
Near optimal	100 – 129	2.59 – 3.35
Borderline high	130 – 159	3.36 – 4.12
High	160 – 189	4.13 – 4.90
Very high	≥ 190	≥ 4.91

LDL can be calculated as {cholesterol – HDL – (triglycerides/5)}. Calculated LDL is an estimation of LDL and valid only if triglycerides level is 400 mg/dL or below.

VIII. Procedural Notes

For *in vitro* diagnostic use.

- PTS Panels® lipid panel test strips can only be used in CardioChek® brand analyzers.
- Recap strip vial immediately and tightly after removing a single test strip.
- Never remove the desiccant from the vial, if applicable.
- Do not lay strips out ahead of time.
- Do not allow strip to be out more than five (5) minutes.
- 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 store MEMo Chip in test strip vial.
- Add all of the blood to the test strip at one time. Do not add additional blood to the same test strip. Instead, test again with a new unused test strip and fresh blood sample.
- When the test is completed, look at reaction areas on the back of test strip to ensure that they are completely and evenly colored. If there is a half-moon shape in the reaction area, this usually means an insufficient specimen was applied.

- Discard the test strip after using. Test strips are to be read once. Never insert or read a used test strip.

IX. Maintenance and Cleaning

There is no user calibration possible with the CardioChek® PA analyzer. All calibration is performed prior to leaving the manufacturer's facility.

A. Analyzer Storage and Handling:

1. Handle the CardioChek PA analyzer with care; do not drop.
2. Do not store or operate the analyzer in direct light, such as sunlight, spotlight, under a lamp, or by a window.
3. Do not expose the analyzer or any of the supplies or accessories to high humidity, extreme heat, cold, dust, or dirt.
4. The analyzer may be stored at a temperature of 50-104°F (10-40°C) and 20-80% Relative Humidity (RH). **Do not freeze.** If the analyzer has been stored under extreme conditions, allow at least 30 minutes at room temperature before use. The analyzer must be operated within the test strip ranges (20 - 30°C).
5. Do not scratch or damage the surface of the check strip.

B. Cleaning Instructions:

Optical Glass

1. Locate the optical glass and the test strip insert opening.
2. Using an alcohol wipe, carefully wipe the optical glass and test strip guides clean. If the area is especially dirty, this may require additional wipes.
3. Immediately dry the optical glass completely with gauze. Make sure the glass is clean, dry, and completely free from any fingerprints, dust, or smudges. The glass must look clean when held at different angles.

Exterior

1. Cleaning and disinfection of the CardioChek® PA analyzer should be after each use. Clean and disinfect before storing and between each patient test. Make sure to read the CardioChek PA user guide and disinfectant manufacturer's product labeling.
2. PTS Diagnostics recommends using Super Sani-Cloth® wipes or any disinfectant with the same EPA registration number. Remember to wear gloves when using Super Sani-Cloth or other disinfectants. Super Sani-Cloth was tested and found to be effective per recommended guidelines when used with the CardioChek PA analyzer. Use of other disinfectants may cause damage to the analyzer. Do not use bleach, peroxide, or window cleaners on the CardioChek PA analyzer.

3. First, obtain a fresh Super Sani-Cloth wipe or another recommended wipe. Using the fresh wipe, wring out excess liquid and carefully wipe the CardioChek® PA analyzer clean. Make sure to clean all surfaces of the analyzer. Handle and dispose of the wipe coming in contact with blood according to universal precautions and guidelines. Allow the analyzer to air dry or dry with cotton gauze.

4. After cleaning the CardioChek® PA analyzer, the next step is to disinfect.

5. Using a fresh wipe, wring out excess liquid from the wipe and carefully wipe all areas of the analyzer thoroughly. The analyzer will need to remain wet for two minutes to allow for sufficient time to kill bloodborne pathogens. Repeatedly wiping the analyzer may be necessary to ensure the disinfectant is in contact with the analyzer for the full two minutes. Remember to dispose of the wipe according to universal precautions and guidelines. Allow the analyzer to air dry completely before use.

6. With cleaning and disinfection complete, make sure to inspect the analyzer for signs of deterioration such as:

    a. Scratches or etching on optical glass

    b. Liquid under optical glass

    c. Loss of adhesion on optical glass

    d. Liquid under display lens

    e. Deterioration of painted surfaces

    f. Or any loose parts

7. Stop using the analyzer and contact PTS Diagnostics Customer Service for a replacement analyzer immediately if you notice any signs of deterioration.

C. Battery Replacement

The CardioChek PA analyzer requires two (2) AAA 1.5-volt high-quality alkaline batteries.

When to Replace the Batteries

When the display reads REPLACE BATTERIES, no more tests can be run until the batteries are changed. Always replace the batteries with high-quality alkaline batteries. When changing batteries, change all batteries using the same brand of batteries – do not mix battery brands. It is recommended to keep a spare set of batteries on hand. To extend battery life, remove the test strip as soon as a result is displayed. The time/date and results stored in memory will not be erased when the batteries are changed.

How to Install/Replace the Batteries:

1. Open the battery door on the back of the CardioChek PA analyzer by pressing and sliding it in the direction of the arrow (toward the MEMo Chip port).

2. Remove old batteries from the compartment and safely discard.

3. Insert the new batteries into the battery compartment with the positive (+) terminal facing to the left on the top battery, and to the right on the bottom battery as marked on the inside compartment.

4. Replace the battery door. To make sure the batteries were installed correctly, push either of the two buttons on the front of the analyzer to turn the CardioChek® PA analyzer on.

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Final Note: Refer to the CardioChek® PA user guide and the PTS Panels® lipid panel test strips package insert for complete instructions for instrument and test performance.