

CardioChek®

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



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Director: _____
Signature Date

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Refer to the CardioChek® PA Operator’s Manual and the PTS Panels® Lipid test strips package insert for complete instructions for instrument and test performance.

I. Purpose

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, atherosclerosis, and various renal and liver diseases.

The CardioChek® PA analyzer from Polymer Technology Systems, Inc. (PTS, Inc.) 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. 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. The 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 venous whole blood collected in 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. Instruct the patient to wash hands in warm, soapy water. Rinse well and dry completely. If an alcohol wipe is used, let the finger air dry before testing.
4. Use a new sterile, disposable lancet to puncture the side of the fingertip.
5. Gently apply pressure to the finger starting at the base of the finger and moving towards the tip.
6. Wipe away the first drop of blood with gauze and use the second blood drop for testing.
7. The blood drop should be hanging down from the finger to make it easier to collect the sample with a capillary pipette or plastic blood collector.
8. In order to prevent air bubbles or gaps, hold the capillary tube at a slight upward angle and draw the blood to the black line.
9. See section VI to perform the test.

B. Venous Whole Blood Samples

1. Collect the venous sample in a green top (Lithium heparin) tube.
2. Gently mix the tube by inversion 10 times.
3. Carefully open the tube and remove a 35-40 μ L sample using either a capillary pipette or plastic blood collector.
4. See section VI to perform the test.

C. Interfering Substances

Dopamine and methyl dopa decreased the results of all analytes. Extremely high doses of ascorbic acid (Vitamin C) decreased the results of all the analytes.

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 triglyceride levels below 400 mg/dL.

A. Equipment:

1. CardioChek[®] PA analyzer

B. Materials:

1. Vial of PTS Panels Lipid Panel test strip
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. Store test strip package in a cool, dry place at room temperature of 68-80°F (20-27°C). Do not freeze.
2. Keep away from heat and direct sunlight.
3. Do not remove or discard the desiccant packet in the vial.

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 either in the analyzer or stored with the original lot of test strips.
7. 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.
8. When a vial is properly stored and kept tightly capped, test strips are stable until the marked expiration date.

V. Quality Control (QC)

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 liquid quality controls when results are questionable or to comply with their own facility's quality control requirements.

The check strip supplied with the CardioChek® PA analyzer may be used to verify that the analyzer's electronics and optics are working properly.

A. Use of the Check Strip

The check strip (included in the analyzer carrying case) verifies that the CardioChek PA analyzer's electronic and optical systems are functioning properly. Each gray check strip is calibrated to read a specific reflectance. It is recommended that the check strip verification be performed:

1. Daily
2. If the analyzer has been dropped

How to Use the Check Strip:

1. Turn the analyzer on by pressing either button.
2. When INSTALL MEMO CHIP or RUN TEST is displayed, press Next until UTILITY is displayed. Press Enter.
3. When CK STRIP is displayed, press Enter.
4. When INSERT STRIP is displayed, insert the check strip with the ribbed side up.
5. Record the result. 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 opening (Section VIII) 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 QC:

1. Insert the MEMo Chip for the lot of Lipid Panel test strips to be checked.
2. Press any button to turn CardioChek PA device on.
3. Press Next until the display reads UTILITY. Press Enter.
4. Press Next until RUN CONTROL scrolls across the display. Press Enter.
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 inversion.
7. Remove control vial cap and turn bottle upside down directly above test strip sample application window.
8. Carefully squeeze vial to deliver one drop of control solution to the test strip.
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 opening (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 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. When INSERT STRIP is displayed, insert the test strip into the analyzer as far as it will go.
4. Obtain blood sample (Section III).
5. When APPLY SAMPLE is displayed, use a capillary pipette or plastic blood collector to apply 35-40 µL of whole blood to the test strip blood application window.
6. The results will be displayed in about two (2) minutes. Press the Next button to display each analyte of the test panel.
7. Remove test strip and discard.

The analyzer automatically shuts down after three minutes of idle time with no test strip inserted.

VII. Expected Results

The expected or reference ranges recommended are from the U.S. National Cholesterol Education Program (NCEP) 2001 Guidelines:

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 Coronary Disease)
- 60 mg/dL (1.55 mmol/L) and above – high HDL (Low risk for Coronary 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 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 the CardioChek® PA analyzer.
- Recap strip vial immediately and tightly after removing a single test strip.
- Never remove the desiccant from the vial.
- 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 68-80°F (20-27°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.
5. Do not scratch or damage the surface of the check strip.
6. Optimal Operating Conditions: 68-80°F/20-27°C

B. Cleaning Instructions:

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.
4. Clean the exterior of the analyzer with a damp (not wet) alcohol wipe or dampen a cloth with water or a medical grade disinfectant (such as Sporocidin) and wipe surfaces and the display area very carefully. Be careful not to get the test strip insert opening (where the test strip is inserted) wet.

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 CHANGE BATTERY, no more tests can be run until the batteries are changed. Always replace the batteries with high-quality alkaline batteries. 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.

X. References

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