

CardioChek[®]

Procedure: CardioChek[®] Plus Test System/PTS Panels[®] Lipid + eGLU[™] Smart Bundle[™] Test Strips



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Refer to the CardioChek® Plus User Guide and the PTS Panels® Lipid Panel and eGLU™ test strips package inserts for complete instructions for instrument and test performance.

I. Purpose

PTS Panels® Lipid + eGLU Smart Bundle (Smart Bundle) test strips measure total cholesterol, HDL cholesterol, triglycerides, and glucose in whole blood. Measurements from the PTS Panels Lipid Panel test strips are used in the diagnosis and treatment of lipoprotein metabolism and lipid disorders, atherosclerosis, and various renal and liver diseases. The PTS Panels eGLU test strips quantitatively measure glucose in whole blood. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders

The CardioChek® Plus analyzer is intended for *in vitro* diagnostic use using fingerstick whole blood samples with the Lipid Panel + eGLU Smart Bundle test strips, or whole blood samples (venous or fingerstick) with the other PTS Panels (reflectance) test strips.

II. Principle

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

A. The CardioChek Plus Test System

The CardioChek Plus test system uses reflectance photometry and electrochemical biosensor technology. Reflectance test strips utilize an enzymatic reaction to produce a color change that is detected by the analyzer after whole blood is applied.

Electrochemical test strips measure an electrical current when whole blood is applied.

B. Test Strips

Test strips are designed for specific analytes. For a reflectance test, a reflectance 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.

For an electrochemical test, an electrochemical test strip is inserted into the electrochemical port, and the blood is wicked into the electrochemical channel at the end of the test strip. The blood starts a chemical reaction that produces an electrical current. The current is converted to a result using the calibration curve stored in the MEMo Chip.

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 the

MEMo Chip is inserted 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 the MEMo Chip is lost or missing, a replacement can be requested by contacting Customer Service.

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® reflectance test strips are designed for use with fresh capillary (fingerstick) whole blood, or venous whole blood collected in EDTA or heparin tubes. Electrochemical test strips are designed for use with fresh capillary (fingerstick) whole blood only. 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. When an alcohol pad is used to thoroughly cleanse the finger, cleanse with a firm wiping motion to ensure the removal of any additional lotion or glycerin-based soap residue, and then wipe excess alcohol with a clean gauze pad before testing.
4. Use a new sterile, disposable lancet to puncture the side of the fingertip.

5. Gently apply pressure to the finger near the first knuckle of the ring or middle finger and engorge the end of the finger with a squeeze and release technique.
6. Use the first drop of blood to immediately dose the tip of the eGLU test strip until the channel is filled and the screen shows a beating heart icon over the glucose strip.
7. Wipe away the residual blood with a clean, dry gauze pad and use the second blood drop to begin the capillary tube collection of 40 μ L of blood to dose the Lipid Panel test strip. With a gentle, but firm squeeze near the first knuckle, produce a large drop at the fingerstick site and touch the tip of the capillary blood collector or calibrated pipette to the drop. With 2 to 3 squeeze-and-release motions, allow the horizontal fill of the capillary tube without the introduction of bubbles or air spaces.
 - In order to prevent air bubbles or gaps, hold the capillary tube at a slight upward angle and fill the capillary tube to the black line.
8. See section VI to perform the test.

B. Venous Whole Blood Samples

1. Collect the venous sample in either a green top (Lithium heparin) or lavender top (EDTA) tube.
2. Gently mix the tube by inversion 10 times.
3. Carefully open the tube and remove a 40 μ L sample using either a capillary blood collector or calibrated pipette.
4. See section VI to perform the test.
5. Venous samples are not suitable for eGLU testing and are only allowed for PTS reflectance test strips, such as the Lipid Panel test portion of the Smart Bundle pack.

C. Interfering Substances

Dopamine and methyl dopa decreased the results of all lipid analytes, while causing higher results for the eGLU testing. Extremely high doses of ascorbic acid (Vitamin C) decreased the results of all the lipid analytes, while having no significant effect on the eGLU results.

IV. Equipment/Materials/Reagents

The Lipid + eGLU Smart Bundle™ consists of three boxes of Lipid Panel test strips which are self-contained disposable test strips preloaded with the reagents necessary to measure total cholesterol, HDL cholesterol, and triglycerides, as well as one box of eGLU™ test strips preloaded with the reagents necessary to measure glucose. Calculated LDL results are available for samples with total cholesterol and HDL cholesterol within the measuring range of the analyzer, and triglycerides levels below 400 mg/dL.

A. Equipment

1. CardioChek® Plus analyzer

B. Materials

1. A Smart Bundle pack consisting of 3 vials of reflectance Lipid Panel test strips and 1 vial of electrochemical eGLU test strips.
2. 1 MEMo Chip® per test strip box (contains lot-specific test strip information)
3. Lancets for fingerstick (or venous blood collection supplies)
4. Gauze
5. A capillary blood collector or other capillary pipette
6. A biohazard disposal receptacle

C. Reagent Preparation

There is no preparation required for Smart Bundle 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. 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. 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. After opening, the test strips are stable until the expiration date if the vial is properly stored and always capped.

V. Quality Control (QC)

Quality Control tests are used to ensure that the total system (analyzer, test strips, and MEMo Chip) is working properly and that the test results are accurate and reliable within the limits of the system. Users should follow good laboratory practice and run Quality Control tests

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

A. Use of the Check Strips

The gray check strips (included in the analyzer carrying case) verify that the CardioChek Plus 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 analyzer reflectance test strip slot (Section IX) and retest. If the results remain outside the specified range, contact Customer Service at +1-877-870-5610 (toll-free inside the U.S. and Canada) or +1-317-870-5610 (direct).

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 + eGLU Smart Bundle test strips requires the use of PTS Panels Multi-Chemistry Controls (for total cholesterol, triglycerides, and glucose) and PTS Panels HDL Cholesterol Controls (for HDL cholesterol).

How to Use PTS Panels Multi-Chemistry Controls

1. With the MEMo Chip out, press any button to turn CardioChek Plus device on.
2. When INSERT MEMO CHIP appears on the screen, press NEXT until display reads UTILITY.
3. Press the ENTER button once, then the NEXT button once to see RUN CONTROL, then press ENTER.
4. INSERT MEMO CHIP appears on the screen. Insert the MEMo Chip for the matching lot of Smart Bundle Lipid Panel test strips to be checked and press ENTER.
5. 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.
6. Insert the test strips into the analyzer in either order. Immediately replace the vial caps, making sure the test strip vials are capped tightly. The CardioChek Plus analyzer will display APPLY SAMPLE with a blood drop icon over the eGLU test strip. This indicates the system is ready for a sample (control) to be applied to the eGLU test strip first.
7. Mix the control material well by gentle inversion at least 3 times.
8. Remove the Multi-Chemistry Controls vial cap and turn the bottle upside down, directing a small drop directly at the tip of the eGLU test strip (not on top). When the sample has adequately wicked into the eGLU test strip channel, the blood drop icon on the display will change to a beating heart and the blood drop icon will now appear over the Lipid Panel test strip.
9. Carefully squeeze the vial to deliver one large hanging drop of control solution to the Lipid Panel test strip and allow it to fall onto the center of the blood application window.
10. Replace the Multi-Chemistry Controls vial cap.
11. Results for both the Lipid Panel analytes and the eGLU testing will be displayed in about two (2) minutes.

Expected Results

All results for the controls should be in the ranges specified on the PTS Panels Multi-Chemistry Control Range Card.

- Check the Multi-Analyte section for Total Cholesterol and Triglycerides results for the level tested.
- Check the Single-Analyte section for the Glucose result for the level tested.

If test results are outside the specified range:

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

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

How to Use PTS Panels HDL Cholesterol Controls

1. With the MEMo Chip out, press any button to turn CardioChek Plus device on.
2. When INSERT MEMO CHIP appears on the screen, press NEXT until display reads UTILITY.
3. Press the ENTER button once, then the NEXT button once to see RUN CONTROL, then press ENTER.
4. INSERT MEMO CHIP appears on the screen. Insert the MEMo Chip for the matching lot of Smart Bundle Lipid Panel test strips to be checked and press ENTER.
5. 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.
6. Hold down the NEXT button until a STRIKE OUT symbol appears over the eGLU test strip display.
7. Insert the Lipid Panel test strip only into the analyzer. Immediately replace the Lipid Panel vial cap, making sure the test strip vial is capped tightly. The CardioChek Plus 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 (control) to be applied to the Lipid Panel test strip.
8. Mix the control materials and carefully squeeze the vial to deliver one large hanging drop of control solution to the test strip and allow it to fall onto the center of the blood application window.
9. Replace the HDL Cholesterol Controls vial cap.
10. Results for the HDL Cholesterol analyte on the Lipid Panel test strip will be displayed in about two (2) minutes.

Expected Results

All results for the controls should be in the ranges specified on the PTS Panels HDL Cholesterol Control Range Card.

- Check the Multi-Analyte section for HDL Cholesterol results for the level tested.

If test results are outside the specified range:

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

If the results remain outside the specified range, contact 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® Lipid Panel and eGLU™ test strips are designed for use with fresh capillary (fingerstick) whole blood for eGLU and Lipid Panel test strips, or venous whole blood collected in EDTA or lithium heparin tubes for the Lipid Panel strips only (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 the CardioChek Plus analyzer on by pressing either button.
3. A short series of auto-checks will appear and a lot number will appear on the screen. For all Smart Bundle Lipid Panel and eGLU test strips, this lot number will begin with **Q**. 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 strips into the analyzer in either order. Immediately replace the vial caps, making sure the test strip vials are capped tightly. The CardioChek Plus analyzer will display APPLY SAMPLE with a blood drop icon over the eGLU test strip. This indicates the system is ready for a sample (control) to be applied to the eGLU test strip first.
5. Obtain a fingerstick blood sample (Section III).
6. Immediately dose the tip of the eGLU test strip with the first drop of blood until the channel is filled and the screen shows a beating heart icon over the glucose strip.
7. Wipe away the residual drop of blood with gauze and use the second blood drop to begin the capillary tube collection of 40µL of blood to dose the reflectance Lipid Panel test strip.

8. The blood drop should be a large drop at the fingerstick site to touch the tip of the capillary tube. With 2 to 3 squeeze-and-release motions, allow the horizontal fill of the capillary tube without the introduction of bubbles or air spaces.
9. When the blood drop icon is over the Lipid Panel test strip, use the filled capillary tube and plunger to hover over the blood application window of the test strip and deposit the entire sample onto the blood application window while hovering. **NOTE:** Do NOT place the tip of the capillary tube on the testing area.
10. The results will be displayed in about two (2) minutes. Press the NEXT button to display the calculated LDL and other calculated results.
11. 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 shown below:

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

Glucose Expected Values

- Below 50 mg/dL (<2.78 mmol/L) – may indicate a serious medical condition
- 50-240 mg/dL (2.78-13.32 mmol/L) – target values specifically appropriate to the patient should be determined by their physician
- Greater than 240 mg/dL (>13.32) – may indicate a serious medical condition

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 + eGLU™ Smart Bundle™ test strips can only be used in the CardioChek® Plus 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 Plus analyzer. All calibration is performed prior to leaving the manufacturer's facility.

A. Analyzer Storage and Handling

1. Handle the CardioChek Plus 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.
5. Do not scratch or damage the surface of the check strip.
6. Operating Temperature Range: 50-104°F (10-40°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 Plus analyzer requires four (4) AA 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. 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 Plus analyzer by releasing the latch and pulling the door away from the back of the analyzer.
2. Remove old batteries from the compartment and safely discard.
3. Insert the new batteries into the battery compartment 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® Plus analyzer on.

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