

CardioChek[®]

Procedure:

CardioChek[®] Plus Test System/PTS Panels[®] Test Strips



Approved

Director: _____
Signature Date

Prepared by Date: _____ Adopted Date: _____

Supersedes Procedure: _____

Review Date: _____

Reviewed By: _____
Signature Date

Distribution List: _____

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Refer to the CardioChek® Plus user guide and the PTS Panels® test strips package inserts for complete instructions for instrument and test performance.

I. Purpose

The CardioChek® Plus test system is a small, portable analyzer and test strip system 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. The test strips are for the quantitative determination of glucose, total cholesterol, HDL cholesterol, and triglycerides in venous whole blood and capillary whole blood from the fingertip. A Chol/HDL ratio and estimated values for LDL cholesterol and non-HDL cholesterol are calculated by the CardioChek Plus analyzer.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL 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, and other diseases involving lipid metabolism or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

PTS Panels test strips are sold separately, and are available as single and multiple-analyte test strips.

II. Principle

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

A. The CardioChek Plus Test System

The analyzer employs both light reflectance and electrochemical biosensor technology to measure an enzymatic chemical reaction. When a blood sample is applied to a reflectance test strip, a chemical reaction occurs that produces a color change on the test strip. When blood is applied to an electrochemical test strip, an electrical current is produced. This color or current is measured and compared to a calibration curve stored in the lot-specific MEMo Chip. The analyzer converts this color or current reading into a test result (the darker the color or greater the electrical current, the higher the analyte concentration). The test result appears on the display screen.

B. PTS Panels Test Strips

PTS Panels test strips are designed for specific analytes. A test strip is inserted into the analyzer, then blood is applied to the blood application window for reflectance tests or the tip of the test strip for electrochemical tests. As previously described, the ensuing chemical reaction produces a color change or an electrical current, which the analyzer measures and compares to the calibration curve stored in the lot-specific MEMo Chip. The analyzer converts this color reading or electrical current measurement 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. Please read the instructions completely before testing.

The CardioChek Plus test system has many different analyte test strips available for use. The test strips outlined in this section are only an example of the available test strips. Not all test strips are available for use in all countries. Please refer to the package insert of each PTS Panels test strip prior to use.

Limitations

PTS Panels eGLU/Glucose Test Strips – Limitations of the Procedure

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

- The analyzer should not be used to test critically ill patients.
- Blood samples from patients in shock, patients with severe dehydration, or patients in a hyperosmolar state (with or without ketosis) have not been tested. It is not recommended to test those samples with this system.
- Not for use on patients who are severely hypotensive.
- **Preservatives:** Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system.
- **Venous Samples:** To minimize glycolysis, venous whole blood samples must be tested within 20 minutes of the draw. Grossly lipemic samples may interfere with some methodologies. Critically ill patients should not be tested by this method, or should be tested with extreme caution.
- **Neonatal Use and Arterial Blood:** This product has not been tested using neonatal or arterial blood. This test system should not be used with these whole blood samples.
- **Acetaminophen (Tylenol) and Dopamine:** These may interfere causing the test result to be higher than the actual glucose. Not every drug was tested.
- **Metabolites:** This test system is specific for glucose. Other sugars and other reducing substances such as ascorbic acid at normal blood concentrations have no significant effect on test results.
- **Hematocrit:** Hematocrit values above 55% or lower than 30% may incorrectly lower the glucose result.
- **Altitude:** Testing at altitudes up to 10,000 feet has no effect on results.
- **Dehydration:** Severe dehydration and excessive water loss may produce falsely low results.

PTS Panels Lipid Panel Test Strips – Limitations of the Procedure

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

- **Preservatives:** EDTA and heparin in venous blood collection tubes had no effect on the results of the test strip.
- **Drugs:** Dopamine and methyldopa decreased the results of all the lipids.
- **Metabolites:** Extremely high doses of ascorbic acid (Vitamin C) decreased the results of all the lipids.
- **Hematocrit:** No hematocrit effect was observed for samples between 30 and 45% HCT.
- **Neonatal Use:** This product has not been tested using neonatal blood. This test system should not be used with these samples.
- **Hand Lotions/Cosmetics:** Cosmetics such as handcreams or lotions often contain glycerol. Use of these products may cause inaccurate results.
- Displayed results are rounded.

C. MEMo Chip

Each package of PTS Panels test strips contains a color-coded lot-specific MEMo Chip. The MEMo Chip contains the settings for each test. The bottom has a label with the test name and lot number. Always insert the MEMo Chip in the port at the top of the analyzer with the lot code number facing down.

NOTE: The analyzer is calibrated at PTS Diagnostics. The calibration curve for each lot of test strips is maintained within the MEMo Chip.

How the MEMo Chip Functions

The MEMo Chip contains proper settings for the test strip lot you are using.

- The MEMo Chip:
 - Stores 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
- Provides the measuring range for the test

Guidelines for Using the MEMo Chip

- The MEMo Chip must be inserted 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(s), 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 misplaced, please call PTS Diagnostics Customer Service for a replacement or use another MEMo Chip from another vial of the same lot number.

The MEMo Chip Port is Located at the Top Center of the Analyzer

- The MEMo Chip is inserted into this port with the lot number facing down.
 - Push firmly, but gently, until the MEMo Chip is fully inserted.
- NOTE:** Be careful not to bend the connector.

III. Use of the Check Strips

A check of the analyzer operation and optics can be performed using one of the two gray check strips in the analyzer carrying case. The check strip verifies that the CardioChek Plus analyzer's electronic and optical systems are functioning properly. To perform this verification, insert the check strip into the analyzer. The analyzer will read the reflectance of the gray check strip and indicate if the reading is within the specified acceptable range by displaying PASSED. When the check strip is not in use, store it in the analyzer carrying case. It is recommended that the check strip verification be performed:

- Daily
- If the analyzer has been dropped
- When a result is not consistent with expected results

How to Use the Analyzer Check Strip

- Turn on the analyzer by pressing either button.
- When INSTALL MEMO CHIP or RUN TEST is displayed, press Next until UTILITY is displayed. Press Enter.
- Press Enter when CHECK STRIP is displayed.
- Hold the check strip at the base and insert the check strip, ribbed side up, into the reflectance test strip slot when INSERT STRIP is displayed.
- The analyzer should display PASSED, along with a checkmark icon. (If the display reads FAILED, see the note at the end of this section.) Remove the check strip and store it in the analyzer carrying case.
- Press Next until EXIT is displayed. Press Enter.
- Press Next until RUN TEST is displayed.
- Press Enter. The analyzer is ready to run tests.

NOTE: If the analyzer displays FAILED:

- Clean the CardioChek Plus analyzer test strip slot (where the check strip is inserted into the analyzer).
- Inspect the check strip to make sure it is not dirty or damaged. Use the spare check strip and repeat.

IV. Quality Control (QC)

- Controls (also known as "quality control materials") are solutions for which an expected analyte concentration range has been established. Controls are tested to check the performance of your test system: CardioChek Plus analyzer, MEMo Chip, and PTS Panels test strips. Use quality control materials provided by PTS Diagnostics.
- Refer to the Range Card provided with the controls or visit <http://www.ptsdiagnostics.com> for control specifications.

- Healthcare professionals should follow their facility’s guidelines and policies regarding quality assurance and the use of quality control materials.

Quality control materials should be run:

- With each new shipment
- With each new lot number
- According to state, local, and federal regulations

To perform a control test you need:

- CardioChek Plus analyzer
- PTS Panels test strips
- Quality control materials
- Quality control instructions
- Quality control range card

A. Quality Control Test Procedure

- Multi-Chemistry Controls
 - Insert MEMo Chip that matches the lot of strips.
 - Press one of the two buttons to turn the instrument ON.
 - Press the NEXT button until the display reads UTILITY.
 - Press the ENTER button.
 - Press the NEXT button until RUN CONTROL is displayed.
 - At the RUN CONTROL analyzer display option, press ENTER.
 - Insert the test strip into the analyzer.
 - Wait until the analyzer displays APPLY SAMPLE.
 - Invert to mix control.
 - Remove cap and turn bottle upside down straight above reflectance test strip sample application window or to the tip of the electrochemical test strip.
 - Carefully squeeze vial to deliver control solution on the test strip. Use one drop of control solution for single-analyte test strips and electrochemical test strips, or two drops for multi-analyte test strips.
 - Replace control vial cap.
 - Results will be displayed on screen.
- HDL Cholesterol Controls (Not required for CardioChek Plus analyzer version 1.09 & above)
 - Insert MEMo Chip that matches the lot of strips.
 - Press one of the two buttons to turn the instrument ON.
 - Press the NEXT button until the display reads UTILITY.
 - Press the ENTER button.
 - Press the NEXT button until RUN CONTROL is displayed.
 - At the RUN CONTROL analyzer display option, press ENTER.
 - Insert the test strip into the analyzer.
 - Wait until the analyzer displays APPLY SAMPLE.
 - Invert to mix control.
 - Remove cap and turn bottle upside down straight above reflectance test strip sample application window.
 - Carefully squeeze vial to deliver control solution on the test strip. Use one drop of control solution for single-analyte test strips and two drops for multi-analyte test strips.
 - Replace control vial cap.
 - Results will be displayed on screen.

NOTE: If testing PTS Panels lipid+eGLU smart bundle test strips, skip the eGLU test by pressing

and holding the NEXT button when INSERT STRIP icon for the eGLU test strip appears.

Expected Results:

Results for the control should be in the range specified on the quality control range card. The control results are also available on the PTS Diagnostics website: www.ptsdiagnostics.com.

- Check the Multi-Chemistry controls range card for level tested:
 - Total Cholesterol
 - HDL Cholesterol (CardioChek Plus analyzer version 1.09 & above only)
 - Triglycerides
 - Glucose
- Check the HDL Cholesterol controls range card for level tested (CardioChek Plus analyzer version 1.08 & below)
- If test results are above or below the range specified:
 - Check to see if the test strips or controls are expired. If they are expired, test again with unexpired strips and controls.
 - Clean the analyzer before retesting (see user guide).
 - For assistance with the PTS Panels multi-chemistry or HDL cholesterol controls, please contact PTS Diagnostics Customer Service (M-F, 6 a.m. - 9 p.m. US EST) or your local authorized dealer.
 - 1-877-870-5610 (Toll-free inside the USA)
 - +1-317- 870-5610 (Direct)
 - +1-317-870-5608 (Fax)
 - E-mail: customerservice@ptsdiagnostics.com
 - Website: ptsdiagnostics.com

V. Equipment/Materials/Reagents

PTS Panels test strips are composed of several layers of filters and reagent-impregnated membranes in a plastic carrier. Each membrane layer performs specific functions to process and facilitate chemical reactions. The dry chemistry membranes are stable at room temperature.

The MEMo Chip is the key link between the test strip and the analyzer. A MEMo Chip is included with each vial of test strips and contains specific calibration and other information that enables the analyzer to "read" each particular test strip.

A. Equipment

- CardioChek® Plus analyzer

B. Materials

Materials Provided

- 1 MEMo Chip® per test strip box (contains lot-specific test strip information)
- PTS Panels® test strips
 - CardioChek Plus smart bundle™ 2-pack
 - Lipid Panel test strips
 - CHOL+HDL+GLU test strips
 - Metabolic Chemistry test strips
 - CHOL+GLU test strips
 - CHOL+HDL test strips
 - eGLU test strips (electrochemical)
 - Total Cholesterol test strips
 - HDL Cholesterol test strips

- Triglycerides test strips
- Glucose test strips (reflectance)

Materials Required but Not Provided

- Lancets for fingerstick (or venous blood collection supplies)
- Gauze
- Alcohol wipe
- Capillary blood collection device
 - PTS Collect™ capillary tubes
 - Capillary tubes and plungers
- Biohazard disposal receptacle

C. Reagent Preparation

There is no preparation required for the PTS Panels test strips.

D. Storage and Handling Requirements

CardioChek Plus Analyzer

- Handle the CardioChek Plus analyzer with care; do not drop.
- Do not store or operate the analyzer in direct light, such as sunlight, spotlight, under a lamp, or by a window.
- Do not expose the analyzer or any of the supplies or accessories to high humidity, extreme heat, cold, dust, or dirt. 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 storage temperature is below 68°F (20°C) allow the device to warm to room temperature 68°F (20°C) before using. If the device has been stored under excessive conditions, allow at least 30 minutes at room temperature for the device to equilibrate to these temperatures.
NOTE: The analyzer temperature must be within the test strip temperature specifications to function as a system.
- Do not scratch or damage the surface of the check strip.

PTS Panels Test Strips

- 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 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.

PTS Panels Controls

- Store in a cool, dry place at room temperature 68-86°F (20-30°C). May be stored in a refrigerator at 35-46°F (2-8°C). **Do not freeze.**

- Product is ready to use and is clear.
- Recap vial after using.
- Use care not to contaminate dropper tip.
- Do not use beyond the expiration date on the vial.
- Opened product is stable for at least ten months at room temperature.

VI. Specimen Collection

PTS Panels® Reflectance Test Strips

- Test strips are designed for use with fresh capillary (fingerstick) whole blood.
- Venous whole blood collected in EDTA or heparin tubes is also an acceptable sample.
- For best results, samples should be obtained from patients in a fasting state (no food or drink, except water, for at least 12 hours).

Electrochemical Glucose Test Strips

- Test strips are designed for use with fresh capillary (fingerstick) whole blood.
- Venous whole blood collected in EDTA or heparin tubes and tested within 20 minutes of the draw is also an acceptable sample.
- 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

A new pair of clean gloves should be worn by the user before testing each patient.

- Use either the middle or ring finger for fingersticking.
- Select the site to allow for convenient collection.
- Clean the site with an alcohol wipe.
- Apply gentle pressure to the finger with lancet and stick the finger left or right of center.
- Gently apply pressure (squeeze and release) to the finger to produce a large drop of blood.
NOTE: Avoid milking the finger. This may cause tissue fluid dilution or hemolysis and affect the accuracy of results.
- Use cotton or gauze to wipe away first drop for all reflectance test strips. Wiping the first drop is optional with electrochemical test strips (e.g. eGLU).
- Hold the capillary tube just below the bulb and level with the angle of the finger.
- Place the tip of the capillary tube just touching the drop of blood allowing the capillary action to draw the blood until the sample reaches the fill line.

B. Venous Whole Blood Samples

- Collect the venous sample in either a green top (lithium heparin) or lavender top (EDTA) tube.
- Gently mix the tube by inversion.
- Carefully open the tube and remove the appropriate sample volume (dependent on test strip being used) using either a capillary blood collector or calibrated precision pipet.

VII. Running a Test with PTS Panels Test Strips

A. How to Run a Reflectance Test

- Press either button to turn the analyzer on.
- Remove the MEMo Chip from the box of test strips.
- Insert the MEMo Chip in the port at the top of the analyzer with the lot code number facing down.
- When “INSERT STRIP” is displayed, remove a test strip from vial and immediately replace the desiccant cap.
- Insert the strip. Ensure that the test strip is inserted fully and the display reads “APPLY SAMPLE.”
- Obtain a blood drop following the correct technique. (If venous blood is used, collect in an EDTA or heparin tube. Invert gently 5-7 times to mix completely. Immediately collect sample with capillary tube or precision pipet and dispense correct volume as specified in test strip instructions for use (package insert) on to the test strip.)
- With a hovering technique to prevent touching and denting the testing area, and a gentle squeeze on the bulb, deposit the entire sample over the oval or circle on the strip.
- Once the sample is applied, results will appear on the analyzer display in about 90 seconds depending on type of test strip.
- Remove and discard test strip in a biohazardous waste container.
- If the analyzer is idle for more than 3 minutes, it will count down 10 seconds and automatically turn off.

B. How to Run an Electrochemical Test

- Insert correct MEMo Chip for the lot of strips in use. Remember to insert MEMo Chip with lot number code facing down.
- Press either button to turn on the analyzer.
- Remove a single electrochemical test strip from the test strip vial and immediately replace the cap (if applicable).
- Insert the electrochemical test strip into the designated electrochemical test strip port.
- APPLY SAMPLE icon appears on the display.
- Obtain a blood drop following the correct technique. (If venous blood is used, collect in an EDTA or lithium heparin tube. Invert gently 5-7 times to mix completely. Collect sample with capillary tube or pipet and touch to end of the test strip.)
- Gently hold the finger to the tip of the electrochemical test strip to apply a drop of blood. Do not place blood on top of the test strip. Do not press the test strip into the finger.
- Blood will be drawn into the strip automatically by capillary action.
- TESTING will appear until the result is displayed.
- Remove and discard test strip in a biohazardous waste container.

C. How to Run an Electrochemical Test with a Reflectance Test

- Insert the MEMo Chip that matches the lot number on both the electrochemical AND the reflectance test strip vials.
- Press either button to turn on the analyzer.
- Remove a single electrochemical test strip from the test strip vial and immediately replace the cap.
- Insert the electrochemical test strip into the designated electrochemical test strip port.
- Remove a single reflectance test strip from test strip vial and immediately replace cap.
- Insert the reflectance test strip into the designated test strip slot.
- The reflectance icon and electrochemical icon will display together.
- For the electrochemical test:
 - Obtain a drop of blood using a lancet per the correct technique.
 - Gently hold finger to the tip of the electrochemical test strip to apply a drop of blood. Do not place blood on top of the test strip. Do not press the test strip into the finger. (If venous blood is used, collect in an EDTA or lithium heparin tube. Invert gently 5-7 times to mix completely. Collect sample with capillary tube or pipet and touch to end of the test strip.)
 - Blood will be drawn into the strip automatically by capillary action.
 - Test result will display upon completion of the reflectance test results.

- For the reflectance test:
 - After applying blood to the electrochemical test strip, wipe the finger to remove any blood with a clean piece of gauze.
 - Obtain a blood drop following the correct technique. (If venous blood is used, collect in an EDTA or heparin tube. Invert gently 5-7 times to mix completely. Immediately collect sample with capillary tube or precision pipet and dispense correct volume as specified in test strip instructions for use (package insert) on to the test strip.)
 - Use a pipet or capillary blood collector to apply whole blood to the test strip blood application window.
 - In about 90 seconds, the results will appear on the display. Remove and discard test strips in a biohazardous waste container. DO NOT add more blood to any test strip that has been used.
- To skip the eGLU test, hold the NEXT button until the analyzer strikes the eGLU test out.

VIII. Expected Results

The expected or reference ranges recommended are from the US National Cholesterol Education Program (NCEP) 2001 Guidelines and are shown below:

A. 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

B. HDL Cholesterol Expected Values

- Below 40 mg/dL (1.04 mmol/L) – Low HDL (High risk for Coronary Heart Disease)
- 60 mg/dL (1.55 mmol/L) and above – High HDL (Low risk for Coronary Heart Disease)

C. 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 (5.65 mmol/L) and above – Very high

D. 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 (4.91 mmol/L) and above – Very high

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

Recommended fasting blood glucose references ranges are from the American Diabetes Association and are shown below:

E. Fasting Glucose Expected Values

- Below 100 mg/dL (5.55 mmol/L) – Normal
- 100 – 125 mg/dL (5.55 – 6.94 mmol/L) – Prediabetes
- 126 mg/dL (6.99 mmol/L) and above – Diabetes

IX. Measuring Ranges

Refer to individual test strip package inserts for out of range values. This test system will display numeric results in the following ranges:

A. Cholesterol (Total)

- 100 – 400 mg/dL (2.59 – 10.36 mmol/L)

B. HDL Cholesterol

- 20 – 120 mg/dL (0.52 – 3.11 mmol/L) – PTS Panels Lipid Panel test strips
- 25 – 100 mg/dL (0.65 – 2.59 mmol/L) – PTS Panels Metabolic Panel test strips
- 15 – 100 mg/dL (0.39 – 2.59 mmol/L) – All other multi-analyte PTS Panels test strips
- 25 – 85 mg/dL (0.65 – 2.20 mmol/L) – PTS Panels HDL Cholesterol test strips

C. Triglycerides

- 50 – 500 mg/dL (0.57 – 5.65 mmol/L)

D. Reflectance Glucose

- 20 – 600 mg/dL (1.11 – 33.3 mmol/L)

E. Electrochemical Glucose

- 40 – 600 mg/dL (2.22 – 33.3 mmol/L)

X. Procedural Notes

For *in vitro* diagnostic use.

- PTS Panels[®] test strips can only be used in the CardioChek[®] brand analyzers.
- Recap test strip vial immediately and tightly after removing a single test strip.
- Never remove the desiccant from the test strip vial (if applicable).
- Do not lay test strips out ahead of time.
- Do not allow test 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.
- When dispensing blood, ensure all blood is dispensed 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 reflectance 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.

XI. Care and Cleaning

A. Cleaning and Disinfection

Cleaning and disinfection of analyzers that come in contact with blood or blood products is critical to avoid transmitting bloodborne pathogens between patients and healthcare professionals. Please refer to the CardioChek Plus User Guide for detailed cleaning and disinfection instructions.

IMPORTANT SAFETY INSTRUCTIONS: It is critical to properly clean and disinfect analyzers that are used with blood products each time they are used, between each patient. Additionally, to avoid transmissions of bloodborne pathogens, only use auto-disabling, single-use lancing devices.

- *Frequency:* Always clean after each use. Always clean and disinfect before storing and between each patient test. Please read the disinfectant manufacturer's product label.
- *Recommended Disinfectant:* Super Sani-Cloth[®] wipes or any disinfectant with the same EPA Reg. No. (EPA Reg. No. 9480-4, Professional Disposables International, Inc (PDI), Orangeburg, NY). The active

ingredients in this disinfectant are n-Alkyl dimethyl ethylbenzyl ammonium chlorides. Super Sani-Cloth was tested and found to be effective per recommended guidelines when used with this system. Please only use this disinfectant. **Use of other disinfectants may cause damage to your analyzer. Do not use bleach, peroxide, or window cleaners on this analyzer.**

- *Cleaning Instructions:* Cleaning removes visible soil, organic material, and most importantly, blood products. Always clean **before** disinfecting.
 - Clean and disinfect all surfaces of this analyzer.
 - Obtain recommended wipes.
 - Using a fresh wipe, wring out excess liquid and carefully wipe to clean.
 - Allow to air dry or dry with cotton gauze.
- *Disinfection Instructions:* After cleaning, the next step is to disinfect. **Always both clean and disinfect.**
 - Using a fresh wipe, wring the wipe to remove excess liquid and wipe all areas thoroughly.
 - Keep area wet for 2 minutes to ensure disinfectant remains in contact for a sufficient time to kill all bloodborne pathogens.
 - Allow to air dry completely.
NOTE: It is important that the analyzer be thoroughly dry before using.
 - The optical glass should be carefully wiped clean with an alcohol wipe and dried with gauze to remove any residue from the disinfectant.
 - Inspect the glass and ensure it is clean when held at different angles.
 - After disinfection, users' gloves should be removed and hands should be thoroughly washed with soap and water before proceeding to the next patient.

B. Battery Use and Replacement

- The CardioChek Plus analyzer requires four (4) AA 1.5 volt high-quality alkaline batteries.

When to Replace the Batteries: The analyzer will give an indication on the display that the batteries need to be changed. 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

- 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.
- Remove old batteries from the compartment and properly discard.
- Insert the new batteries into the battery compartment with the positive (+) terminals correctly facing as marked on the inside compartment.
- 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 on the CardioChek Plus analyzer.

XII. References

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