pts Diagnostics

User Guide

CardioChek® PA Test System

For Professional Use
Portable Whole Blood Test System

Materials Provided

REF 1708 CardioChek® PA analyzer (1)

Materials Needed but not Provided

Appropriate sterile, disposable, auto-disabling, single-use lancet

PTS Panels® test strips are available in single- and multi-analyte tests

Product availability will vary per country

Lot-specific MEMo Chip® included with test strips

PTS Collect™ capillary tubes, laboratory pipet, or capillary blood collector—

appropriate volume specific to PTS Panels test strip.

Refer to test strip package insert for required sample size.

Alcohol wipes

Gauze pads or cotton balls

Bandages

Optional

The CardioChek PA test system may be used with optional CardioChek/PTS Connect™ solutions, which include: printer and optional software solutions (a software accessory to provide personalized health-related information using cholesterol results).

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1 Introduction

CardioChek PA System *Intended Use*

The CardioChek PA test system (consisting of the CardioChek PA analyzer and PTS Panels test strips) is for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip and is 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.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) 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, 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.

A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek PA analyzer.

The CardioChek PA analyzer from PTS Diagnostics is intended for *in vitro* diagnostic use, using whole blood samples. This point-of-care (POC) test system is designed for professional use. The CardioChek PA test system has an optional printer and the CardioChek Link® software solution to assist in data reporting.

The CardioChek PA analyzer is fast, portable, and reliable. This analyzer is a component of a test system that includes PTS Panels test strips. The PTS Panels test strip box includes a MEMo Chip that contains the assay calibration curve and other important information about the assay. PTS Panels test strips are sold separately, and are available as single- and multiple-analyte test strips.

This test system uses reflectance photometry technology. An enzymatic reaction on the test strip produces a color change that is detected by the analyzer after whole blood is applied.

This user guide includes all the information that you need to run POC assays using the CardioChek PA test system. Before you begin testing, please read this entire user guide and the package inserts, which are included with the PTS Panels test strips.

Please remember to return the enclosed warranty card to PTS Diagnostics to ensure that you receive product updates and other important information.

The CardioChek PA test system has many different analyte test strips available for use. 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.

For questions or additional assistance with your CardioChek PA test system, please contact PTS Diagnostics (Hours: 8:00 a.m. to 8:00 p.m. US EST) using the following contact information:

PTS Diagnostics
4600 Anson Boulevard, Whitestown, IN 46075 USA

Direct: +1-317-870-5610 • **Toll-free inside the US:** 1-877-870-5610
Fax: +1-317-870-5608

Email: customerservice@ptsdiagnostics.com • **Website:** ptsdiagnostics.com

Important Safety Instructions

Users should adhere to standard precautions when handling or using this analyzer. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.

The analyzer should be cleaned and disinfected after use on each patient. This system may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.

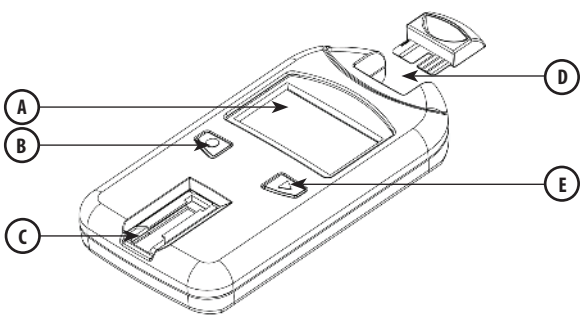
Only auto-disabling, single-use lancing devices should be used with this analyzer.

2 About the CardioChek PA Test System

The CardioChek PA Test System and Operating Principle

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

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



A Display
Display shows test results, messages, time, date and stored results.

B Enter Button
Press this button to turn on the analyzer or to accept the current menu choice.

C Test Strip Slot
The test strip slot is positioned in the lower front of the analyzer. The test strip and/or check strip is inserted here with the raised lines facing up.

D MEMo Chip Port
The MEMo Chip port is located at the top of the analyzer.

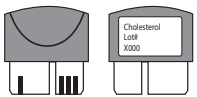
E Next Button
Press this button to turn on the analyzer or to advance to the next menu option.

The 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 make sure you insert the MEMo Chip into the port at the top of the analyzer with the finger notch facing up (with the lot code number facing down).

What does the MEMo Chip do?

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



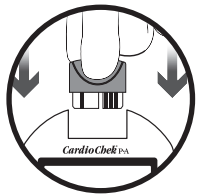
The MEMo Chip:

- 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, 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 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 finger notch facing up (with the lot number facing down). Push firmly, but gently, until the MEMo Chip is fully inserted.

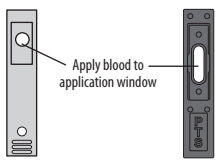


Important: Be careful not to bend the connector.

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. As previously described, the ensuing chemical reaction produces a color change, which the analyzer measures and compares to the calibration curve stored in the lot-specific MEMo Chip. The analyzer converts this color reading 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.

Examples of reflectance test strips



The CardioChek PA 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.

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.

1. **PRESERVATIVES:** EDTA and heparin in venous blood collection tubes had no effect on the results of the test strip.
2. **DRUGS:** Dopamine and methyldopa decreased the results of all the lipids.
3. **METABOLITES:** Extremely high doses of ascorbic acid (Vitamin C) decreased the results of all the lipids.
4. **HEMATOCRIT:** No hematocrit effect was observed for samples between 30 and 45% HCT.
5. **NEONATAL USE:** This product has not been tested using neonatal blood. This test system should not be used with these samples.
6. **HAND LOTIONS/COSMETICS:** Cosmetics such as handcreams or lotions often contain glycerol. Use of these products may cause inaccurate results.
7. Displayed results are rounded.

Each test strip is for a single test only. Do not reuse the strips. Use a new test strip each time you test. Use only fresh capillary whole blood from the finger or venous whole blood (EDTA or heparin). Performance testing was done using EDTA and heparin preserved whole blood. Do not use serum or plasma unless specified in the package insert. Each test strip has a package insert which contains instructions for use specific to that test strip.

Only auto-disabling, single-use lancing devices should be used with this analyzer.

PTS Panels Glucose Test Strips – Limitations of the Procedure

1. The analyzer should not be used to test critically ill patients.
2. 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.
3. Not for use on patients who are severely hypotensive.
4. **PRESERVATIVES:** Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system.
5. **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 blood samples.
6. Acetaminophen (Tylenol) and dopamine may interfere causing the test result to be higher than the actual glucose. Not every drug was tested.
7. **METABOLITES:** This test system is specific for glucose. Other sugars and other reducing substances such as ascorbic acid (Vitamin C) at normal blood concentrations have no significant effect on test results.
8. **HEMATOCRIT:** Hematocrit values above 55% or lower than 30% may incorrectly lower the glucose result.
9. **ALTITUDE:** Testing at altitudes up to 10,000 feet has no effect on results.
10. **DEHYDRATION:** Severe dehydration and excessive water loss may produce falsely low results.

Note: Please refer to package insert for each test strip for Limitations of the Procedure.

3 Setup

Battery Use and Replacement

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

When to Replace the Batteries

The analyzer will give you 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. 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.

When the REPLACE BATTERIES message is displayed, replace the batteries with **2 new AAA alkaline batteries of the same brand.**
Do not use NiCad or rechargeable batteries.
Caution: Improper installation of batteries can result in decreased battery life or damage to the analyzer.

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 properly discard.
3. Insert the new batteries into the battery compartment with the positive (+) terminals correctly facing 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 on the CardioChek PA analyzer.

Warning: Dispose of the old batteries properly. 

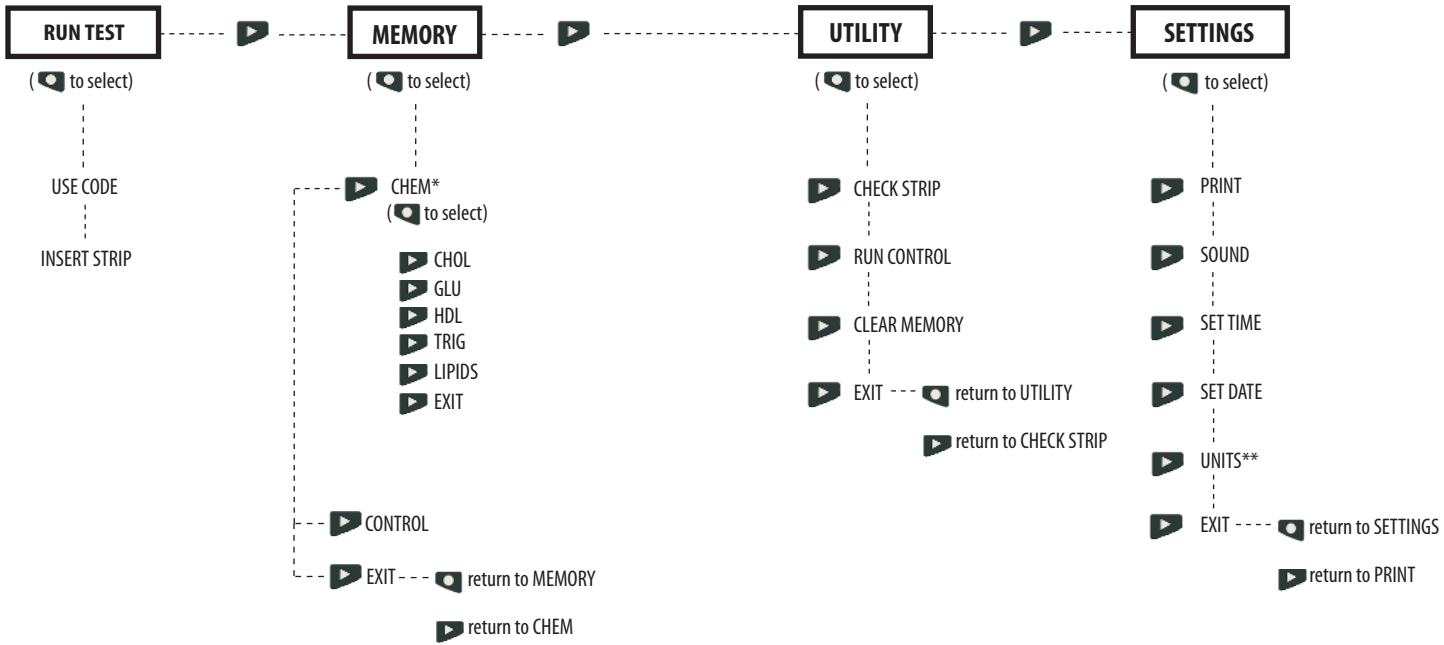
CardioChek PA Analyzer Menus

The following diagram provides a layout of the menus within the CardioChek PA analyzer. Detailed information on the use of each menu follows. Use the following buttons to navigate the menus:

Enter Button 
Press this button to turn on the analyzer or to accept the current menu choice.

Next Button 
Press this button to turn on the analyzer or to advance to the next menu option.

Note: Hold and  down at the same time for three seconds to turn off the analyzer.



*Memory results will only be shown for chemistries that have been run.

**If the units are locked, the UNITS screen does not appear.

How to Turn Off the Analyzer

To turn off the analyzer, press both buttons (Enter and Next) at the same time for three seconds. After three minutes of idle time (without a test strip or check strip inserted), the analyzer will perform a 10-second countdown and turn off. To stop shutdown, press either button. You can also remove the batteries to turn off the analyzer.

Setting Language

The first time the analyzer is turned on, you will be required to set the language, date, and time. The language menu consists of the following choices: English (ENGLISH), Spanish (ESPAÑOL), Italian (ITALIANO), German (DEUTSCH), French (FRANÇAIS), Portuguese (PORTUGSE), Dutch (NEDERL), Chinese (中文), and Russian (РУССКИЙ).
Note: Languages may vary based on analyzer version used.

How to Set the Language (First-Time Use)

1. Turn on the analyzer by pressing either button (Enter or Next).
2. The display will read LANGUAGE. Press Enter.
3. ENGLISH will be displayed. Press Enter if English is desired.
4. For other languages press Next until the desired language is displayed, then press Enter. To set the date and time, proceed to **How to Set the Time** and **How to Set the Date** sections.

How to Reset the Language

1. Turn off the analyzer.
2. Press and hold down Enter for approximately 5 seconds during the analyzer power-up stage until LANGUAGE is displayed.
3. Press Enter. Press Enter again to select English or press Next to scroll through the language choices.
4. Press Enter to select the desired language that is displayed.

How to Set the Time

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read either INSTALL MEMO CHIP (if a current MEMo Chip is not installed) or INSERT STRIP (if a current MEMo Chip is installed). Press Enter. The display will read RUN TEST.
2. Press Next until SETTINGS is displayed.
3. Press Enter. Press Next until SET TIME is displayed.
4. Press Enter and the clock format is displayed: 12/24 HR.
5. Press Next to alternately display the 12-hour AM/PM clock or the 24-hour clock. Press Enter to accept the displayed clock format. The display will read HOUR and the numerical hour. If 12-hour clock was chosen, AM/PM appears in the lower left hand corner of the display.
6. Press Next to increment the hour.
7. Press Enter to accept the displayed hour. The display will read MINUTE and the numerical minute.
8. Press Next to increment the minutes.
9. Press Enter to accept the displayed minute. The display will read SET TIME. To set the date, proceed to **How to Set the Date** - Step 4.
10. To exit, press Next until EXIT is displayed. Press Enter.
11. Press Next to return the display to RUN TEST.

How to Set the Date

1. If RUN TEST is displayed, go to Step 3. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Next. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed. Press Enter.
4. Press Next until SET DATE is displayed.
5. Press Enter and the numerical month is displayed.
6. Press Next to increment the month.
7. Press Enter to accept the displayed month. The display will read DAY and the numerical day of the month.
8. Press Next to increment the day.
9. Press Enter to accept the displayed day. The display will read YEAR and the numerical year.
10. Press Next to increment the year.
11. Press Enter to accept the displayed year. The display will read SET DATE.
12. Press Next until EXIT is displayed. Press Enter.
13. Press Next to return the display to RUN TEST.

How to Set the Units

The CardioChek PA analyzer may be shipped with preset units.

Note:

- If the SETTINGS menu does not display UNITS, the analyzer is locked in preset units
- The units cannot be changed if the system has been locked
- To confirm current configuration of the analyzer's units, run a check strip in the RUN TEST mode and observe the units that are displayed

If your analyzer's units have not been preset, follow the steps listed below to change your units to mg/dL, mmol/L, or g/L:

1. If RUN TEST is displayed, go to Step 3. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Enter. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter. The display will read PRINT.
5. Press Next until UNITS is displayed. If UNITS is not shown on the display, the units on this analyzer have been locked and cannot be changed. If UNITS appears on the display screen, proceed to the next step.
6. Press Enter. The display will read mg/dL. If mmol/L or g/L is desired, press Next until the desired unit appears on the display screen.
7. Press Enter to select the desired units. The display will then read UNITS.
8. Press Next until EXIT is displayed.
9. Press Enter to return to SETTINGS.
10. Press Next to return to RUN TEST.

How to Set the Sound

The CardioChek PA analyzer sound has been preset to BEEP ON. To turn the sound on or off, please follow the steps listed below:

1. If RUN TEST is displayed, go to Step 3. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Next. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter, then Next until SOUND is displayed.
5. Press Enter. The display will read BEEP ON or BEEP OFF .
6. Press Next to select either BEEP ON or BEEP OFF .
7. Press Enter to accept the sound choice displayed.
8. Press Next until EXIT is displayed.
9. Press Enter to return display to SETTINGS.
10. Press Next to return to RUN TEST.

Introduction to the CardioChek PA and Printer System

The CardioChek PA analyzer (with software version 2.55 and higher) supports printing in two formats, label or paper, on the CardioChek/PTS Connect™ printer or portable printer. To verify CardioChek PA test system software, turn on the analyzer by pressing either button. The software version will appear on the display.

How to Set Up the CardioChek PA for Printing

For complete details, refer to each printer's user guide.

Testing the Printer

1. If the analyzer is off, press either button to turn on the analyzer. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
   Note: If RUN TEST is displayed, go to Step 3.
2. Press Next. The display will read RUN TEST.
3. Press Next until SETTINGS is displayed.
4. Press Enter, then Next until PRINT is displayed.
5. Press Enter, then Next until TEST PRINTER is displayed.
6. Press Enter and a sample printout will be generated.

How to Print Results From Memory

(Up to 30 test results per chemistry and up to 10 control results are alternatively stored)

1. Turn the CardioChek PA analyzer on by pressing either button.
2. Press Enter until RUN TEST is displayed.
3. From the RUN TEST menu press Next.
4. MEMORY will be displayed. Press Enter.
5. Press Enter to select CHEM.
6. Press Next to select the type of test, LIPIDS for example.
7. Press Next to select the date/time of the test result you want to print.
8. Press Enter to print the selected number of copies of results.
9. Control results can be printed by selecting CONTROL instead of CHEM and then selecting the type of result as stated above.

4 Checking the System

Analyzer Check Strip

A check of the analyzer operation and optics can be performed using one of the two gray check strips. Two are included in the analyzer carrying case. The check strip verifies that the CardioChek PA 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 acceptable range by displaying PASSED. When the check strip is not in use, please 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

Check Strip

How to Use the Analyzer Check Strip:

1. Turn on the analyzer by pressing either button.
2. When INSTALL MEMO CHIP or RUN TEST is displayed, press Next until UTILITY is displayed. Press Enter.
3. Press Enter when CHECK STRIP is displayed.
4. Hold the check strip at the base and insert the check strip, ribbed side up, into the test strip slot when INSERT STRIP is displayed.
5. The analyzer should display PASSED. (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.
6. Press Next until EXIT is displayed. Press Enter.
7. Press Next until RUN TEST is displayed.
8. Press Enter. The analyzer is ready to run tests.

Note: If the analyzer displays FAILED:

1. Clean the CardioChek PA analyzer test strip slot (where the check strip is inserted into the analyzer). See Section 8, **Care and Cleaning**.
2. Inspect the check strip to make sure it is not dirty or damaged. Use the spare check strip and repeat.
3. See Section 9, **Troubleshooting** in this user guide.

5 Quality Control Testing

Quality Control

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 PA 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

Important: Check the expiration date printed on the control bottles. Do not use control solutions that have expired.

For performing a quality control test, see the instructions below.

To perform a control test you need:

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

How to Run a Quality Control Test

Refer to the instructions for use provided with your quality control materials.

If Quality Control Results Are Not in Range
IMPORTANT: Patient tests should not be performed until control results are within range.

1. Ensure test strip slot area is clean.
2. Make sure neither the test strips nor the controls are past the expiration date printed on the label.
3. Make sure the MEMo Chip matches the test strip lot.
4. Repeat the test again using fresh materials.
5. Call Customer Service for assistance.

6 Running a Test

Blood Testing

A test strip package insert is included with each box of test strips. Please read the test strip package insert and this section of the user guide completely and carefully before testing.

Testing Supplies

To perform a blood test you need:

- CardioChek PA analyzer
- PTS Panels test strips
- Lot-specific MEMo Chip
- Sterile, auto-disabling, single-use lancet
- Pipet or capillary blood collector
- Gauze or cotton balls
- Alcohol wipe

This analyzer requires whole blood for testing. Do not operate the analyzer in direct light. It is very important to keep the analyzer on a flat, stable surface and not move it during testing. See Section 8, **Care and Cleaning** for more information.

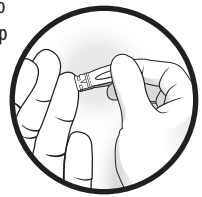
Helpful Hints on Getting a Good Drop of Blood

1. Instruct the patient to wash hands in warm, soapy water.
2. Rinse well and dry completely. If an alcohol wipe is used, let the finger air dry before testing. Clean gauze may be used to dry alcohol.
3. Warm the fingers to increase blood flow.
4. Let the arm hang down at the patient's side briefly to allow blood flow to the fingertips.

How to Obtain a Blood Sample from a Fingerstick

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

1. Clean the finger. Be sure the finger is completely dry.
2. Use a new, sterile, disposable lancet to puncture the skin.
3. Stick the finger on the side of the fingertip, instead of the center. See picture.
4. To get a drop of blood, gently apply pressure to the finger starting at the end of the finger closest to the hand and moving towards the tip. (Pressure should be intermittent and it is important not to milk the finger.) Lance the finger, wipe away the first drop of blood with gauze, and use the second blood drop for testing. The blood drop should be hanging down from the finger to make it easier to collect the sample with a pipet or capillary blood collector.



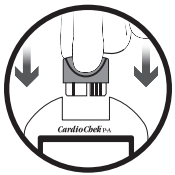
5. Follow the specific instructions found in the test strip package insert for each test for sample application and volume ranges. For reflectance tests, use of a pipet or capillary blood collector ensures a sufficient volume of blood has been applied to the test strip.
6. Make sure the test strip is inserted all the way into the test strip slot immediately before testing.
7. Use the test strip and lancet one time only. Only auto-disabling, single-use lancing devices may be used with this device. Dispose of properly.

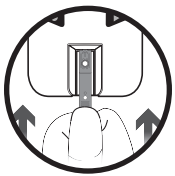
Precaution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines. All parts of the system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals.

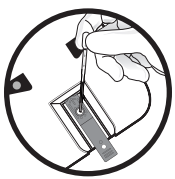
It is recommended that users refer to the following practice guidelines:
Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/bmbl5/. "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.

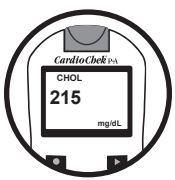
Quick Reference - How to Run a Test

1. Press either button to turn the analyzer on.
2. Remove the MEMo Chip from the box of test strips.
3. Insert the MEMo Chip into the port at the top of the analyzer with the finger notch facing up (with the lot code number facing down).
4. When INSERT STRIP is displayed, remove a test strip from the vial and immediately replace the cap.
5. Insert the strip. Ensure that the test strip is inserted fully and the display reads APPLY SAMPLE.
6. 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) onto the test strip.)
7. Hold the capillary tube by the bulb and position above the blood application window on the test strip. Use care to avoid touching the test strip with the capillary tube. Squeeze the bulb gently to deposit the entire sample on the strip.
8. Once the sample is applied, results will appear on the analyzer display in about 90 seconds depending on type of test strip.
9. Remove test strip and **dispose of properly.**
10. If the analyzer is idle for more than 3 minutes, it will count down 10 seconds and automatically turn off.









* Refer to each specific test strip package insert for sample volume and sample application instructions.
Each test strip is for a single test only. Do not reuse the test strips. Use a new test strip each time you test.

7 Memory

Test results are automatically stored in the CardioChek PA analyzer's memory. The analyzer can store up to 30 results of each chemistry and 10 results for control tests. The analyzer allows review of the results in order from the most recent to the oldest. Each result is displayed with time and date. Results stored in memory are not deleted when the batteries are changed.

How to Review Results Stored in Memory:

1. Press either button to turn on the analyzer. If the display reads INSTALL MEMO CHIP, go to Step 2. If the display reads INSERT STRIP, press Enter.
2. Press Next until MEMORY is displayed.
3. Press Enter. CHEM is displayed.
4. Press Enter, then Next to select the desired chemistry.
   Note: Until the chemistry has been run at least once, the test name is not displayed.
5. Press Enter to view the test result including time and date.
   a. To recall control results, press Next until EXIT is displayed. Press Enter. Press Next until CONTROL is displayed.
   b. Press Enter when the desired control test is displayed.
   c. For example, to review lipid panel results, from the CHEM display, press Next until LIPIDS is displayed, then Enter. The time and date will be displayed. Press Enter when the desired test time and date is displayed. Press Next to scroll through results.
6. To exit, press Next until the display reads EXIT, then press Enter. Repeat this step until you return to RUN TEST.

How to Clear Results Stored in Memory:

1. Press either button to turn on the analyzer. Wait for the display to read either INSTALL MEMO CHIP or INSERT STRIP.
2. Press Enter, then press Next until UTILITY is displayed. Press Enter.
3. Press Next until CLEAR MEMORY is displayed. Press Enter.
4. Press Next until the display reads CLEAR, YES. Press Enter. The display will read ERASE and then CLEAR MEMORY.
5. To exit, press Next until the display reads EXIT, then press Enter. Press Next until you return to RUN TEST.

8 Care and Cleaning

Storage and Handling

- Handle the CardioChek PA 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 50-104ºF (10-40ºC) and 20-80% Relative Humidity (RH). **Do not freeze.**
- If storage temperature is below 68ºF (20ºC) allow the device to warm to room temperature 68ºF (20ºC) 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.
- Do not scratch or damage the surface of the check strip.
- Please read the test strip package insert for storage and handling information that applies to each test strip.

Cleaning and Disinfection

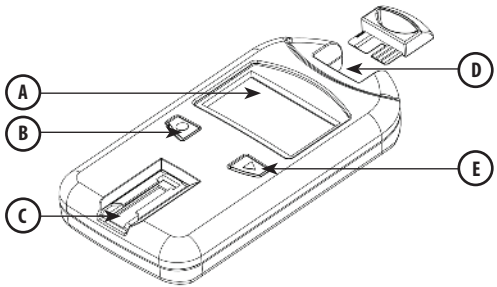
Cleaning and disinfection of analyzers that come in contact with blood or blood products is critical to avoid transmitting bloodborne pathogens between patients and healthcare professionals.

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. Please see references at the end of this section for further information.

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), concentration of active ingredients (0.25%) and with a contact time of 2 minutes. 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.** If you have any questions or need to know where to purchase the disinfectant wipes, call PTS Diagnostics Customer Service at 1-877-870-5610 (US) or +1-317-870-5610. There are a large number of distributors of this disinfectant. If you cannot obtain from the distributor who supplies your other supplies, please contact us for assistance.

The entire case surface should be cleaned and disinfected.



- **A** Display
- **B** Enter Button
- **C** Test Strip Slot (Optical Block and Glass)
- **D** MEMo Chip Port
- **E** Next Button

Cleaning Instructions

Cleaning removes visible soil, organic material, and most importantly, blood products. Always clean **before** disinfecting.

1. Please see picture above. Clean and disinfect all surfaces of this analyzer.
2. Obtain recommended wipes.
3. Using a fresh wipe, wring out excess liquid and carefully wipe to clean.
4. Allow to air dry or dry with cotton gauze.

Disinfection Instructions

After cleaning, the next step is to disinfect. Always both clean and disinfect.

1. Using a fresh wipe, wring the wipe to remove excess liquid and wipe all areas thoroughly.
2. Keep area wet for 2 minutes to ensure disinfectant remains in contact for a sufficient time to kill all bloodborne pathogens.
3. Allow to air dry completely.
   Note: It is important that the analyzer be thoroughly dry before using.
4. The optical glass should be carefully wiped clean with an alcohol wipe and dried with gauze to remove any residue from the disinfectant.
5. Inspect the glass and ensure it is clean when held at different angles. If it is not, repeat Step 4.

Following cleaning and disinfection, inspect the analyzer for the following signs of deterioration. These include:

- Scratches on optical glass
- Etching on optical glass
- Liquid under optical glass
  - liquid intrusion, or
  - condensation
- Loss of adhesion on optical glass
- Liquid under display lens
- Loss of adhesion on display lens
- Deterioration of painted surfaces (polymer crazing, cracking, swelling, softening, peeling, etc.)
- Any loose parts

IMPORTANT: Keep area wet with disinfectant for two minutes. **DO NOT** soak, saturate, or immerse the analyzer or allow liquid to collect on any surface. Always make sure the analyzer is dry before use.

After disinfection, user's gloves should be removed and hands should be thoroughly washed with soap and water before proceeding to the next patient.

The CardioChek PA analyzer has been validated for 11,001 cleaning and disinfection cycles. Please obtain a new analyzer after cleaning and disinfecting the analyzer 11,001 times or once the lifetime of the analyzer (3 years) has been reached, whichever comes first. The use of this analyzer beyond its anticipated lifetime is at the user's sole risk and discretion and is not recommended by the manufacturer.

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

If you have any questions, call PTS Diagnostics Customer Service.

Direct: +1-317-870-5610 • **Toll-free inside the US:** 1-877-870-5610
Fax: +1-317-870-5608

Email: customerservice@ptsdiagnostics.com • **Website:** ptsdiagnostics.com

References:

1. "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010). http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.
2. "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010). http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.
3. Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/bmbl5/. "Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.

9 Troubleshooting

Message or Issue	Probable Cause	What to Do
Desired language is not displayed.	Language has been set incorrectly.	Turn off analyzer. See Section 3, Setup - How to Reset the Language.
The wrong date and/or time is displayed.	Date and time have not been set correctly.	See Section 3, Setup - How to Set the Date and/or How to Set the Time.
FAILED is displayed during a check strip test.	Analyzer needs to be cleaned.	Wipe the test strip slot with a clean, damp, and lint-free cloth.
	Check strip is dirty or damaged.	Use spare check strip. If check strip still fails, call Customer Service.
TOO MUCH LIGHT	Test is being performed in direct light or outside.	Test inside, away from windows, and away from direct lamp light.
MEMO CHIP ERROR	MEMo Chip is defective.	Use another MEMo Chip from the same lot.
TEST ERROR	Insufficient sample has been added to test strip.	Test again with a new test strip and make sure the correct volume of sample is used.
LANGUAGE	Analyzer is new or language option has not been set.	See Section 3, Setup - Setting the Language.
TEST NOT ALLOWED	Test selected by MEMo Chip installed cannot be run on your analyzer.	Check MEMo Chip and make sure that the correct MEMo Chip is inserted. Call Customer Service.
LOW TEMP	Analyzer is below acceptable operating temperature.	Move to warmer environment and test after analyzer reaches proper temperature.
HIGH TEMP	Analyzer is above acceptable operating temperature.	Move to acceptable environment and test after analyzer reaches proper temperature.
INSTALL MEMO CHIP	MEMo Chip is not properly inserted or is defective.	Insert same or new MEMo Chip properly.
EXPIRED LOT	Test strips are expired, wrong MEMo Chip is inserted, or date is not set properly.	Check test strip expiration date and make sure correct MEMo Chip is inserted. Check date setting – see Section 3, Setup – How To Set the Date and/or How to Set the Time.

Message or Issue	Probable Cause	What to Do
REPLACE BATTERIES	Batteries need to be replaced.	Replace all batteries with new high-quality AAA batteries. (The analyzer will not run tests until batteries are replaced.)
TEST ABORTED	Test strip was not properly inserted or was removed before test was complete. Analyzer was moved during testing or not placed on a flat, stable surface.	Test again with a new test strip.
PRINT ERROR	Communication cable was improperly connected.	Check all connections. Reprint test results stored in memory.
	Printer cover is not closed properly. (Printer indicator light is red.)	Close printer cover correctly, ensuring that the printer indicator light is green. Reprint test results stored in memory.
	Labels/paper were not loaded in the printer.	See Printer System Setup/Operating System Instruction Sheet packaged with the printer.
Results are not as expected.	Test strips are improperly stored.	Repeat test using a different vial of test strips. Run controls and confirm that results are in range.
	Batteries are defective.	Change batteries.
	The analyzer was improperly stored.	Make sure the analyzer was not exposed to high or low temperatures or humidity and repeat test.
	Test strip insert slot is dirty.	Clean the test strip insert slot.
	MEMo Chip and test strips are not the same lot number.	Use MEMo Chip and test strips with the same lot number.

10 Interpreting Results

All test results must be assessed by a qualified medical professional. Depending on the analyte being assessed, high or low results may have medical consequences.

If the result reads > (greater than) or < (less than) or results are not as expected, always repeat the test correctly with a new unused test strip. If a test result is displayed that is not expected, consult the following table.

Message or Issue	Probable Cause	What to do
A displayed result reads < (less than) a value.*	Result is below the measuring range of the test. Analyzer has not been placed on a flat, stable surface while testing or has been moved during testing causing the test strip to slip out of position.	Repeat the test. Run controls and confirm that controls are in range.
A displayed result reads > (greater than) a value.*	Result is above the measuring range of the test. Analyzer has not been placed on a flat, stable surface while testing or has been moved during testing causing the test strip to slip out of position.	Repeat the test. Run controls and confirm that controls are in range.
TRIGS TOO HIGH LDL N/A	Lipid panel test triglycerides result was 400 mg/dL (4.52 mmol/L) or greater.	No action needed. LDL will not be calculated on samples with triglycerides of 400 mg/dL (4.52 mmol/L) or greater.

* See Measuring Range section of each test strip package insert for the measuring range for that specific test strip.

11 CLIA Information

General CLIA Information (US Only)

(Please read before testing)

1. CLIA-waived. Each laboratory or testing site using the PTS Panels test strips MUST have a CLIA Certificate of Waiver (or other CLIA operating license) before testing. To obtain a Certificate of Waiver or any other type of laboratory license, call your state health department or PTS Diagnostics at 1-877-870-5610 (Toll-free) or +1-317-870-5610 for an application (form CMS 116).
2. Before you start testing, carefully read all instructions, including quality control. Failure to follow instructions, including quality control instructions, will result in high complexity rating and subject the facility to all applicable CLIA requirements for high complexity testing. For complete information including performance, please refer to the product-specific package insert and user guide. The glucose and lipid panel test systems are currently CLIA waived. The original CLIA waiver was under the analyzer name BioScanner Plus.
3. CLIA-waived for whole blood (fingerstick and venous EDTA or heparin) testing only.

USA: Rx Only

12 Specifications

CardioChek PA Analyzer

Calibration Curve: Input from MEMo Chip per test strip lot
Batteries: 2 AAA 1.5 volt alkaline
Operating Temperature Range: 50-104°F (10-40°C)
Note: The analyzer temperature must be within the test strip temperature specifications to function as a system.
Humidity Range: Between 20 and 80% RH
Dimensions:
Width: 3.0 in (7.62 cm)
Length: 5.5 in (13.97 cm)
Height: 1.0 in (2.54 cm)
Weight (without batteries): 4-6 oz. (113.4 - 170.1 g)

PTS Panels Test Strips

Please read the instructions (package insert) included with the test strips for information specific to each chemistry.

Optional CardioChek/PTS Connect™ Printer/Power Supply

For complete details, refer to each printer's user guide.

13 Contact Information

Help

For assistance with the CardioChek PA test system, please contact PTS Diagnostics Customer Service (M-F, 8 a.m.- 8 p.m. US EST) or your local authorized CardioChek dealer.

PTS Diagnostics
4600 Anson Boulevard, Whitestown, IN 46075 USA

Direct: +1-317-870-5610 • **Toll-free inside the US:** 1-877-870-5610
Fax: +1-317-870-5608

Email: customerservice@ptsdiagnostics.com • **Website:** ptsdiagnostics.com

14 Warranty

CardioChek PA Analyzer Limited One-Year Warranty

PTS Diagnostics warrants to the original purchaser only, that the CardioChek PA analyzer shall be free of any defects in materials or workmanship for a period of one year from the date of original purchase. Activation of this warranty shall be conditioned upon completion and return of the warranty registration card to PTS Diagnostics.
If the analyzer becomes inoperative during this time, PTS Diagnostics will replace the analyzer with equivalent analyzer, at its option, at no cost to the purchaser. The warranty becomes void if the analyzer is modified, improperly installed or operation not in accordance with the user guide, damaged by accident, or neglect, or if any parts are improperly installed or replaced by the user.

Note: Removing or loosening screws from the back of the analyzer voids all warranties. There are no user serviceable parts inside the case.

15 Explanation of Symbols

Symbols


Consult instructions for use


Temperature limitation

In vitro diagnostic medical device

Serial number


Manufacturer


Date of manufacture

Catalog number

Authorized representative in the European Community


This product fulfills the requirements of European Directive 98/79/EC for *in vitro* diagnostic medical devices.


Product requires separate collection for electrical and electronic equipment per the WEEE Directive


Keep away from sunlight


Keep dry

Control


Humidity limitation

Batch code


Use by


Caution

Prescription required (USA only)

This product fulfills the requirements of UK Medical Device Regulations 2002 and Directive 98/79/EC on *in vitro* diagnostic medical devices (EU IVDD).

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pts Diagnostics

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Schiffgraben 41
30175 Hannover, Germany

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