

pts panels®

Multi-Chemistry Controls

For professional use with CardioChek® PA and
CardioChek® Plus professional analyzers

INTENDED USE

For use with PTS Panels® test strips as quality control materials to estimate precision and to detect systematic analytical deviations of your test system.

SUMMARY AND EXPLANATION

PTS Panels Multi-Chemistry controls contain cholesterol, triglycerides, and glucose, which react with test strips to produce color or an electrical current depending on the test strips used. The result for each level of control should be in the range specified on the quality control range card included with these materials. Controls should be run to verify the test system performance, when results are questionable, to comply with your facility's quality control requirements, or as required by local accrediting and regulatory bodies.

Note: HDL cholesterol results are reported when using multi-chemistry controls (Lot MC24 and up) on CardioChek® Plus version 1.09 analyzers and above. HDL cholesterol controls are required for all other CardioChek professional analyzers.

CHEMICAL COMPOSITION

PTS Panels Multi-Chemistry controls contain: glucose, glycerol, cholesterol, DL-β hydroxybutyric acid, preservatives (isothiazolones), and inert ingredients.

PRECAUTIONS

- For *in vitro* diagnostic use. Intended for professional use only.
- Do not eat or drink contents.
- Avoid contact with eyes or skin.
- Materials may be disposed of in normal trash.

STORAGE AND HANDLING

Store in a cool, dry place at room temperature of 20-30°C (68-86°F). May be stored in a refrigerator at 2-8°C (35-46°F). Do not freeze. Product is ready to use and is clear. Recap 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.

MATERIALS PROVIDED

- Two (2) vials of multi-chemistry controls (one each of Level 1 and Level 2)

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek PA or CardioChek Plus professional analyzer
- PTS Panels test strips and MEMO Chip® of same lot number

PROCEDURE

IMPORTANT: Read all instructions carefully before testing.

Note: Refer to your specific analyzer to identify the software version before testing (the version is displayed automatically when the analyzer is turned on). See each analyzer user guide for more details about finding the version information.

Multi-Chemistry Controls Test Procedure

CardioChek PA Analyzer and CardioChek Plus Analyzer (version 1.11 or below)

1. Press one of the two buttons to turn the analyzer ON.
2. Press the Next button until the display reads UTILITY.
3. Press the Enter button.
4. Press the Next button until RUN CONTROL is displayed.
5. Insert MEMO Chip then press Enter.

Note: Continue test procedure by following Steps 6-13.

CardioChek Plus Analyzer (Steps 1-5 apply to version 1.12 only)

1. Press one of the two buttons to turn the analyzer ON.
2. Press the Enter button to select QUALITY CONTROL from the Main Menu.
3. RUN CONTROL is displayed. Press Enter.
4. Analyzer display will read INSTALL MEMO CHIP.
5. Insert MEMO Chip that matches the lot of strips.

6. A lot number will appear on the display, followed by INSERT STRIP.
7. Insert the test strip into the analyzer.
8. Wait until analyzer displays APPLY SAMPLE.
9. Invert to mix controls (4-6 times).
10. Remove cap and turn bottle upside down straight above reflectance test strip sample application window or to the tip of the electrochemical test strip.
11. 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 and one drop of control solution to the tip of the electrochemical test strip.
12. Replace control vial cap.
13. Results will be displayed on screen.

Note: To skip the eGLU or lipid panel test when using the PTS Panels Lipid+eGLU smart bundle test strips, refer to CardioChek Plus professional analyzer user guide.

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

USA: RX ONLY

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

EXPECTED RESULTS

Results for the control should be in the range specified on the quality control range card. The most up-to-date control results are available on the PTS Diagnostics website: www.ptsdiagnostics.com. 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 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)

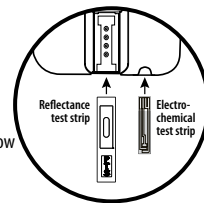
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EXPLANATION OF SYMBOLS



Use by



Batch code



In vitro diagnostic medical device



Catalog number



Consult instructions for use



Control



Manufacturer



Temperature limitation



Caution



Authorized representative in the European Community



Prescription required (USA only)



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