

PTS PANELS® HDL Cholesterol Controls

for use with CardioChek® Brand Test Systems

PS-007504E Rev. 4 02/07

INTENDED USE

For use with PTS PANELS HDL Cholesterol Test Strips as a quality control material to check for proper performance of your test system.

SUMMARY AND EXPLANATION

PTS PANELS HDL Cholesterol Controls contain cholesterol, which reacts with test strips to produce color. The darker the color, the higher the HDL cholesterol concentration. 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 or to comply with your facility's quality control requirements.

CHEMICAL COMPOSITION

PTS PANELS HDL Cholesterol Controls contain cholesterol, preservative (5-chloro-2-methyl-4-isothiazolin-3-one) and inert ingredients.

PRECAUTIONS

- Do not eat or drink contents.
- For *in vitro* diagnostic use.
- Avoid contact with eyes or skin.

STORAGE AND HANDLING

Store in a cool dry place at room temperature of 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. 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.

PROCEDURE

Materials provided:

Two (2) vials of HDL Cholesterol Control (one each of Level 1 and Level 2)

Materials required, but not provided:

- CardioChek Brand Analyzer
- PTS PANELS Test Strips and MEMo Chip™ of same lot number

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE TESTING

Test Procedure:

Please reference analyzer User Guide for the proper procedure on how to run a quality control test. The following procedure applies to CardioChek brand analyzers:

- 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 analyzer.
- Wait until analyzer displays APPLY SAMPLE.
- Invert to mix control.
- Remove cap and turn bottle upside down straight above test strip sample application window.
- Carefully, squeeze vial to deliver one drop of control solution to the test strip.
- Replace control vial cap.
- Results will be displayed in about two minutes.

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 website:

www.cardiochek.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 customer service and/or technical support call PTS Customer Service at **877-870-5610** (toll-free, inside US) or **317-870-5610**. email: inforequest@cardiochek.com

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Use By/
Expiration date

REF Catalog number



Batch Code
Lot number



Manufacturer



For in vitro
diagnostic use



Store at/
Temperature
limitation

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



Consult
instructions
for use