

PTS PANELS™ HDL Cholesterol Controls

for use with CardioChek™ Brand and BioScanner 2000™ Test Systems

PS-007504E Rev. 2 07/04

INTENDED USE

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

SUMMARY AND EXPLANATION

PTS PANELS HDL Cholesterol Controls contain cholesterol, which reacts with test strips to produce a color. The darker the color, the higher the HDL cholesterol concentration is. 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, skin and clothing.

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 until expiration date when stored according to directions.

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 or BioScanner 2000 Analyzer
PTS PANELS HDL Cholesterol Test Strips and
MEMo Chip of same lot number

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE TESTING

Test Procedure:

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

- 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 instrument 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 a minute.

EXPECTED RESULTS

Results for the control should be in the range specified on the Quality Control Range Card. 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).

CE 0197



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Explanation of Symbols



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