PTS PANELS® Multi-Chemistry Controls

for use with CardioChek® Brand Analyzers

PS-000597E Rev. 5 02/07

INTENDED USE

Use these controls with PTS PANELS Test Strips as quality control materials to check for proper performance of your analyzer.

SUMMARY AND EXPLANATION

PTS PANELS Multi-Chemistry Controls contain cholesterol, triglycerides, glucose, and ketone, which react with test strips to produce color. The darker the color, the higher the analyte 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.(Reference analyzer User Guide)

CHEMICAL COMPOSITION

PTS PANELS Multi-Chemistry Controls contain glucose, glycerol, cholesterol, DL-ß-Hydroxybutyric Acid, MIT (methyl isothiazoldone) 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 and is clear. Discard if appears cloudy. 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 Multi-Chemistry Control Materials (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 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 applyzers.

- 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 on the test strip.
- Replace control vial cap.
- Results will be displayed in about 2 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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C € 0197 This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic

medical devices

IVD



Consult instructions for use

Catalog number