

PTS PANELS™ Multi-Chemistry Controls

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

INTENDED USE

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

SUMMARY AND EXPLANATION

PTS PANELS Multi-Chemistry Controls contain cholesterol, triglycerides, glucose, and ketones, which reacts with test strips to produce a color. The darker the color is, 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. (Refer to analyzer User Guide)

CHEMICAL COMPOSITION

PTS PANELS Multi-Chemistry Controls contain glucose, glycerol, cholesterol, DL-β-Hydroxybutyric Acid, MIT (methyl isothiazolidone) 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 four 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 or BioScanner 2000 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 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.
- For most PTS PANELS Test Strips, results will be displayed in about a minute (Lipid Panel Test Strips in about 2 minutes).

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



Distributed by: **CLIAwaived.com™**
San Diego, CA 92121
tel 858-481-5031
toll free 888-882-7739
www.cliawaived.com



Use By/
Expiration date

REF

Catalog number



Batch Code/
Lot number



Manufacturer



For in vitro
diagnostic use



Store at /
Temperature
limitation

CE 0197

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



Consult
instructions for use