

pts panels®

Multi-Chemistry Self-Test Controls

INTENDED USE

For use with CardioChek® self-test and CardioChek® Plus self-test analyzers and PTS Panels® self-test strips as quality control materials to estimate precision and to detect systematic analytical deviations of your test system. For self-testing use only.

SUMMARY AND EXPLANATION

PTS Panels self-test 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, and when results are questionable.

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

CHEMICAL COMPOSITION

PTS Panels self-test multi-chemistry controls contain:

Glucose (from corn)	≥ 60 mg/dL
Glycerol (synthetic)	≥ 12.35 mg/dL
Cholesterol, (from sheep's wool)	≥ 140 mg/dL
DL-β hydroxybutyric acid (synthetic)	≥ 11 mg/dL
Preservatives (isothiazolones)	≤ 0.01%
Inert ingredients	

Note that levels are variable

PRECAUTIONS

- For *in vitro* diagnostic use. For self-testing use only.
- Do not eat or drink contents.
- Avoid contact with eyes or skin.
- Keep out of reach of children.

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. Unused materials may be disposed of in normal household trash.

MATERIALS PROVIDED

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

MATERIALS NEEDED BUT NOT PROVIDED

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

PROCEDURE

IMPORTANT: Read all instructions carefully before testing.

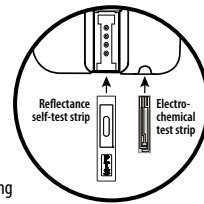
Multi-Chemistry Controls Test Procedure

- 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.
- Insert MEMO Chip that matches the lot of strips.
- At the RUN CONTROL analyzer display option, press ENTER.
- Insert the test strip into the analyzer.
- Wait until analyzer displays APPLY SAMPLE.
- Invert 4-6 times to mix control.
- Remove cap and turn bottle upside down straight above the strip sample application window or to the tip of the electrochemical test strip.

- 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.
- Replace control vial cap.
- Results will be displayed on screen.

Note: If testing PTS Panels self-test Lipid+eGLU smart bundle test strips, skip the eGLU test by pressing and holding the NEXT button when INSERT STRIP icon for the lipid panel test strip appears.

- Dispose of used test strip in normal household trash.



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).

If an unexpected result is obtained: Never take any decisions of medical relevance without first consulting your medical practitioner. When self-testing results are used for monitoring of an existing disease, you should **only** adapt the treatment if you have received the appropriate training to do so.

For assistance with the PTS Panels self-test 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)

+1-317-870-5610 (Direct)

+1-317-870-5608 (Fax)

E-mail: customerservice@ptsdiagnostics.com

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EXPLANATION OF SYMBOLS

	Use by		Manufacturer
	Batch code		Temperature limitation
	<i>In vitro</i> diagnostic medical device		Caution
	Catalog number		Authorized representative in the European Community
	Consult instructions for use		
	Control		
	This product fulfills the requirements of European Directive 98/79/EC for <i>in vitro</i> diagnostic medical devices		