

pts panels®

HDL Cholesterol

Controls

For professional use with CardioChek® PA and CardioChek® Plus (v1.08 and below) professional analyzers

INTENDED USE

For use with PTS Panels® professional test strips as quality control materials to estimate precision and to detect systematic analytical deviations of your test system.

SUMMARY AND EXPLANATION

PTS Panels professional 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, to comply with your facility's quality control requirements, or as required by local accrediting and regulatory bodies.

Note: CardioChek® Plus v. 1.09 professional analyzers and above do not require HDL cholesterol controls.

CHEMICAL COMPOSITION

PTS Panels self-test HDL cholesterol controls contain:

Glucose (from corn)	≥ 680 mg/dL
Glycerol (synthetic)	≥ 58.5 mg/dL
Cholesterol (from sheep's wool)	≥ 30 mg/dL
Preservatives (isothiazolones)	≤ 0.01%
Inert ingredients	

Note that levels are variable

PRECAUTIONS

- For *in vitro* diagnostic use. Intended for professional use only.
- Do not eat or drink contents.
- Avoid contact with eyes or skin.
- Materials may be disposed of in normal trash.

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. 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.

MATERIALS PROVIDED

- Two (2) vials of HDL cholesterol controls (one each of Level 1 and Level 2)

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek PA or CardioChek Plus professional analyzer
- PTS Panels professional test strips and MEMo Chip® of same lot number

PROCEDURE

IMPORTANT: Read all instructions carefully before testing.

HDL Cholesterol Controls Test Procedure

1. Insert MEMo Chip that matches the lot of strips.
2. Press one of the two buttons to turn the instrument ON.
3. Press the Next button until the display reads UTILITY.
4. Press the Enter button.
5. Press the Next button until RUN CONTROL is displayed.
6. At the RUN CONTROL analyzer display option, press Enter.
7. Insert the test strip into analyzer.
8. Wait until analyzer displays APPLY SAMPLE.
9. Invert to mix control.
10. Remove cap and turn bottle upside down straight above reflectance test strip sample application window.

11. 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.

12. Replace control vial cap.

13. Results will be displayed on screen.

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

Caution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.

USA: RX ONLY

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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).

For assistance with the PTS Panels professional HDL cholesterol 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		Prescription required (USA only)
	Control		
	This product fulfills the requirements of European Directive 98/79/EC for <i>in vitro</i> diagnostic medical devices		

