INTENDED USE
The CardioChek PA and CardioChek Plus test systems (consisting of the CardioChek PA and CardioChek Plus analyzers and PTS™ lipid panel test strips) are for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol, and triglycerides in venous whole blood and capillary whole blood from the fingertip and are intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders. A TC/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol are calculated by the CardioChek PA and CardioChek Plus analyzers.

SUMMARY
PTS Panels lipid panel test strips measure total cholesterol, HDL cholesterol, and triglycerides in whole blood with the CardioChek PA or the CardioChek Plus professional analyzer, and provide a quantitative result. PTS Panels test strips are designed for use with fresh, capillary (fingerstick) whole blood, or fresh venous whole blood collected in EDTA or heparin tubes. A MEMo Chip® is provided with each package of test strips and must be properly inserted into the analyzer before any test can be run. The MEMo Chip contains the test name, calibration curve, lot number, and test strip expiration date. After the test strip is inserted into the analyzer and blood applied to the test strip, test results are displayed in as little as 90 seconds.

PRINCIPLES OF THE TEST
When blood is applied to a test strip, the reagents react to produce color that is read by the analyzer using reflectance photometry. The amount of color produced is proportional to the concentration. The enzymatic reactions that occur are listed below.

- **Cholesterol**
  - Cholesterol ester + H₂O → Cholesterol + fatty acid
  - Cholesterol oxidase + peroxidase
  - 2H₂O₂ + 4-AAP + Disubstituted Aniline → Quinazoline dye + 4H₂O

- **HDL Cholesterol**
  - VLDL, LDL, plasma
  - Cholesterol esterase
  - Cholesterol oxidase
  - 2H₂O₂ + 4-AAP + Disubstituted Aniline
  - Quinazoline dye + 4H₂O

- **Triglycerides**
  - Triglyceride + H₂O → Glycerol + 3 fatty acids
  - Triglyceride hydrolysis
  - Glycerol kinase
  - ATP
  - Mg
  - Glycero phosphate oxidase
  - 2H₂O₂ + 4-AAP + N, N-disubstituted aniline
  - Quinazoline dye + 4H₂O

MATERIALS PROVIDED
- PTS Panels lipid panel test strips
- MEMo Chip (contains lot-specific test strip information)
- Instructions for use

MATERIALS NEEDED BUT NOT PROVIDED
- CardioChek PA or CardioChek Plus professional analyzers
- Quality control materials
- Lancets for fingerstick (or venous blood collection supplies)
- Alcohol wipes and gauze
- Capillary blood collector or other precision pipet for blood collection and application

CHEMICAL COMPOSITION
Each PTS Panels lipid panel test strip contains the following active ingredients:

- **Cholesterol Esterase** (Microorganism) ≤ 1.75 I.U.
- **Cholesterol Oxidase** (Microorganism) ≤ 1 I.U.
- **Peroxidase** (Horse Radish) ≤ 10 I.U.
- **4-aminomucomurpureine** ≤ 64 µg
- **Substituted aniline derivatives** ≤ 60 µg
- **Phosphotungstic acid** ≤ 0.3 mg
- **N, N-disubstituted aniline** ≤ 50 µg
- **Glycerol-3-Phosphate Oxidase** (Microorganism) ≤ 1.5 I.U.
- **Glycero Kinase** (Microorganism) ≤ 2.0 I.U.
- **ATP** (Microorganism) ≤ 50 µg
- **Lipoprotein lipase** (Microorganism) ≤ 4.5 I.U.

Test strips are contained in a desiccated vial to control moisture. Silica gel (not more than 5g) and molecular sieves are either in a desiccant packet or integrated into the vial.

STORAGE AND HANDLING
- Store test strip package in a cool, dry place at room temperature 68-86°F (20-30°C) or refrigerated at 35-46°F (2-4°C). Test strips must be brought to room temperature 68-86°F (20-30°C) before using. Do not freeze.
- Keep away from heat and direct sunlight.
- If a desiccant packet is included in the vial, do not remove or discard it.
- Always replace vial cap immediately after removing a test strip.
- Use test strip as soon as you have removed it from the vial.
- Keep the MEMo Chip in the original box that held the test strips.
- Store the test strips in the original vial. Do not combine with other test strips and do not store the MEMo Chip in the test strip vial.
- After opening, the test strips are stable until expiration date if vial is properly stored and always capped.

WARNINGS AND PRECAUTIONS
- **For in vitro diagnostic use.**
- PTS Panels lipid panel test strips can only be used in the CardioChek professional analyzers.
- Make sure the MEMo Chip and test strip lot numbers match. Never use a MEMo Chip from a different lot than the test strip.
- Out-of-date or expired strips cannot be used in your test system. Check vial for expiration date before use.
- Add all of the blood to the test strip at one time. If you do not get all of the blood on the strip, do not add blood to the same test strip. Test again with a new unused test strip and a fresh blood sample.
- Discard test strip after using. Test strips are to be read once. Never insert or re-use a used test strip.
- If you get an unexpected result, test again.
- Do not ingest.
- Users should adhere to Standard Precautions when handling or using this analyzer. All parts of the system should be considered potentially infectious and are capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007”, http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.
- The analyzer should be cleaned and disinfected after use on each patient. This test system may only be used for testing multiple patients when Standard Precautions and the manufacturer’s disinfection procedures are followed.
- Please refer to the analyzer user guide for cleaning and disinfection instructions. This procedure is important to prevent the potential transmission of infectious diseases.
- Only auto-disabling, single-use lancing devices may be used with this analyzer.

SPECIMEN COLLECTION AND PREPARATION
PTS Panels lipid panel test strips are designed for use with fresh capillary (fingerstick) whole blood or fresh venous whole blood collected in EDTA or heparin tubes. To obtain a drop of blood from a fingerstick, follow the steps below:

- **Use of lotions and handcreams should be avoided before testing.**
- Hands should be washed in warm water with antibacterial soap, rinsed and dried thoroughly.
- If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, disposable lancet to puncture the side of the fingertip.
- Wipe away the first drop of blood with a clean piece of gauze.
- Use of lotions and handcreams should be avoided before testing.
- Capillary blood collector or other precision pipet to collect blood.
- Discard used materials properly.

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

DIRECTIONS FOR USE - TESTING
IMPORTANT: Read all instructions carefully before testing.
For best results, test patient in a fasting state (no food or drink, except water, for at least 12 hours).

1. Insert the MEMo Chip that matches the lot number on the test strip and press one of the buttons to turn the analyzer ON.
2. Hold the test strip by the end marked “PTS”. Insert the opposite end of the test strip into the analyzer. Push the test strip in as far as it will go.
3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 35-40 µL of whole blood to the test strip blood application window.
4. In as little as 90 seconds, the results will appear on the display automatically on the analyzer. As necessary, press NEXT to view additional results. Remove and discard test strip. Do not add more blood to a test strip that has been used.
**EXPECTED VALUES**

The expected or reference ranges recommended are from the US National Cholesterol Education Program (NCEP) 2001 Guidelines and are:9

**Cholesterol (Total) Expected Values**
- Below 200 mg/dL (5.18 mmol/L) – desirable
- 200-239 mg/dL (5.18-6.20 mmol/L) – borderline high
- 240 mg/dL (6.21 mmol/L) and above – high

**HDL Cholesterol Expected Values**
- Below 40 mg/dL (1.04 mmol/L) – low HDL (High risk for CHD*)
- 60 mg/dL (1.55 mmol/L) and above – high HDL (Low risk for CHD*)

**Triglycerides Expected Values**
- Below 150 mg/dL (1.70-2.25 mmol/L) – borderline high
- 200-499 mg/dL (2.26-5.64 mmol/L) – high
- 500 mg/dL and above (5.65 mmol/L) – very high

**LDL Cholesterol Expected Values**
- Below 100 mg/dL (2.59 mmol/L) – optimal
- 100-129 mg/dL (2.59-3.35 mmol/L) – near optimal
- 130-159 mg/dL (3.36-4.12 mmol/L) – borderline high
- 160-189 mg/dL (4.13-4.90 mmol/L) – high
- 190 mg/dL and above (4.91 mmol/L) – very high

**MEASURING RANGE**

This test system will display numeric results in the following ranges:

- Cholesterol: 100-400 mg/dL (2.59-10.36 mmol/L)
- HDL Cholesterol: 20-120 mg/dL (0.52-3.11 mmol/L)
- Triglycerides: 50-500 mg/dL (0.57-5.65 mmol/L)

Results above the range will, “LOW” or “<100 mg/dL (2.59 mmol/L) (cholesterol),” “<20 mg/dL (0.52 mmol/L) (HDL cholesterol),” or “<50 mg/dL (0.57 mmol/L) (triglycerides).

**LIMITATIONS OF THE PROCEDURE**

Studies were performed to test for substances that may interfere with these tests. The results are as follows:

1. **Preservatives:** EDTA and heparin in venous blood collection tubes had no effect on the results of the test strip.
2. **Drugs:** Dopamine and methyldopa decreased the results of all the lipids.
3. **Metabolites:** Extremely high doses of ascorbic acid (Vitamin C) decreased the results of all the lipids.
4. **Hematocrit:** No hematocrit effect was observed for samples between 30 and 45% HCT.
5. **Neonatal Use:** This product has not been tested using neonatal blood. This test system should not be used with these samples.
6. **Hand Lotions/Cosmetics:** Cosmetics such as handcreams or lotions often contain glycerol. Use of these products may cause inaccurate results.
7. **Displayed results are rounded.**

**REFERENCE**


**CUSTOMER SERVICE**

For assistance with the PTS Diagnostics products, please contact PTS Diagnostics Customer Service (M-F 6 a.m. - 9 p.m. EST) at 1-877-870-5610 (Toll-free inside the USA) or 1-317-870-5610 (Direct) +1-877-870-5608 (Fax)

E-mail: customerservice@ptsdiagnostics.com

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