**INTENDED USE**

The CardioChek PA and CardioChek Plus test systems (consisting of the CardioChek PA and CardioChek Plus professional analyzers and PTS Panels® CHOL+HDL test strips) is for the quantitative determination of total cholesterol and HDL (high density lipoprotein) cholesterol in venous whole blood and capillary whole blood from the fingertip and is 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).
- A CHOL/HDL ratio is calculated by the CardioChek PA and CardioChek Plus analyzers.

**SUMMARY**

PTS Panels CHOL+HDL test strips measure total cholesterol and HDL cholesterol in whole blood with the CardioChek PA or CardioChek Plus analyzers, and provide a quantitative result. 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 blood reacts 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 esterase**
  - Cholesterol ester + H₂O → Cholesterol + fatty acid
- **Cholesterol oxidase**
  - Cholesterol + H₂O + O₂ → Cholesterol-4-en-3-one + H₂O₂
  - **Peroxidase**
    - 2H₂O₂ + 4-AAP + Disubstituted Aniline → Quinoneimine dye + 4H₂O

### HDL Cholesterol

- **VLDL, LDL, depleted plasma**
  - Cholesterol + fatty acid
- **Cholesterol esterase**
  - Cholesterol ester + H₂O → Cholesterol + fatty acid
  - **Cholesterol oxidase**
    - Cholesterol + H₂O + O₂ → Cholesterol-4-en-3-one + H₂O₂
  - **Peroxidase**
    - 2H₂O₂ + 4-AAP + Disubstituted Aniline → Quinoneimine dye + 4H₂O

**MATERIALS PROVIDED**

- PTS Panels CHOL+HDL test strips
- MEMo Chip (contains lot-specific test strip information)
- Instructions for use

**MATERIALS NEEDED BUT NOT PROVIDED**

- CardioChek PA or CardioChek Plus professional analyzer
- Quality control materials
- Lancets for fingertip (or venous blood collection supplies)
- Alcohol wipes and/or gauze
- Capillary blood collector or other precision pipet for blood collection and application

**CHEMICAL COMPOSITION**

Each PTS Panels CHOL+HDL test strip contains the following active ingredients:

- **Cholesterol Esterase** (Microorganism) ≥ 1.35 I.U.
- **Cholesterol Oxidase** (Microorganism) ≥ 1.3 I.U.
- **Peroxidase** (Horseradish) ≥ 2 I.U.
- 4-aminoantipyrine ≥ 24 µg
- Substituted aniline derivatives ≥ 60 µg
- Magnesium chloride hexahydrate ≥ 500 µg
- D-Sorbitol ≥ 3 mg
- Tris Buffer ≥ 150 µg
- Dextran Sulfate ≥ 200 µg
- PVA (polyvinyl alcohol) ≥ 300 µg
- MO PS ≥ 200 µg
- Sucrose ≥ 500 µg

**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 (2-8°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.
- Always replace vial cap immediately after removing a test strip.
- Discard 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 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 CHOL+HDL test strips can only be used in the CardioChek PA or CardioChek Plus 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.
- Do not use if vial cap is open or damaged.
- 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 test strip, do not add additional 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 read 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 device. All parts of the system should be considered potentially infectious and 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/2007/hip/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 transmission of infectious diseases.
- Only auto-disabling, single-use lancing devices may be used with this device.

**SPECIMEN COLLECTION AND PREPARATION**

PTS Panels test strips are designed for use with fresh capillary (fingertip) whole blood. To obtain a drop of blood from a fingertip, follow the steps below:

- **Use of lotions and hand creams should be avoided before testing.**
  - Hands should be washed in warm water with antibacterial soap and rinsed and dried thoroughly.
  - Clean the fingertip with alcohol. Be sure that the alcohol dries completely before sticking the finger.
  - Use a sterile, auto-disabling, single-use lancet to puncture the side of the fingertip.
  - Wipe away the first drop of blood with a clean piece of gauze.
  - Gently, without force, apply pressure to the fingertip to accumulate a drop of blood.
  - Excessive squeezing of the finger may alter test results.
  - See the “TESTING” section for information on how to apply the blood to the test strip.
  - 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**

1. Insert the MEMo Chip that matches the lot number on the test strip vial and press one of the buttons to turn the analyzer ON.
2. Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the test strip into 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 30 µL of whole blood to the test strip blood application window.
4. In as little as 90 seconds, the cholesterol result will appear on the display. 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.

To verify that enough blood has been applied to the test strip, after testing is completed, remove test strip and check back of test strip. If areas are not completely and evenly colored, discard test strip and test again. See diagram.
**HDL Cholesterol Expected Values**

1. Results are below.

Studies were performed to test for substances that may interfere with these tests. The result for any test, test again with a new unused test strip. If you get a result of one of these results, or an unexpected (cholesterol) or “>100 mg/dL (2.59 mmol/L)” (HDL cholesterol).

Results above these ranges will read, “HIGH” , “>400 mg/dL (10.36 mmol/L)” (cholesterol) or “<15 mg/dL (0.39 mmol/L)” (HDL cholesterol).

100-400 mg/dL (2.59-10.36 mmol/L)

*CHD - Coronary Heart Disease

**Cholesterol (Total) Expected Values**

- Below 200 mg/dL (5.18 mmol/L) – desirable
- 200-239 mg/dL (5.18-6.20 mmol/L) – borderline to 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**)

*CHD - Coronary Heart Disease

**EXPECTED VALUES**

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

- Cholesterol (Total) Expected Values
- HDL Cholesterol Expected Values

**PERFORMANCE CHARACTERISTICS**

1. ACCURACY: Results from clinical studies comparing the PTS Panels test strips to the Cholesterol Reference Method Laboratory Network (CRLMN) serum methods are listed below:

**PTS Panels Cholesterol Test Strips vs. Abell-Kendall Traceable Method**

<table>
<thead>
<tr>
<th>n</th>
<th>range of samples tested:</th>
<th>y = 1.01x - 1.83</th>
<th>r = 0.91</th>
</tr>
</thead>
<tbody>
<tr>
<td>125</td>
<td>125 to &gt;400 mg/dL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PTS Panels HDL Cholesterol Test Strips vs. Abell-Kendall Method**

<table>
<thead>
<tr>
<th>n</th>
<th>range of samples tested:</th>
<th>y = 1.01x - 4.1</th>
<th>r = 0.89</th>
</tr>
</thead>
<tbody>
<tr>
<td>87</td>
<td>&lt;25 to 80 mg/dL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The PTS Panels CHOL+HDL test strips were run by professionals on a CardioChek PA analyzer and the results were compared to results from an automated analyzer. The results are listed by test as follows:

**Cholesterol Comparison**

<table>
<thead>
<tr>
<th>n</th>
<th>range of samples tested:</th>
<th>y = 1.023x - 2.95</th>
<th>r = 0.914</th>
</tr>
</thead>
<tbody>
<tr>
<td>101</td>
<td>117 to 370 mg/dL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Bias at 200 mg/dL = + 0.85% Bias at 240 mg/dL = + 1.09%

**HDL Cholesterol Comparison**

<table>
<thead>
<tr>
<th>n</th>
<th>range of samples tested:</th>
<th>y = 1.061x - 2.89</th>
<th>r = 0.933</th>
</tr>
</thead>
<tbody>
<tr>
<td>121</td>
<td>24 to 79 mg/dL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Bias at 40 mg/dL = -1.15% Bias at 60 mg/dL = + 1.26%

The PTS Panels CHOL+HDL test strips compare well to the PTS Panels cholesterol and HDL cholesterol test strips.

2. PRECISION: Laboratory professionals tested two levels of whole blood for cholesterol and HDL cholesterol using PTS Panels CHOL+HDL test strips. The following results were obtained:

**Cholesterol**

No. of Observations (n) | 20 | 20 | 20 |
Mean Chol Conc. (mg/dL) | 208.6 | 221.3 | 237.5 |
Std. Deviation (mg/dL) | 5.03 | 4.29 | 6.92 |
Coefficient of Variation (%) | 2.41 | 1.94 | 2.92 |

**HDL Cholesterol**

No. of Observations (n) | 20 | 20 |
Mean HDL Conc. (mg/dL) | 36.55 | 60.55 |
Std. Deviation (mg/dL) | 1.10 | 1.05 |
Coefficient of Variation (%) | 3.01 | 1.73 |

This product meets NCEP Guidelines for total cholesterol and HDL cholesterol.

3. INTERFERENCE: See Limitations Section.

**REFERENCES**