PTS PANELS® CHOL+HDL+GLU Panel Test Strips

for Professional Use with CardioChek® P•A and CardioChek® Plus Analyzers

INTENDED USE

PTS PANELS CHOL+HDL+GLU Test Strips measure Total cholesterol, HDL cholesterol and Glucose in whole blood. Lipid measurements are used in the diagnosis and treatment of lipoprotein metabolism and lipid disorders (such as diabetes mellitus), atherosclerosis, and various renal and liver diseases. Glucose measurements are used in the management of carbohydrate metabolism disorders. Use this product at the frequency your doctor recommends testing for cholesterol and HDL cholesterol. This does not replace a glucose meter.

SUMMARY

CHOL+HDL+GLU Test Strips measure Total cholesterol, HDL cholesterol and Glucose in whole blood with the CardioChek P•A or CardioChek Plus analyzers. 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 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 strip, test results are displayed in about two minutes.

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 oxidase**
- **Peroxidase**

2H2O2 + 4-AAP + Disubstituted Aniline → Quinoneimine dye + 4H2O

**HDL Cholesterol**

- **Cholesterol esterase**
- **Cholesterol oxidase**
- **Peroxidase**

2H2O2 + 4-AAP + Disubstituted Aniline → Quinoneimine dye + 4H2O

**Glucose**

- **Beta-D-Glucose oxidase**
- **Peroxidase**

2H2O2 + 4-AAP + Disubstituted Aniline → Quinoneimine dye + 4H2O

MATERIALS PROVIDED

- Vial of test strips and desiccant
- MEMo Chip (contains lot-specific test strip information)
- Instructions

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek P•A or CardioChek Plus analyzer
- Quality Control Materials
- Lancets for fingerstick (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 CHOL+HDL+GLU Test Strip contains the following active ingredients:

- Cholesterol Esterase (Microorganism) ≥ 1.75 I.U.
- Cholesterol Oxidase (Microorganism) ≥ 10 I.U.
- Peroxidase (Horseradish) ≥ 0.3 mg
- 4-Aminoantipyrine ≥ 3.64 µg
- Substituted aniline derivatives ≥ 60 µg
- Phosphorunginic acid ≥ 20.3 mg
- N,N-disubstituted aniline ≥ 50 µg
- Glucose oxidase (Aspergillus niger) ≥ 2.02 I.U.

Each vial contains not more than 5g silica gel desiccant.

STORAGE AND HANDLING

- Store test strip package in a cool, dry place at room temperature of 68-86°F (20-30°C). Strips may be stored in a refrigerator at 35-46°F (2-8°C), but must be brought to room temperature before using. Do not freeze.
- Keep away from heat and direct sunlight.
- Do not remove or discard the desiccant packet in the vial.
- 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 either in the analyzer or stored with the original lot of 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.

PRECAUTIONS

- For in vitro diagnostic use.
- CHOL+HDL+GLU Test Strips can only be used in the CardioChek P•A 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.
- Out-of-date or expired strips cannot be used in your test system. Check vial for expiration date.
- 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 strip. Test again with a new unused test strip and fresh blood sample.
- Discard test strip after using. Strips are to be read once. Never insert or read a used test strip.
- Do not ingest.

SPECIMEN COLLECTION AND PREPARATION

PTS PANELS Test Strips are designed for use with fresh capillary (fingerstick) whole blood. Fresh venous whole blood collected in EDTA or heparin tubes is also an acceptable sample. To obtain a drop of blood from a fingerstick, follow the steps listed 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.
- 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.
- 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.

TESTING

IMPORTANT: Read all instructions carefully before 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 strip into analyzer. Push the 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 about two minutes, the cholesterol result will appear on the display. (On the CardioChek P•A, press the NEXT button to display HDL Cholesterol. To display Glucose, press the NEXT button again. All results will automatically appear on one screen on the CardioChek Plus analyzer.) Remove and discard 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 strip and check back of strip. If areas are not completely and evenly colored, discard strip and test again. See diagram.

TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL) or in millimoles per liter (mmol/L). The mg/dL measurement is a US version, while mmol/L is used in many countries around the world. The CardioChek P•A and CardioChek Plus are preset to US units by the manufacturer. No calculation of results is necessary. To change to INTL (mmol/L) units, please see CardioChek P•A or CardioChek Plus User Guide.

Manufactured by
Polymer Technology Systems, Inc.
Indianapolis, IN 46268 USA
PTC CUSTOMER SERVICE (877) 870-5610 (toll-free inside the U.S.)
(317) 870-5610, FAX (317) 870-5608
QUALITY CONTROL TESTS

Quality Control tests are used to ensure that the total system (analyzer, strips, MEMo Chip) is working properly and that the test results are accurate and reliable within the limits of the system. Users should run controls when results are questionable or to comply with their own facility's quality control requirements. See the CardioChek P•A or CardioChek Plus User Guide for instructions on how to run controls. The CardioChek P•A and CardioChek Plus are factory calibrated before they are packaged. Use the Check Strip supplied to verify that the analyzer’s electronics and optics are working properly. The Check Strip is NOT a Quality Control test. Please refer to the CardioChek P•A or CardioChek Plus User Guide for the proper procedure to be used to perform a Quality Control test.

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**
- Below 200 mg/dL (5.18 mmol/L) – desirable
- 200-239 mg/dL (5.18-6.2 mmol/L) – borderline high
- \( y = 0.983x + 5.64 \) (0.92-0.99 correlation) and above – high

**HDL Cholesterol Expected Values**
- Below 40 mg/dL (1.04 mmol/L) – low HDL (High risk for CHD*)
- \( y = 1.02x - 2.25 \) (0.90 correlation)

**Glucose Expected Values**
- Above 40 mg/dL (1.04 mmol/L) – low HDL (High risk for CHD*)
- \( y = 0.94x + 0.01 \) (0.98 correlation)

* CHD - Coronary Heart Disease

Glucose levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise. Your physician or healthcare professional will discuss “target values” that is, highs and lows specifically appropriate for you. A glucose level below 50 mg/dL (2.78 mmol/L) or exceed 240 mg/dL (13.32 mmol/L) may indicate a serious medical condition. If your test result should fall below 50 mg/dL (2.78 mmol/L) or exceed 240 mg/dL (13.32 mmol/L), you should contact your physician or healthcare professional as soon as possible. Expected values are for a fasting person, who does not have diabetes.

**LIMITATIONS OF THE PROCEDURE**

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

1. **PRESERVATIVES:** Blood samples preserved with Fluorde or Oxalate should not be used for testing with this system. EDTA and heparin tubes are appropriate for collection of venous blood.
2. **DRUGS:** Dopamine and methylmopina decreased the results of HDL cholesterol.
3. **METABOLITES:** Extremely high doses of ascorbic acid (Vitamin C) may decrease HDL results. Normal medication dosages, stress or exercise. Your physician or health-care professional will discuss “target values” specifically appropriate for you. A glucose level below 50 mg/dL (2.78 mmol/L) or exceed 240 mg/dL (13.32 mmol/L) may indicate a serious medical condition. If your test result should fall below 50 mg/dL (2.78 mmol/L) or exceed 240 mg/dL (13.32 mmol/L), you should contact your physician or healthcare professional as soon as possible. Expected values are for a fasting person, who does not have diabetes.

**MEASURING RANGE**

**CHOL+HDL+GLU Test Strips** will display numeric results in the following ranges:

- Cholesterol: 100 - 400 mg/dL (2.59-10.36 mmol/L)
- HDL Cholesterol: 15 - 100 mg/dL (0.39-2.59 mmol/L)
- Glucose: 20 - 600 mg/dL (1.11-33.3 mmol/L)

Results below the range will read, “<___” (less than the measuring range). Results above this range will be used to perform a Quality Control test.

**PERFORMANCE CHARACTERISTICS**

1. **ACCURACY:** Results from clinical studies comparing the PTS PANELS Test Strips to the Cholesterol Reference Method Laboratory Network (CRMLN) serum methods and to automated glucose hexokinase method follow:

   - **PTS PANELS Cholesterol** vs. Abell-Kendall traceable method
     - \( n = 125 \) samples
     - range of samples tested: 125 to >400 mg/dL
     - \( y = 1.01x - 1.83 \) (r = 0.91 correlation)
   - **PTS PANELS HDL Cholesterol** vs. Abell-Kendall method run by a CRMLN laboratory
     - \( n = 87 \) samples
     - range of samples tested: <25 to 80 mg/dL
     - \( y = 1.10x - 4.1 \) (r = 0.99 correlation)
   - **PTS PANELS Glucose** vs. Automated Hexokinase method
     - number of patients = 120
     - slope = 0.951
     - y-intercept = 5.36
     - r = 0.99

   The CHOL+HDL+GLU Test Strips were run by professionals on a CardioChek P•A and the results were compared to were compared to a commercially available automated laboratory method. The results are listed by test as follows:

   - **Cholesterol Comparison**
     - \( n = 62 \) samples
     - range of samples tested: 113 to 297 mg/dL
     - \( y = 0.995x + 6.86 \) (r = 0.903 correlation)

   When cholesterol results were classified according to NCEP criteria, 93.5% were correctly classified. Of the misclassified results, 1.8% were incorrectly low and 4.8% incorrectly high, which means a small percentage of the time your cholesterol may be higher than the reading you obtain.

   - **HDL Cholesterol Comparison**
     - \( n = 61 \) samples
     - range of samples tested: 26 to 79 mg/dL
     - \( y = 1.02x - 2.25 \) (r = 0.90 correlation)

   - **Glucose Comparison**
     - \( n = 62 \) samples
     - range of samples tested: 53 to 364 mg/dL
     - \( y = 0.94x + 0.01 \) (r = 0.98 correlation)

   The CHOL+HDL+GLU Test Strips compare well to automated laboratory methods.

2. **PRECISION:** Laboratory professionals tested multiple levels of whole blood for cholesterol, HDL cholesterol, and glucose using CHOL+HDL+GLU Test Strips. The following results were obtained:

   - **Cholesterol**
     - \( n = 20 \)
     - Mean Chol Conc. (mg/dL) = 278.5
     - Std. Deviation (mg/dL) = 6.9
     - Coefficient of Variation (%) = 2.6
   - **HDL Cholesterol**
     - \( n = 20 \)
     - Mean HDL Conc. (mg/dL) = 27.8
     - Std. Deviation (mg/dL) = 1.9
     - Coefficient of Variation (%) = 6.9
   - **Glucose**
     - \( n = 20 \)
     - Mean Glucose Conc. (mg/dL) = 28.5
     - Std. Deviation (mg/dL) = 2.3
     - Coefficient of Variation (%) = 8.4

**CLIA INFORMATION (US only)**

Complexity Categorization: Waived

**AVAILABLE**

REF/CAT NO.  | DESCRIPTION
------------|------------------
1708        | CardioChek P•A Analyzer
2700        | CardioChek Plus Analyzer
2412        | CHOL+HDL+GLU Panel Test Strips, 15 count
0722        | PTS PANELS Multi-Chemistry Controls – Level 1 & Level 2
0722        | PTS PANELS HDL Cholesterol Controls – Level 1 & Level 2

**REFERENCES**


**CUSTOMER SERVICE**

PTS Customer Service is available to answer questions. Outside Customer Service hours, please contact your healthcare professional.

(877) 870-5610 (M-F toll-free inside the USA)
(317) 870-5610, FAX (317) 870-5608
E-mail: info@cardiocheck.com

The CardioChek P•A, CardioChek Plus, and PTS PANELS CHOL+HDL+GLU Test Strips are manufactured in the US by Polymer Technology Systems, Inc., Indianapolis, IN 46268.

Copyright © 2014 by Polymer Technology Systems, Inc.

**Explanation of Symbols**

<table>
<thead>
<tr>
<th>Use By/</th>
<th>Catalog number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiration date</td>
<td></td>
</tr>
<tr>
<td>File number</td>
<td></td>
</tr>
<tr>
<td>Consult instructions for use</td>
<td></td>
</tr>
<tr>
<td>Batch Code/</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>Lot number</td>
<td>Store at/Temperature limitation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>REF</th>
<th>Catalog number</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>IVD</td>
<td>Store at/Temperature limitation</td>
</tr>
</tbody>
</table>

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