PTS PANELS CHOL+GLU Test Panel Test Strips
for use with CardioChek P+A™ Analyzer

INTENDED USE
PTS Panels CHOL+GLU Test Panel test strips are intended to measure cholesterol and glucose in whole blood on a CardioChek P+A analyzer. The test strips are intended to be used by healthcare professionals and individuals at home to measure blood cholesterol and glucose. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Glucose measurements are used in the management of carbohydrate metabolism disorders. Those testing at home should use this product at the frequency that their doctor recommends cholesterol testing. This does not replace a glucose meter.

SUMMARY
PTS PANELS CHOL+GLU Test Panel test strips measure total cholesterol, and glucose in whole blood with the CardioChek P+A analyzer. 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.

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 analyzer
- Quality Control Materials
- Lancets for fingerstick (or venous blood collection supplies)
- Alcohol wipes and/or gauze
- Capillary Blood Collectors or other precision pipet for blood collection and application

CHEMICAL COMPOSITION
Each CHOL+GLU Test Panel test strip contains the following active ingredients:
- Cholesterol Esterase (Microorganism) 2.0 I.U.
- Cholesterol Oxidase (Microorganism) 2.0 I.U.
- Peroxidase (Horseradish) 2.0 I.U.
- 4-aminoantipyrine 15 µg
- N,N-disubstituted aniline 15 µg

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.
- Keep the MEMo Chip either in the analyzer or stored with the original lot of strips.
- Always replace vial cap immediately after removing a test strip.
- Do not remove or discard the desiccant packet in the vial.
- Keep away from heat and direct sunlight.
- Store test strip package in a cool, dry place at room temperature of 68-86°F (20-30°C). Strips may be freeze.

PRECAUTIONS
- For in vitro diagnostic use.
- CHOL+GLU Test Panel test strips can only be used in the CardioChek P+A analyzer.
- 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.
- Remove strip after testing and check back side of reaction area. Reaction area should be completely and evenly colored. If the area is not completely and evenly colored, discard the used test strip and test again.

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 handcreams should be avoided before testing.
- Rinses should be washed in warm water with antibacterial soap and rinsed and dried thoroughly.
- If you wipe the finger tip 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.
- Discard used materials properly.

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

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 25-30 µL of whole blood to the test strip blood application window.

4. In about two minutes, the CHOL result will appear on the display. To display GLU, press the (NEXT) button. Remove and discard strip. DO NOT add more blood to a test strip that has been used.

ADDITIONAL CONSIDERATIONS
1. If no result is displayed, make sure:
   - Enough blood was added to the test strip to completely fill the blood application window.
   - Analyzer is ON. (If it won't turn ON, refer to analyzer User Guide section on changing batteries.
   - MEMo Chip is properly installed in port.
   - Analyze User Guide Troubleshooting section for additional help.

2. If you get a reading of <___, >___ or any unexpected result, test again.


4. To verify enough blood has been applied to the test strip, remove strip after testing and check back side of reaction area. Reaction area should be completely and evenly colored. If the area is not completely and evenly colored, discard the used test strip and test again.

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 is 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 User Guide.

Manufactured by
Polymer Technology Systems, Inc.
Indianapolis, IN 46268 USA

CUSTOMER SERVICE (877) 870-5610 (toll-free inside the U.S.)
(317) 870-5610, FAX (317) 870-5608
Glucose

1. ACCURACY:

- Bias at 80 mg/dL = -4.93%
- Bias at 128 mg/dL = -2.51%

The CHOL+GLU Test Panel test strips compare well to the PTS PANELS Cholesterol and Glucose Test Strips.

2. PRECISION: Laboratory professionals tested two levels of whole blood for cholesterol and glucose using CHOL+GLU Test Panel test strips. The following results were obtained:

<table>
<thead>
<tr>
<th>Cholesterol</th>
<th>No. of Observations (n)</th>
<th>20</th>
<th>20</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Chol Conc. (mg/dL)</td>
<td>158.1</td>
<td>196.7</td>
<td>217.4</td>
<td></td>
</tr>
<tr>
<td>Std. Deviation (mg/dL)</td>
<td>9.1</td>
<td>11.7</td>
<td>8.1</td>
<td></td>
</tr>
<tr>
<td>Coefficient of Variation (%)</td>
<td>5.76</td>
<td>5.95</td>
<td>3.73</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Glucose</th>
<th>No. of Observations (n)</th>
<th>20</th>
<th>20</th>
<th>20</th>
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<tbody>
<tr>
<td>Mean Glu Conc. (mg/dL)</td>
<td>44.8</td>
<td>59.0</td>
<td>249.5</td>
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<tr>
<td>Std. Deviation (mg/dL)</td>
<td>3.9</td>
<td>3.2</td>
<td>8.2</td>
<td></td>
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<tr>
<td>Coefficient of Variation (%)</td>
<td>8.71</td>
<td>5.42</td>
<td>3.29</td>
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</table>

3. INTERFERENCE: See Limitations Section.

CLIA INFORMATION (US only)

Complexity Categorization: Waived

REFERENCES


CUSTOMER SERVICE

Customer Service is available to answer questions regarding the CardioChek P+A and CHOL+GLU Test Panel Test Strips. Outside Customer Service hours, please contact your healthcare professional. (317) 870-5610, FAX (317) 870-5608

E-mail inforequest@cardiochek.com

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

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per IVDD 98/79/EC

MDSS GmbH
D-30163 Hannover
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| 0197 |

Explanation of Symbols

- Use By/Expiration date
- Catalog number
- Consult instructions for use
- Manufacturer
- Store at/Temperature limitation

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