PTS PANELS™ LDL Cholesterol Test Strips

for use with CardioChek™ PA Test Systems

INTENDED USE
PTS PANELS LDL Cholesterol Test Strips provide a quantitative measurement of LDL (low density lipoprotein) cholesterol in whole blood. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This system is intended for professional use.

SUMMARY
Low density lipoproteins (LDL) are also sometimes called “bad cholesterol.” Elevated LDL cholesterol is a risk factor for coronary artery disease because it clogs the arteries and reduces blood flow. The National Cholesterol Education Program Adult Treatment Panel (ATP III) lists elevated LDL cholesterol as a primary criterion for treatment.

To measure LDL with this system, the MEMo Chip™ provided with each package of test strips 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. A test strip is then inserted into the analyzer and blood applied to the strip. LDL test results are displayed in about two minutes.

PRINCIPLES OF THE TEST
LDL Cholesterol test results are based on a reading of light reflected off a test strip that has changed color after blood is applied. The intensity of the color is directly proportional to the concentration of LDL cholesterol in the sample. The analyzer converts this reading into a LDL cholesterol result and displays it. This test, which selectively measures LDL cholesterol, is an enzymatic columniform test based on the “Trend Method” for the determination of cholesterol. In the presence of oxygen, cholesterol is oxidized by cholesterol oxidase to cholesterol 4-en-one and hydrogen peroxide. In the presence of peroxidase, hydrogen peroxide reacts with 4-aminoantipyrine and N,N-disubstituted aniline to form a blue dye.

Cholesterol esters → Surfactants → LDL cholesterol esters + non-LDL cholesterol esters

LDL-cholesterol esters → Cholesterol Esterase → LDL Cholesterol + free fatty acids

LDL-Cholesterol + O2 → Cholesterol Oxidase → Cholesterol-4-en-one + H2O2

2H2O2 + 4-AAP + N,N-disubstituted aniline → Quinoneimine dye + 4H2O

MATERIALS PROVIDED
• PTS PANELS LDL Cholesterol Test Strips
• MEMo Chip (contains lot-specific test strip information)
• Instructions

MATERIALS NEEDED BUT NOT PROVIDED
• CardioChek™ PA analyzer
• Quality Control materials
• Lancets for fingerstick (or venous blood collection supplies)
• Alcohol wipes and/or gauze
• Capillary Blood Collector / Capillary Tube or other precision pipet for blood collection and application

CHEMICAL COMPOSITION
Each LDL Cholesterol Test Strip contains the following active ingredients:

Cholesterol Esterase (Microorganism) ≥ 0.75 I.U.
Cholesterol Oxidase (Microorganism) ≥ 0.5 I.U.
4-aminoantipyrine ≥ 12 µg
Peroxidase (Horseradish) ≥ 11 µU.
Substituted aniline derivatives ≥ 30 µg

Also: MOPS (3-morpholinopropane sulfonic acid) buffer, MES (2-(N-Morpholino) ethanesulfonic acid) buffer, surfactants, polyanions, nonionic surfactants, PEG derivatives, modified cyclic sugars, and protecting agents.

STORAGE AND HANDLING
• Store the 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 use. 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.
• PTS PANELS LDL Cholesterol Test Strips can only be used in a CardioChek™ PA Test System.
• 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 once. 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.

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 opposite the blood application window. 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 µL of whole blood to the test strip blood application window.

4. In about a minute, the result will appear on the display. 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.
2. If you get a reading of “<___” or “>___” 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 analyzer is preset to US units by the manufacturer. No calculation of results is necessary. To change to INTL (mmol/L) units, please see the analyzer User Guide.

QUALITY CONTROL
Please refer to the analyzer User Guide for the proper procedure and materials to be used to perform Quality Control tests. Quality Control tests are used to ensure that the system (analyzer, strips, and MEMo Chip) is working properly. Users should run controls at least monthly or with each new lot of test strips, when results are questionable or to comply with their own facility's quality control requirements.

EXPECTED VALUES
LDL cholesterol levels may vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise.

The expected or reference ranges recommended are as follows from the US National Cholesterol Education Program (NCEP) 2001 Guidelines:
- **Below 100 mg/dL (2.59 mmol/L) - Optimal**
- **100-129 mg/dL (2.59-3.35 mmol/L) - Near optimal/above optimal**
- **130-159 mg/dL (3.36-4.12 mmol/L) - Borderline high**
- **160-189 mg/dL (4.13-4.91 mmol/L) - High**
- **190 mg/dL and above - Very high**

At least two measurements of LDL cholesterol on separate occasions should be made before a medical decision is made, since a single reading may not be representative of a patient's usual LDL cholesterol concentration. Results around decision points should be followed with a repeat measurement. Elevated results should be confirmed by follow-up testing in a clinical laboratory. An elevated LDL cholesterol level is only one risk factor for heart disease and should not be used as the sole basis of medical decisions.

MEASURING RANGE
PTS PANELS LDL Cholesterol Test Strips measure LDL cholesterol levels from 50-200 mg/dL (1.29-5.18 mmol/L) and will display a numeric value for results in this range. If the display reads “<___” (less than measuring range), the LDL cholesterol level is below 50 mg/dL (1.29 mmol/L). Results above 200 mg/dL (5.18 mmol/L) will read “>” (greater than measuring range). If a “<” or “>” result is displayed, always test again. Samples with LDL values > 200 mg/dL (5.18 mmol/L) should not be diluted.

A linearity covering the range of 45-244 mg/dL (1.24-6.32 mmol/L) had a correlation coefficient of 0.973 with the regression line of y = 0.9905x + 13.24, with an average recovery of 103.3%.

LIMITATIONS OF THE PROCEDURE
1. **Preservatives:** Blood samples preserved with Fluoride or Oxalate should not be used for testing with values > 200 mg/dL (5.18 mmol/L) should not be diluted.
2. **Neonatal Use:** This product has not been tested using neonatal blood. Until testing is done this test system should not be used on neonatal blood samples.
3. **Hematocrit:** Hematocrit values above 57% may incorrectly lower the results. Hematocrit lower than 35% may incorrectly increase the result.
4. **Ascorbic acid up to 3 mg/dL, acetaminophen up to 20 mg/dL, ibuprofen up to 40 mg/dL, and Salicylate up to 50 mg/dL do not interfere. Bilirubin up to 10 mg/dL, hemoglobin up to 500 mg/dL, uric acid up to 20 mg/dL, and triglycerides up to 500 mg/dL do not interfere. HDL cholesterol up to 85 mg/dL** do not interfere. **HDL cholesterol above 85 mg/dL may increase the LDL result.**

A ten day total precision study testing three levels of control material gave the results listed below:

<table>
<thead>
<tr>
<th>Target conc. (mg/dL)</th>
<th>Mean LDL Conc. (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>78</td>
<td>79.1</td>
</tr>
<tr>
<td>108</td>
<td>110.3</td>
</tr>
<tr>
<td>134</td>
<td>131.1</td>
</tr>
</tbody>
</table>

CV (%) 4.7% 5.3% 5.2%

**95% CI:** 91.2% to 99.9% 100%  (60/60)

**Observed Range:** 67 - 96 95 - 126 116 - 152

Percent of Results in the Range:
- Mean ± 15% of Mean 98.3% (59/60)
- 95% CI: 91.2% to 99.9% 100% (60/60)
- 95% CI: 94.0% to 100% 100% (60/60)

REFERENCES
1. Data on file

AVAILABILITY

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<thead>
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<th>REF/CAT NO.</th>
<th>DESCRIPTION</th>
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<td>1753</td>
<td>PTS PANELS LDL Cholesterol Test Strips – 25 Tests</td>
</tr>
<tr>
<td>1754</td>
<td>PTS PANELS LDL Cholesterol Test Strips – 6 Tests</td>
</tr>
<tr>
<td>1708</td>
<td>CardioChek PA Analyzer</td>
</tr>
<tr>
<td>0721</td>
<td>PTS PANELS Multi-Chemistry Controls – Level 1 and Level 2</td>
</tr>
</tbody>
</table>

CLIA INFORMATION (US only)
Complexity Categorization: Waived
Results of Untrained User Study
An "untrained user" study was conducted in which participants were given only the test instructions and asked to perform testing of three (3) samples in random order. The samples consisted of control material with LDL concentrations at three target levels of 78 mg/dL, 108 mg/dL and 134 mg/dL. The participants were not given any training on the use of the test. A total of 60 participants were enrolled from 5 sites, representing a diverse demographic (educational, age, gender, etc) population.

Tables below present the summary of the performance:

<table>
<thead>
<tr>
<th>N</th>
<th>Target conc. (mg/dL)</th>
<th>Mean (mg/dL)</th>
<th>SD (mg/dL)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>60</td>
<td>78</td>
<td>79.1</td>
<td>3.7</td>
<td>4.7%</td>
</tr>
<tr>
<td>60</td>
<td>108</td>
<td>110.3</td>
<td>5.9</td>
<td>5.3%</td>
</tr>
<tr>
<td>60</td>
<td>134</td>
<td>131.1</td>
<td>6.8</td>
<td>5.2%</td>
</tr>
</tbody>
</table>

**Observed Range:** 67 - 96 95 - 126 116 - 152

Percent of Results in the Range:
- Mean ± 15% of Mean 98.3% (59/60)
- 95% CI: 91.2% to 99.9% 100% (60/60)
- 95% CI: 94.0% to 100% 100% (60/60)

Customer Service is available in the US to answer questions regarding the CardioChek P•A analyzer and PTS Panels Test Strips. Outside Customer Service hours, please contact your healthcare professional.

Performance Characteristics

1. **Accuracy:** A clinical study was performed by healthcare professionals who measured LDL cholesterol levels on fresh capillary blood specimens from 120 non-fasting persons. The results below show that the PTS LDL Cholesterol Test Strips compares well to a commercially available direct LDL cholesterol method that is certified as traceable to the Center for Disease Control's Cholesterol Reference Method Laboratory Network accuracy base. The PTS PANELS LDL Test Strips have not been tested or certified by the Cholesterol Reference Method Laboratory Network (CRLMN).

   PTS PANELS LDL Cholesterol vs. Direct LDL Method
   Number of patients = 128
   slope = 0.9348
   y-intercept = +5.31
   r = 0.90
   Range of samples tested: 53 to 244 mg/dL, LDL Bias at 100 mg/dL, LDL = +2.99%
   Bias at 130 mg/dL, LDL = +0.80%
   Bias at 160 mg/dL, LDL = -0.56%

2. **Precision:**
   a. With-In-Run
   Laboratory professionals tested twenty replicates of various levels of LDL cholesterol in whole blood. The following results were obtained:
   - No. of Samples: 20
   - Mean LDL Conc. (mg/dL): 79.8 113.6 151.6
   - Std. Deviation (mg/dL): 3.79 6.11 7.38
   - Coefficient of Variation (%): 4.75 5.38 4.67
   - b. Total Precision
   A ten day total precision study testing three levels of control material gave the results listed below:
   - No. of Days: 10
   - Mean LDL Conc. (mg/dL): 96.8 140.5 171.3
   - Within-Run (mg/dL): 2.96 5.49 7.84
   - Within-Run CV (%): 2.65 3.91 4.58
   - Total S.D. (mg/dL): 4.03 5.96 9.02
   - Total CV (%): 4.16 4.24 5.26

3. **Interferences:** See LIMITATIONS section.