INTENDED USE

PTS PANELS™ HDL Cholesterol Test Strips provide a quantitative measurement of High Density Lipoprotein (HDL) Cholesterol. This system is intended to assist in screening for decreased HDL Cholesterol, a risk factor in coronary heart disease, and is intended for in-home (self-testing) or professional use.

SUMMARY

HDL Cholesterol, often referred to as “good cholesterol”, is an important component of a lipid profile. A low HDL indicates increased risk of coronary heart disease, while a high HDL indicates decreased risk.

In order to use this test, a MEMo Chip™ is provided with each package of test strips and must be properly inserted into the analyzer before any test can 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 is applied to the strip, test results are displayed in about a minute.

PRINCIPLE OF THE TEST

HDL Cholesterol test results are based on a reading of light reflected off a test strip that has changed color after blood is applied. The deeper the color is, the higher the HDL level. The analyzer converts this reading into an HDL result and displays it. This procedure is based on the “Trinder Method” for the determination of cholesterol.

MATERIALS PROVIDED

- PTS PANELS™ HDL Cholesterol Test Strips
- MEMo Chip (contains lot-specific test strip information)
- Instructions.

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek™ Brand 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 HDL Test Strip contains the following active ingredients:

- Cholesterol Esterase (Microorganism) ≥ 0.75 I.U.
- Cholesterol Oxidase (Microorganism) ≥ 1 I.U.
- Sodium Chloride ≥ 700 μg
- Phosphotungstic acid ≥ 900 μg
- EDTA ≥ 150 μg
- Peroxidase (Horse radish) ≥ 12 μg
- 4-aminoantipyrine ≥ 30 μg
- Substituted aniline derivatives

Each vial contains not more than 5 g 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 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 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. Intended for self-testing.
- PTS PANELS™ HDL Cholesterol Test Strips can only be used in the CardioChek™ Brand 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.

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 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 15 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.

S U M M A R Y

Cholesterol, a risk factor in coronary heart disease, and is intended for in-home (self-testing) or professional use.

Individuals should consult their healthcare professional with any questions about HDL levels and when to use this test. 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 is applied to the strip, test results are displayed in about a minute.

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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.

*As an alternative, the test strip may be inserted into the analyzer within 10 seconds AFTER blood is applied to the strip, when blood is applied to the strip directly from a finger. Touch a drop of blood from a fingerstick, follow the steps listed 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.
- 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.

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 “LOW”, “< ___”, “HIGH”, “> ___” 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.

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
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 when results are questionable or to comply with their own facility’s quality control requirements.

EXPECTED VALUES
Blood cholesterol levels will 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 from the US National Cholesterol Education Program (NCEP) 2001 Guidelines and are:
- • 40 mg/dL and below (1.04 mmol/L)-Low (increased risk for coronary heart disease)
- • 60 mg/dL and above (1.55 mmol/L and above)-High (increased risk of coronary heart disease)

A healthcare professional will discuss values that are specifically appropriate for each patient.

MEMO Chip) is working properly. Users should run controls when results are questionable or to comply with their own facility’s quality control requirements.

LIMITATIONS OF THE PROCEDURE

1. PRESERVATIVES: Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system. EDTA and Heparin do not interfere with the test. Fresh whole blood is the specimen of choice.

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. METABOLITES: Reducing substances such as Vitamin C may falsely decrease the test result.

4. HEMATOCRIT: Hematocrit values above 45% or lower than 30% may incorrectly lower the HDL cholesterol result.

5. Bilirubin up to 20 mg/dL and hemoglobin up to 775 mg/dL do not interfere.

PERFORMANCE CHARACTERISTICS

1. ACCURACY: A clinical study was performed at three sites. HDL cholesterol levels were measured on fresh capillary blood specimens from 88 persons by healthcare professionals. The HDL Cholesterol Test Strips were compared to results from a reference method.

PTS PANELS HDL Cholesterol vs. Reference Method
Number of patients = 88
Range of patient results: <25 to >85 mg/dL
slope = 1.1
y-intercept = -4.1
r = 0.89
Bias at 35 mg/dL = -0.2 mg/dL

In another study, the HDL Cholesterol Test Strips were run by professionals on 87 patients from four sites and results compared to those run on the same patients by the Abell-Kendall method in a Cholesterol Reference Method Laboratory Network (CRMLN) laboratory. The results were:

PTS PANELS HDL Cholesterol vs. Abell-Kendall Method
Range of patient results: < 25 to 80 mg/dL
slope = 0.85
y-intercept = 2.2
r = 0.85
bias at 35 mg/dL = -3.1 mg/dL

In a consumer study eighty-seven (87) consumers tested their HDL cholesterol with the PTS PANELS HDL Test Strips. These consumer results were compared to a reference HDL method that is recommended by the Centers for Disease Control (CDC).

None of the consumers in the study obtained a result that indicated that their HDL Cholesterol was 35 mg/dL or greater when their HDL was actually below 35 mg/dL by the reference method. About 28% of the consumers in this study who tested their own HDL Cholesterol one time obtained results that indicated that their HDL level was less than 35 mg/dL when their HDL was 35 mg/dL or higher by reference method. When a test was run a second time (repeated), this rate improves to 16%. This means that when you run your own HDL, you may at times get a result below 35 mg/dL when your HDL is actually 35 mg/dL or greater. Duplicate testing is especially important to confirm results below 35 mg/dL.

PRECISION: Twenty replicates of various levels of whole blood were tested for HDL cholesterol.

The following results were obtained:

<table>
<thead>
<tr>
<th>No. of Samples</th>
<th>Mean HDL Cholesterol Conc. (mg/dL)</th>
<th>Std. Deviation (mg/dL)</th>
<th>Coefficient of Variation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>28.9</td>
<td>4.8</td>
<td>17.5</td>
</tr>
<tr>
<td>19</td>
<td>28.9</td>
<td>4.8</td>
<td>17.5</td>
</tr>
</tbody>
</table>

INTERFERENCES: See LIMITATIONS section.

REFERENCES


CUSTOMER SERVICE
Customer Service is available to answer questions regarding the CardioChek brand analyzers and PTS Panels Test Strips. Outside Customer Service hours, please contact your healthcare professional.

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