pts panels®

HDL Cholesterol

Test Strips

For professional use with CardioChek® PA and CardioChek® Plus analyzers

INTENDED USE

PTS Panels® HDL cholesterol test strips are intended to measure High Density Lipoprotein (HDL) cholesterol. 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

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. 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 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 strip, test results are displayed in as little as 45 seconds.

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.

HDL Cholesterol

VLDL, LDL, HDL plasma → VLDL, LDL, depleted plasma

Cholesterol ester+H_2O —(cholesterol esterase)→ Cholesterol+fatty acid

Cholesterol+H_2O+O_2 —(cholesterol oxidase)→ Cholesterol-4-en-3-one+H_2O_2

$2H_2O_2$+4-AAP+Disubstituted Aniline —(peroxidase)→ Quinoneimine dye+$4H_2O$

MATERIALS PROVIDED

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

MATERIALS NEEDED BUT NOT PROVIDED

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

CHEMICAL COMPOSITION

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

Cholesterol Esterase (Microorganism)	≥ 0.6 I.U.
Cholesterol Oxidase (Microorganism)	≥ 0.8 I.U.
Magnesium chloride hexahydrate	≥ 500 µg
D-sorbitol	≥ 3 mg
Tris buffer	≥ 150 µg
Dextran sulfate	≥ 200 µg
PVA (polyvinyl alcohol)	≥ 300 µg
MOPS	≥ 200 µg
Sucrose	≥ 500 µg
Peroxidase (Horseradish)	≥ 1 I.U.
4-aminoantipyrine	≥ 12 µg
Substituted aniline derivatives	≥ 30 µg

Test strips are contained in a desiccated vial to control moisture. Molecular sieve is integrated into the vial.

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.
- If a desiccant packet is included in the vial, do not remove or discard it.
- 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 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 test strips can only be used in the CardioChek PA and CardioChek Plus professional 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 test 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.
- Keep out of reach of children under the age of 3 years.
- Users should adhere to Standard Precautions when handling or using this device. All parts of the system should be considered potentially infectious and are 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/2007ip/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 potential 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 (fingerstick) whole blood or fresh venous whole blood collected in EDTA or heparin tubes. To obtain a drop of blood from a fingerstick, follow the steps below:

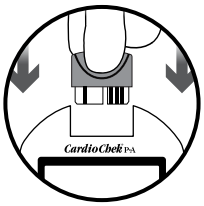
- **Use of lotions and handcreams should be avoided before testing.**
- Hands should be washed in warm water with soap, rinsed and dried thoroughly.
- Clean the fingertip with alcohol. Be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, auto-disabling, single-use lancet 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 "DIRECTIONS FOR USE - 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.

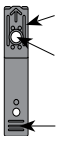
DIRECTIONS FOR USE - TESTING

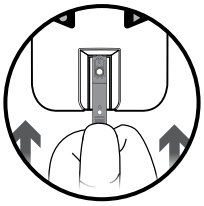
IMPORTANT: Read all instructions carefully before testing.

1. Insert the MEMo Chip that matches the lot number on the test strip vial and press one of the buttons to turn on the analyzer.

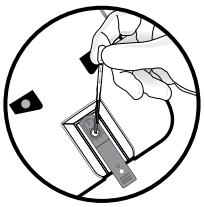


2. Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the test strip into the analyzer. Push the test strip in as far as it will go.

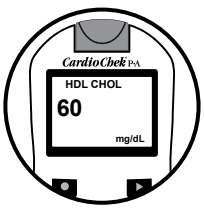




3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 15 µL of whole blood to the test strip blood application window.

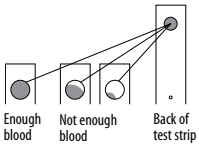


4. In as little as 45 seconds, the result will appear on the display. Remove and discard the test strip. Do not add more blood to a test strip that has been used.



ADDITIONAL CONSIDERATIONS

- 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.
- If you get a reading of "LOW", "<___", "HIGH", ">___" or any unexpected result, **test again.**
- See analyzer user guide Troubleshooting section for additional help.
- To verify enough blood has been applied to the test strip, remove test strip after testing is completed and check back of test strip. If areas are not completely and evenly colored, discard test strip and test again. See diagram.



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TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL) or in millimoles per liter (mmol/L). The analyzer is preset to mg/dL, which is the appropriate unit in the United States and many other countries. Other countries use mmol/L. Select the units that are correct for your country. For instructions on how to change the units, please see the analyzer user guide. No calculation of results is necessary.

QUALITY CONTROL

Quality control tests are used to ensure that the total system (analyzer, test strips, MEMo Chip) is working properly. Users should run controls when results are questionable or to comply with their own facility's quality control requirements. See instructions for use provided with the quality control materials for information on how to run controls. The CardioChek PA and CardioChek Plus professional analyzers are factory calibrated before they are packaged. Use the gray check strip supplied with the analyzer to verify that the analyzer's electronics and optics are working properly. The check strip is NOT a quality control test.

CAUTION: If your quality control test result falls outside the control range shown on the control range card, DO NOT use the system to test blood. The system may not be working properly. If you cannot correct the problem, contact Customer Service for help.

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:[9]

- 40 mg/dL (1.04 mmol/L) and below - Low (increased risk for coronary heart disease)
- 60 mg/dL (1.55 mmol/L) and above - High (decreased risk of coronary heart disease)

MEASURING RANGE

This test system will detect HDL levels from 25-85 mg/dL (0.65-2.20 mmol/L) and will display a number value for results in this range.

Results below this range will read, "LOW" or "<25 mg/dL (0.65 mmol/L)."

Results above this range will read, "HIGH" or ">85 mg/dL (2.20 mmol/L)."

IMPORTANT: If you get one of these results, or an unexpected result for any test, test again with a new unused test strip.

At least two measurements of HDL cholesterol on separate occasions should be obtained before a medical decision is made, since a single reading may not be representative of a patient's usual HDL cholesterol concentration. This test does not replace a lipid panel run by a laboratory.

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. Bilirubin up to 10 mg/dL and hemoglobin up to 750 mg/dL do not interfere. Triglycerides up to 1000 mg/dL do not interfere.
4. **HEMATOCRIT:** No hematocrit effect was observed for samples between 33% and 49% HCT.
5. **DRUGS:** Both dopamine and α-methyldopa interfered at all levels tested starting at levels of 1.75 mg/dL for dopamine and 0.625 mg/dL for α-methyldopa.

PERFORMANCE CHARACTERISTICS

1. **ACCURACY:**

In a two-site clinical study, correlation was established between a new modified test strip and a previous formulation of the test strip. HDL cholesterol of 40 subjects was measured on both the new and the previous test strip formulation. The results for the comparison follow.

PTS Panels HDL Cholesterol Test Strips New vs. Original

Number of patients = 40 Range of patient results: 29 to 83 mg/dL
slope = 0.835 y-intercept = 5.6 r = 0.96
Bias at 40 mg/dL = -1.0 mg/dL

The following three studies were performed using the original test strip formulation to which the new test strip was compared above.

A professional clinical study was performed at three sites. HDL cholesterol levels were measured on fresh capillary blood specimens from 88 persons by healthcare professionals. The PTS Panels HDL cholesterol test strips were compared to results from an automated HDL method.

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

Number of patients = 87 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 cholesterol 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' results in this study indicated their HDL cholesterol was 35 mg/dL or greater when their HDL was below 35 mg/dL by the reference method. About 28% of consumers in this study who tested their own HDL one time obtained results less than 35 mg/dL when their HDL was 35 mg/dL or higher by the reference method. When the test was repeated, this rate improved to 16%. This means that when you test your own HDL, you may at times get results below 40 mg/dL when your results are actually above 40 mg/dL. Duplicate testing is especially important to confirm results below 40 mg/dL.

2. **PRECISION:** A laboratory professional tested twenty replicates of three levels of whole blood for HDL cholesterol. The following results were obtained:

No. of Samples	20	20	20
Mean HDL Cholesterol Conc. (mg/dL)	36.4	45.5	65.0
Std. Deviation (mg/dL)	1.67	2.56	4.73
Coefficient of Variation (%)	4.59	5.63	7.28

Two lay persons tested blood at two levels of HDL cholesterol with the following results:

	Lay person 1		Lay person 2	
No. of Samples	20	20	20	20
Mean HDL Cholesterol Conc. (mg/dL)	45.8	69.4	45.2	64.3
Std. Deviation (mg/dL)	2.73	5.06	2.95	3.34
Coefficient of Variation (%)	5.97	7.29	6.52	5.19

This means that results should not vary more than about 8%.

3. **INTERFERENCES:** See LIMITATIONS section.

CLIA INFORMATION (US ONLY)

Complexity Categorization: Waived

USA: RX ONLY

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1708	CardioChek PA professional analyzer
2700	CardioChek Plus professional analyzer
1714	PTS Panels HDL cholesterol test strips – 25 tests
2863	PTS Collect™ capillary tubes, 15µL – 25 count
0721	PTS Panels multi-chemistry controls – Level 1 & Level 2
0722	PTS Panels HDL cholesterol controls – Level 1 & Level 2

REFERENCES

1. Data on file, Polymer Technology Systems, Inc., Indianapolis, IN 46268.
2. Clinical Diagnosis and Management by Laboratory Methods, Eighteenth Edition, John Bernard Henry, Editor,.W.B. Saunders Company, Philadelphia, 1991.
3. NCCLS Proposed Guideline EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
4. NCCLS Tentative Guideline EP7-T. Interference Testing in Clinical Chemistry. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
5. National Cholesterol Education Program. Report of expert panel on detection, evaluation, and treatment of high blood cholesterol in adults. National Heart, Lung and Blood Institute, NIH, Bethesda, MD, Arch. Int. Med., 148:36-69 (1988).
6. NCCLS. User evaluation of precision performance of clinical chemistry devices: tentative guidelines. 1984:2(1):1-48.EP5-T.
7. National Cholesterol Education Program. ATP III Guidelines At-A-Glance Quick Desk Reference. National Institutes of Health. National Heart, Lung and Blood Institute. NIH Publication No. 01-3305, May 2001.

CUSTOMER SERVICE

For assistance with PTS Diagnostics products, please contact PTS Diagnostics Customer Service (M-F, 6 a.m. - 9 p.m. US EST) or your local authorized dealer.

1-877-870-5610 (Toll-free inside the USA)
+1-317-870-5610 (Direct)
+1-317-870-5608 (Fax)
E-mail: customerservice@ptsdiagnostics.com

PTS Panels test strips are manufactured in the United States by Polymer Technology Systems, Inc., Indianapolis, IN 46268 USA.

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CE

EXPLANATION OF SYMBOLS

Use by	Manufacturer
LOT Batch code	Temperature limitation
IVD *In vitro* diagnostic medical device	Keep away from sunlight
REF Catalog number	Keep dry
Consult instructions for use	Caution
CE This product fulfills the requirements of European Directive 98/79/EC on *in vitro* diagnostic medical devices	Contains sufficient for <n> tests
	EC REP Authorized representative in the European Community
Rx only Prescription required (USA only)	