PS-002582E Rev. 2 10/05

PTS PANELS™ HDL Cholesterol Test Strips

for use with CardioChek™ Brand Analyzers

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. 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 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 (Horseradish)	≥ 1 I.U.
4-aminoantipyrine	≥ 12 µg
Substituted aniline derivatives	≥ 30 µg

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 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.

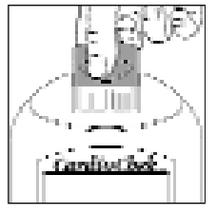
PRECAUTIONS
- For *in vitro* diagnostic use. Intended for self-testing.
- PTS PANELS Test Strips can only be used in the CardioChek brand analyzer.
- Make sure the MEMO Chip and test strip lot numbers match. Never use a MEMo Chip from a different lot than the test strip.
- Out-of-date or expired strips 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.**

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.
- 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.

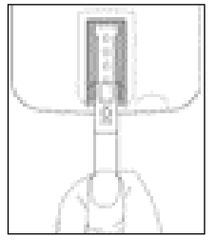
Caution: Handle and dispose of all materials coming in contact with blood according to universal precautions and guidelines.

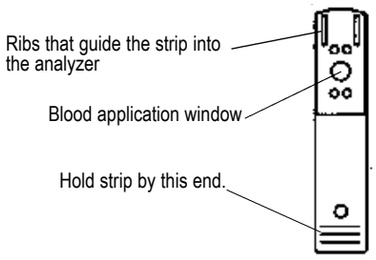
TESTING
IMPORTANT: Read all instructions carefully before testing.

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.

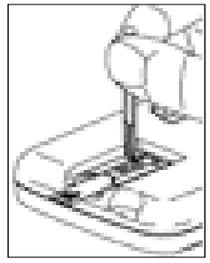


2.* Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the strip into analyzer. Push the strip in as far as it will go.





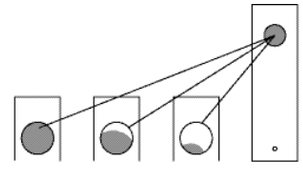
3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 15 µL of whole blood to the test strip blood application window.



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.

*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 hanging from the finger to the blood application window of the test strip. The blood drop must fill the entire window. Insert the strip into the analyzer. In about a minute, read result.

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.
3. See analyzer User Guide Troubleshooting section for additional help.
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 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:[9]
• 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 (decreased risk of coronary heart disease)
A healthcare professional will discuss values that are specifically appropriate for each patient. ALWAYS CONSULT A HEALTHCARE PROFESSIONAL BEFORE MAKING ANY CHANGES IN TREATMENT PLANS OR MEDICATION.

MEASURING RANGE
The HDL cholesterol 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. If the display reads "LOW" or "<___ " (less than measuring range), the HDL cholesterol level is below 25 mg/dL (0.65 mmol/L). Results above 85 mg/dL (2.20 mmol/L) will read "HIGH" or ">___" (greater than measuring range). If a "LOW", "HIGH", "<" or ">" result is displayed, always test again.
At least two measurements of HDL 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 HDL Cholesterol concentration.
This test does not replace a lipid profile run by a laboratory. Never make any medical decisions based on your results. Always contact your health care professional for advice.

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.
2. PRECISION: Twenty replicates of various levels of whole blood were tested for HDL cholesterol. The following results were obtained:

No. of Samples	20	20	19
Mean HDL Cholesterol Conc. (mg/dL)	28.9	48.6	70.5
Std. Deviation (mg/dL)	1.45	4.18	5.11
Coefficient of Variation (%)	5.01	8.60	7.25

3. INTERFERENCES: See LIMITATIONS section.

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1714	PTS PANELS HDL Cholesterol Test Strips – 25 Tests
1715	PTS PANELS HDL Cholesterol Test Strips – 6 Tests
1788	PTS PANELS HDL Cholesterol Test Strips – 3 Tests
730 / 1709	CardioChek Analyzer
1708	CardioChek P•A Analyzer
0722	PTS PANELS HDL Cholesterol Controls – Level 1 & Level 2

CLIA INFORMATION (US only)
Complexity Categorization: Waived

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
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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CE 0197

[redacted]

Explanation of Symbols

	Use By/Expiration date	REF	Catalog number
LOT	Batch Code/Lot number		Consult instructions for use
IVD	For in vitro diagnostic use		Manufacturer
CE 0197	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.		Store at/Temperature limitation