

PS-002414 E Rev. 0 07/07

PTS PANELS® CHOL+HDL+GLU Panel Test Strips

for Professional Use with CardioChek P•A® Analyzers

INTENDED USE

PTS PANELS CHOL+HDL+GLU Test Strips measure Total cholesterol, HDL cholesterol and Glucose in whole blood. Lipid measurements are used in the diagnosis and treatment of lipoprotein metabolism and lipid disorders (such as diabetes mellitus), atherosclerosis, and various renal and liver diseases. Glucose measurements are used in the management of carbohydrate metabolism disorders. Use this product at the frequency your doctor recommends testing for cholesterol and HDL cholesterol. This does not replace a glucose meter.

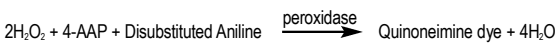
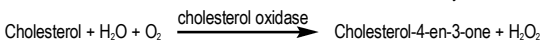
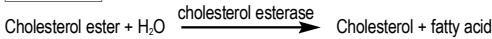
SUMMARY

CHOL+HDL+GLU Test Strips measure Total cholesterol, HDL 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.

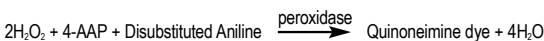
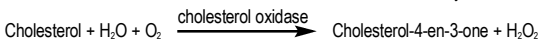
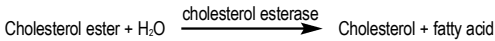
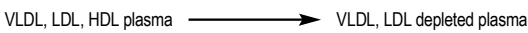
PRINCIPLES OF THE TEST

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. The enzymatic reactions that occur are listed below.

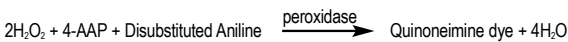
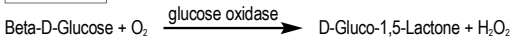
Cholesterol



HDL Cholesterol



Glucose



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 Collector or other precision pipet for blood collection and application

CHEMICAL COMPOSITION

Each CHOL+HDL+GLU Test Strip contains the following active ingredients:

Cholesterol Esterase (Microorganism)	≥ 1.75 I.U.
Cholesterol Oxidase (Microorganism)	≥ 1 I.U.
Peroxidase (Horseradish)	≥ 10 I.U.
4-aminantipyrene	≥ 64 µg
Substituted aniline derivatives	≥ 60 µg
Phosphotungstic acid	≥ 0.3 mg
N,N-disubstituted aniline	≥ 50 µg
Glucose oxidase (Aspergillus niger)	≥ 0.2 I.U.

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.
- 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.
- CHOL+HDL+GLU 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.
- 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:

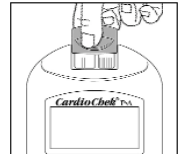
- Use of lotions and handcreams should be avoided before testing.
- Hands should be washed in warm water with antibacterial soap and rinsed and dried thoroughly.
- If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, disposable 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

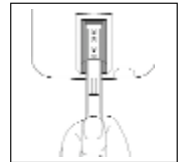
IMPORTANT: Read all instructions carefully before testing.

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.

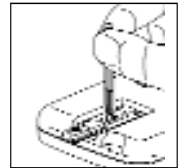


Blood application window

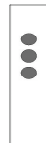
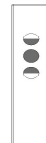
Hold strip by this end.



3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 35-40 µL of whole blood to the test strip blood application window.
4. In about two minutes, the cholesterol result will appear on the display. (To display HDL Cholesterol, press the (NEXT) button. To display Glucose press the (NEXT) button again) Remove and discard strip. **DO NOT** add more blood to a test strip that has been used.



To verify that enough blood has been applied to the test strip, after testing is completed, remove strip and check back of strip. If areas are not completely and evenly colored, discard strip and test again. See diagram.



Example of not enough blood

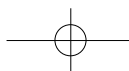
Example of enough blood

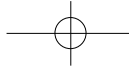
TEST RESULTS

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





CALIBRATION AND QUALITY CONTROL

Quality Control tests are used to ensure that the total system (analyzer, strips, MEMO Chip) is working properly and that the test results are accurate and reliable within the limits of the system. Users should run controls when results are questionable or to comply with their own facility's quality control requirements. See the CardioChek P+A User Guide for instructions on how to run controls. The CardioChek P+A is factory calibrated before it is packaged. Use the Check Strip supplied to verify that the analyzer's electronics and optics are working properly. The Check Strip is NOT a Quality Control test. Please refer to the CardioChek P+A User Guide for the proper procedure to be used to perform a Quality Control test.

EXPECTED VALUES

The expected or reference ranges recommended are from the US National Cholesterol Education Program (NCEP) 2001 Guidelines and are:⁹

Cholesterol (Total) Expected Values

- Below 200 mg/dL (5.18 mmol/L) – desirable
- 200-239 mg/dL (5.18-6.20 mmol/L) – borderline to high
- 240 mg/dL (6.21 mmol/L) and above – high

HDL Cholesterol Expected Values

- Below 40 mg/dL (1.04 mmol/L) – low HDL (High risk for CHD*)
- 60 mg/dL (1.55 mmol/L) and above – high HDL (Low risk for CHD*)

* CHD - Coronary Heart Disease

Glucose Expected Values

Blood glucose levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise. Your physician or healthcare professional will discuss "target values" (that is, highs and lows) specifically appropriate for you. A glucose level below 50 mg/dL (2.78 mmol/L) or above 240 mg/dL (13.32 mmol/L) may indicate a serious medical condition. If your test result should fall below 50 mg/dL (2.78 mmol/L) or exceed 240 mg/dL (13.32 mmol/L), you should contact your physician or healthcare professional as soon as possible. Expected values are for a fasting person, who does not have diabetes are: 70-105 mg/dL (3.9-5.8 mmol/L).⁶

LIMITATIONS OF THE PROCEDURE

Studies were performed to test for substances that may interfere with these tests. The results are below.

1. PRESERVATIVES: Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system. EDTA and heparin tubes are appropriate for collection of venous blood.
2. DRUGS: Dopamine and methyl dopa decreased the results of HDL cholesterol.
3. METABOLITES: Extremely high doses of ascorbic acid (Vitamin C) may decrease HDL results. Normal concentrations of Vitamin C did not effect the glucose results.
4. HEMATOCRIT: No hematocrit effect was observed for samples between 30 and 45% HCT.
5. ALTITUDE: Testing at altitudes up to 5280 feet has no effect on glucose results.
6. DEHYDRATION: Severe dehydration and excessive water loss may produce falsely low glucose results.

Additional Consideration:

NEONATAL USE: There have been no data generated to validate the use of this system with neonatal blood specimens. Until such data become available, this test system should not be used on neonatal samples.

MEASURING RANGE

CHOL+HDL+GLU Test Strips will display numeric results in the following ranges:

- Cholesterol: 100 - 400 mg/dL (2.59 - 10.36 mmol/L)
- HDL Cholesterol: 15 - 100 mg/dL (0.39 - 2.59 mmol/L)
- Glucose: 20 - 600 mg/dL (1.11 - 33.3 mmol/L)

Results below the range will read, "< ___" (less than the measuring range). Results above this range will read, "> ___" (greater than the measuring range).

IMPORTANT: If you get a result of "< ___" (less than), "> ___" (greater than) or an unexpected result for any test, test again with a new unused test strip.

PERFORMANCE CHARACTERISTICS

1. ACCURACY: Results from clinical studies comparing the PTS PANELS Test Strips to the Cholesterol Reference Method Laboratory Network (CRMLN) serum methods and to automated glucose hexokinase method follow:

PTS PANELS Cholesterol vs. Abell-Kendall traceable method

n = 125 samples
range of samples tested: 125 to >400 mg/dL
y = 1.01x - 1.83
r = 0.91

PTS PANELS HDL Cholesterol vs. Abell-Kendall method run by a CRMLN laboratory

n = 87 samples
range of samples tested: <25 to 80 mg/dL
y = 1.10x - 4.1
r = 0.89

PTS PANELS Glucose vs. Automated Hexokinase method

number of patients = 120
range of samples tested: <20 to 532 mg/dL
slope = 0.951
y-intercept = 5.36
r = 0.99

The CHOL+HDL+GLU Test Strips were run by professionals on a CardioChek P+A and the results were compared to were compared to a commercially available automated laboratory method. The results are listed by test as follows:

Cholesterol Comparison

n = 62 samples
range of samples tested: 113 to 297 mg/dL
y = 0.95x + 6.86
r = 0.903

When cholesterol results were classified according to NCEP criteria, 93.5% were correctly classified. Of misclassified results, 1.6% were incorrectly low and 4.8% incorrectly high. This means a small percentage of the time your cholesterol may be higher than the reading you obtain.

HDL Cholesterol Comparison

n = 61 samples
range of samples tested: 26 to 79 mg/dL
y = 1.02x - 2.25
r = 0.90

Glucose Comparison

n = 62 samples
range of samples tested: 53 to 364 mg/dL
y = 0.94x + 0.01
r = 0.98

The CHOL+HDL+GLU Test Strips compare well to the PTS Panels Cholesterol, HDL Cholesterol and Glucose Test Strips.

2. PRECISION: Laboratory professionals tested multiple levels of whole blood for cholesterol, HDL cholesterol and glucose using CHOL+HDL+GLU Test Strips. The following results were obtained:

Cholesterol

No. of Observations (n)	20	20
Mean Chol Conc. (mg/dL)	176.4	232.7
Std. Deviation (mg/dL)	4.87	6.78
Coefficient of Variation (%)	2.76	2.91

HDL Cholesterol

No. of Observations (n)	20	20
Mean HDL Conc. (mg/dL)	27.8	68.5
Std. Deviation (mg/dL)	1.50	2.65
Coefficient of Variation (%)	5.40	3.86

Glucose

No. of Observations (n)	20	20	20	20	20
Mean Glucose Conc. (mg/dL)	29.85	74.35	92.65	170.50	270.15
Std. Deviation (mg/dL)	2.39	3.50	3.33	4.51	5.32
Coefficient of Variation (%)	8.01	4.71	3.59	2.65	1.97

INTERFERENCE: See Limitations Section.

CLIA INFORMATION (US only)

Complexity Categorization: Waived

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1708	CardioChek P+A Analyzer
2412	CHOL+HDL+GLU Panel Test Strips, 15 count
0721	PTS PANELS Multi-Chemistry Controls – Level 1 & Level 2
0722	PTS PANELS HDL Cholesterol Controls – Level 1 & Level 2

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10. Friedewald et al. Clin Chem. 1972. 18(6):499-502.
11. Castelli, WP, et al. Circulation 1983. 67(4): 730-734.

CUSTOMER SERVICE

PTS Customer Service is available to answer questions regarding the CardioChek P+A and CHOL+HDL+GLU Test Strips. Outside Customer Service hours, please contact your healthcare professional. (877) 870-5610 (8 a.m. – 5 p.m. EST, M-F toll-free inside the USA)

(317) 870-5610, FAX (317) 870-5608
E-mail: inforequest@cardiochek.com

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

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AUTHORIZED EUROPEAN REPRESENTATIVE

per IVDD 98/79/EC
MDSS
Schiffgraben 41
D-30175 Hannover
Germany

Explanation of Symbols

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

