PS-003541E Rev.4 09/05

PTS PANELS CHOL+GLU Test Panel Test Strips

for use with CardioChek P•A™ Analyzer

INTENDED USE

PTS Panels CHOL+GLU Test Panel test strips are intended to measure cholesterol and glucose in whole blood on a CardioChek P•A analyzer. The test strips are intended to be used by healthcare professionals and individuals at home to measure blood cholesterol and glucose. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Glucose measurements are used in the management of carbohydrate metabolism disorders. Those testing at home should use this product at the frequency that their doctor recommends cholesterol testing. This does not replace a glucose meter.

SUMMARY

PTS PANELS CHOL+GLU Test Panel test strips measure total 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.

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 Collectors or other precision pipet for blood collection and application

CHEMICAL COMPOSITION

Each CHOL+GLU Test Panel test strip contains the following active ingredients:

Cholesterol Esterase (Microorganism)	≥ 0.6 I.U.
Cholesterol Oxidase (Microorganism)	≥ 0.4 I.U.
Peroxidase (Horseradish)	≥ 1 I.U.
4-aminoantipyrine	≥ 15 µg
Substituted aniline derivatives	≥ 20 µg
Glucose oxidase (Aspergillus niger)	≥ 0.2 I.U.
N, N-disubstituted aniline	≥ 15 µg

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+GLU Test Panel 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:

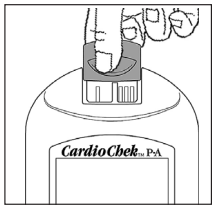
- Use of lotions and handcreams should be avoided before testing.
- Hands should be washed in warm water with antibacterial soap and rinsed and dried thoroughly.
- If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, disposable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

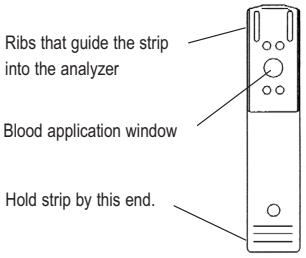
TESTING

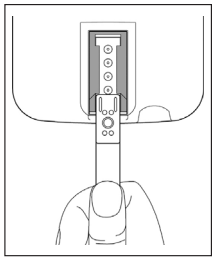
IMPORTANT: Read all instructions carefully before testing.

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.

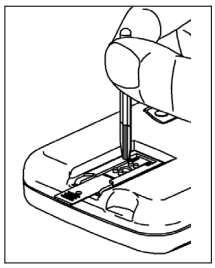


2. Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the strip into analyzer. Push the strip in as far as it will go.

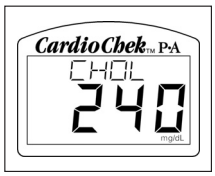




3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 25-30 µL of whole blood to the test strip blood application window.

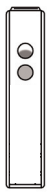


4. In about two minutes, the CHOL result will appear on the display. To display GLU, press the (NEXT) button. Remove and discard strip. DO NOT add more blood to a test strip that has been used.

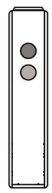


ADDITIONAL CONSIDERATIONS

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 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.



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.

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San Diego, CA 92121
tel 858-481-5031
toll free 888-882-7739
www.cliawaived.com

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[9] and are:
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
The frequency of home cholesterol testing should be determined in consultation with your physician.
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]

MEASURING RANGE
CHOL+GLU Test Panel test strips will provide numeric results in the following ranges:
Cholesterol: 100-400 mg/dL (2.59 - 10.36 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 "LOW", "<___" (less than), "HIGH", ">___" (greater than) or an unexpected result for any test, test again with a new unused test strip.

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 do not interfere with the test. Fingerstick 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 cholesterol test result. This test system is specific for glucose. Other sugars and other reducing substances such as Vitamin C at normal blood concentrations have no significant effect on test results.
4. HEMATOCRIT: Hematocrit values above 55% and below 30% may incorrectly lower the glucose results. Hematocrits above 50% for lower than 30% may incorrectly lower the cholesterol results.
5. Bilirubin up to 20 mg/dL and hemoglobin up to 200 mg/dL do not interfere.
6. ALTITUDE: Testing at altitudes up to 5280 feet has no effect on glucose results.
7. DEHYDRATION: Severe dehydration and excessive water loss may produce falsely low glucose results.

PERFORMANCE CHARACTERISTICS
1. ACCURACY:
Cholesterol
Results from clinical studies comparing the PTS PANELS Test Strips to the Cholesterol Reference Method Laboratory Network (CRMLN) serum methods are listed below:
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
Glucose
PTS PANELS Glucose Test strip results are calibrated to provide plasma glucose values. The Glucose Test Strips were calibrated to an automated glucose hexokinase laboratory method run on plasma samples. In a method comparison to a leading commercially available glucose system (a biosensor glucose dehydrogenase method) that is calibrated to provide "plasma-like" values[5], the results below show that the PTS PANELS Glucose Test Strips compare well. This means that the PTS PANELS Glucose Test Strips should compare well to a laboratory plasma method:
PTS PANELS Glucose vs. Commercially Available Glucose System
Number of patients = 120
slope = 0.951
y-intercept = 5.36
r = 0.99
CHOL+GLU
The CHOL+GLU Test Panel test strips were run by professionals using a CardioChek P•A and the results were compared to results from PTS PANELS single analyte Cholesterol and Glucose Test Strips run on The results were as follows:
Cholesterol Comparison
n = 112 samples
y = 0.895x +21.4
r = 0.905
Bias at 200 mg/dL = +0.20%
Bias at 240 mg/dL = -1.58%
Glucose Comparison
n = 113 samples
y = 1.017x -5.3
r = 0.986
Bias at 80 mg/dL = -4.93%
Bias at 126 mg/dL = -2.51%
The CHOL+GLU Test Panel test strips compare well to the PTS PANELS Cholesterol and Glucose Test Strips.
2. PRECISION: Laboratory professionals tested two levels of whole blood for cholesterol and glucose using CHOL+GLU Test Panel test strips. The following results were obtained:

Cholesterol

No. of Observations (n)	20	20	20
Mean Chol Conc. (mg/dL)	158.1	196.7	217.4
Std. Deviation (mg/dL)	9.1	11.7	8.1
Coefficient of Variation (%)	5.76	5.95	3.73

Glucose

No. of Observations (n)	20	20	20
Mean Glu Conc. (mg/dL)	44.8	59.0	249.5
Std. Deviation (mg/dL)	3.9	3.2	8.2
Coefficient of Variation (%)	8.71	5.42	3.29

3. INTERFERENCE: See Limitations Section.

CLIA INFORMATION (US only)
Complexity Categorization: Waived

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1708	CardioChek P•A Analyzer
1765	CHOL+GLU Test Panel Test Strips, 25 count
0721	PTS PANELS Multi-Chemistry Controls – Level 1 & Level 2

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San Diego, CA 92121
tel 858-481-5031
toll free 888-882-7739
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Explanation of Symbols

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