### MATERIALS PROVIDED
- PTS Panels CHOL+HDL+GLU test strips
- MEMo Chip (contains lot-specific test strip information)
- Instructions for use

### MATERIALS NEEDED BUT NOT PROVIDED
- CardioChek PA or CardioChek Plus professional analyzer
- Quality control materials
- Lancets for fingertip (or venous blood collection supplies)
- Alcohol wipes and/or gauze
- Capillary blood collector or other precision pipet for blood collection

### 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
- Cholesterol esterase
- Cholesterol oxidase

#### HDL Cholesterol
- LDL, HDL, depleted plasma
- Peroxidase (Horseradish)

#### Glucose
- Glucose oxidase

### CHEMICAL COMPOSITION
Each PTS Panels CHOL+HDL+GLU test strip contains the following active ingredients:
- Cholesterol Esterase (Microorganism) ≥ 1.75 IU
- Cholesterol Oxidase (Microorganism) ≥ 1.1 IU
- Peroxidase (Horseradish) ≥ 10 IU
- 4-aminoantipyrine ≥ 64 µg
- Substituted aniline derivatives ≥ 60 µg
- Phosphotungstic acid ≥ 0.3 mg
- N,N-disubstituted aniline ≥ 50 µg
- Glucose oxidase (Aspergillus niger) ≥ 0.2 IU

### STORAGE AND HANDLING
- Store test strip package in a cool, dry place at room temperature 68-86°F (20-30°C) before use.
- Do not freeze.

### Warnings and Precautions
- For in vitro diagnostic use.
- PTS Panels CHOL+HDL+GLU test strips can only be used in the CardioChek PA and CardioChek Plus 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- Out-of-date or expired test strips cannot be used in your test system.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. Do not add additional blood to the same test strip.
- Do not re-use the same 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.

### 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 fingertip, follow the steps below:
- Use of lotions and hand creams should be avoided before testing.
- Hands should be washed in warm water with antibacterial soap and 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 “TESTING” section for information on how to apply the blood to the test strip.
- Discard used materials properly.

### Direction for Use - Testing
1. Insert the MEMo Chip that matches the lot number on the test strip and press one of the buttons to turn the analyzer on.
2. Hold the test strip by the end marked “PTS.”
   - Insert the opposite end of the test strip into 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 35–40 µL of whole blood to the test strip blood application window.
4. In as little as 90 seconds, the result will appear on the display. As necessary, press next to view additional results. Remove and discard test 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 test strip and check back of test strip. If areas are not completely and evenly colored, discard test strip and test again. See diagram.

### Directions for Use - Testing Continued
Using a capillary blood collection device, draw blood by fingerstick and spread over the test strip. The CardioChek PA and CardioChek Plus test systems (consisting of the CardioChek PA and CardioChek Plus professional analyzers and PTS Panels® CHOL+HDL+GLU test strips) is for the quantitative determination of total cholesterol, HDL (high density lipoprotein) cholesterol and glucose in venous whole blood and capillary whole blood from the fingertip and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lanceting devices. This system is for in vitro diagnostic use only.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet carcinoma.

A Chol/HDL ratio is calculated by the CardioChek PA and CardioChek Plus analyzers.
2. **Expected Blood Glucose Values**

   - **Fasting Blood Glucose** in a person without diabetes is ≤99 mg/dL (5.5 mmol/L).
   - The expected 2-hour postprandial blood glucose is ≤139 mg/dL (7.7 mmol/L).

3. **Contact Your Physician**

   If your blood glucose falls below 50 mg/dL (2.78 mmol/L) or exceeds 240 mg/dL (13.32 mmol/L), you should contact your physician or health care professional as soon as possible.

4. **Target Values**

   Your physician or healthcare professional will discuss “target values” (that is, highs and lows) specifically 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.

5. **Nutritional and Physical Activity Considerations**

   Blood glucose levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress, or exercise.

6. **Quality Control**

   The Check Strip is NOT a quality control test. It is recommended to 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.

7. **Expected Values**

   - **Glucose Expected Values**
     - Below 40 mg/dL (1.04 mmol/L) — low HDL (High risk for CHD*)
     - 40-60 mg/dL (1.04-1.69 mmol/L) — borderline to high
     - >60 mg/dL (1.69 mmol/L) — high HDL (Low risk for CHD*)

   - **HDL Cholesterol Expected Values**
     - <10 mg/dL (0.39 mmol/L) — high HDL (Low risk for CHD*)
     - 10-15 mg/dL (0.39-0.59 mmol/L) — borderline to high
     - >15 mg/dL (0.59 mmol/L) — high HDL (Low risk for CHD*)

   - **LDL Cholesterol Expected Values**
     - <20 mg/dL (0.52 mmol/L) — low LDL (Low risk for CHD)
     - 20-40 mg/dL (0.52-1.03 mmol/L) — borderline to high
     - >40 mg/dL (1.03 mmol/L) — high LDL (High risk for CHD)

   - **Total Cholesterol Expected Values**
     - <100 mg/dL (2.59 mmol/L) — desirable
     - 100-199 mg/dL (2.59-5.02 mmol/L) — desirable
     - >200 mg/dL (5.18 mmol/L) — desirable

   * CHD - Coronary Heart Disease

8. **Quality Control Considerations**

   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.

9. **Statistical Analysis**

   - **Cholesterol Comparison**
     - The CHOL+HDL+GLU test strips were run by professionals on a CardioChek PA analyzer and the results were compared to a commercially available automated laboratory method. The results are listed by test as follows:
       - **Cholesterol**
         - n = 62 samples
         - range of samples tested: 113 to 297 mg/dL
         - y = 0.95x + 6.86
         - r = 0.903
       - **HDL Cholesterol**
         - 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

   - **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
       - Mean Chol Conc. (mg/dL) = 176.4
       - Std. Deviation (mg/dL) = 232.7
       - Coefficient of Variation (%) = 2.76
     - **HDL Cholesterol**
       - No. of Observations (n) = 20
       - Mean HDL Conc. (mg/dL) = 27.8
       - Std. Deviation (mg/dL) = 68.5
       - Coefficient of Variation (%) = 5.40
     - **Glucose**
       - No. of Observations (n) = 20
       - Mean Glucose Conc. (mg/dL) = 92.65
       - Std. Deviation (mg/dL) = 170.50
       - Coefficient of Variation (%) = 4.51

10. **Usual Use**

    - **Neonatal Use**
      - Neonatal or arterial blood. This test system should not be used with these blood samples.
      - Patients in a hyperosmolar state (with or without ketosis) have not been tested.
      - Hematocrit: 40-45% HCT.
      - Cholesterol: ≤60 mg/dL (1.55 mmol/L) and above - high HDL (Low risk for CHD)
      - Below 40 mg/dL (1.04 mmol/L) - low HDL (High risk for CHD)
      - Low Hematocrit: ≤60 mg/dL (1.55 mmol/L) and above - high HDL (Low risk for CHD)
      - Below 40 mg/dL (1.04 mmol/L) - low HDL (High risk for CHD)

11. **Limitations of the Procedure**

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

12. **Preservatives**

    - Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system. EDTA and heparin tubes do not interfere with the test.

13. **Neonatal Use and Arterial Blood**

    - This product has not been tested using neonatal or arterial blood. This test system should not be used with these blood samples.

14. **Drug Interactions**

    - Dopamine and methylprednisopect the results of HDL cholesterol.

15. **Metabolites**

    - Extremely high doses of ascorbic acid (Vitamin C) may decrease HDL results. Normal concentrations of Vitamin C did not affect the glucose results.

16. **Hemocrit**

    - No hemocrit effect was observed for samples between 30 and 45% HCT.

17. **Altitude**

    - Testing at altitudes up to 10,000 feet has no effect on glucose results.

18. **Dehydration**

    - Severe dehydration and excessive water loss may produce falsely low glucose results.

19. **Analyzers**

    - The analyzer should not be used to test critically ill patients.

20. **Blood Samples**

    - Blood samples from patients in shock, patients with severe dehydration, or patients in a hyperosmolar state (with or without ketosis) have not been tested. It is not recommended to test those samples with this system.

21. **For use on patients who are severely hypotensive**

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**REFERENCES**


**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.

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