

PTS PANELS CHOL+HDL Panel Test Strips

for Professional use with CardioChek P•A® Analyzer

INTENDED USE

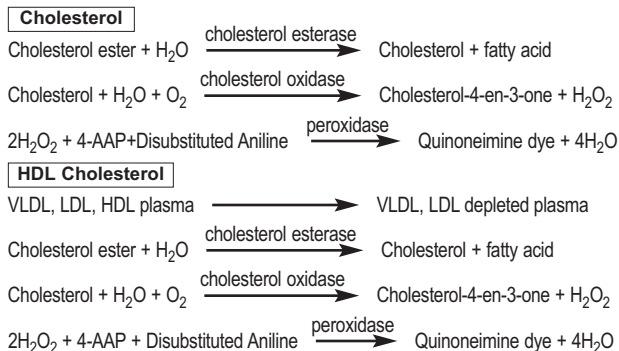
PTS PANELS CHOL+HDL Panel Test Strips measure total cholesterol and HDL cholesterol in whole blood. Cholesterol and HDL cholesterol measurements are used in the diagnosis and treatment of lipoprotein metabolism and lipid disorders (such as diabetes mellitus), atherosclerosis, and various renal and liver diseases.

SUMMARY

CHOL+HDL Panel Test Strips measure total cholesterol, and HDL cholesterol 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.



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 Panel Test Strip contains the following active ingredients:

Cholesterol Esterase (Microorganism)	≥ 1.35 I.U.
Cholesterol Oxidase (Microorganism)	≥ 1.3 I.U.
Peroxidase (Horseradish)	≥ 2 I.U.
4-aminoantipyrine	≥ 24 µg
Substituted aniline derivatives	≥ 60 µg
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

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 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:

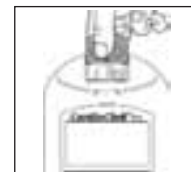
- Use of lotions and handcreams should be avoided before testing.
- Hands should be washed in warm water with antibacterial soap and rinsed and dried thoroughly.
- If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, disposable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

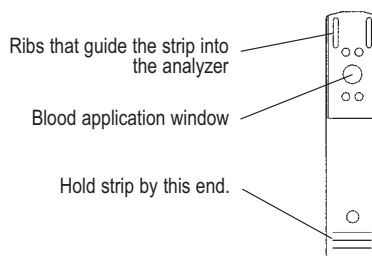
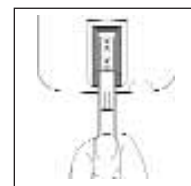
TESTING

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.



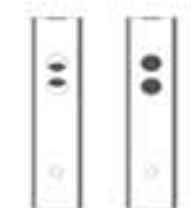
3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 30 µL of whole blood to the test strip blood application window.



4. In about two minutes, the Cholesterol result will appear on the display. (To display HDL and TC/HDL, press the (NEXT) button.) 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.



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