INTENDED USE
PTS PANELS® Metabolic Chemistry Panel Test Strips measure glucose, HDL cholesterol and triglycerides in fingerstick whole blood. Glucose measurements are used in the management of carbohydrate metabolism disorders. HDL cholesterol and triglycerides 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. The frequency of HDL cholesterol and triglycerides testing should be determined in consultation with your physician. Use this product at the frequency that your doctor recommends testing for HDL cholesterol and triglycerides. This does not replace a glucose meter.

SUMMARY
Metabolic Chemistry Panel Test Strips measure glucose, HDL cholesterol and triglycerides 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.

Glucose

\[
\text{Beto-D-Glucose + O}_2 \rightarrow \text{D-Gluco-1,5-Lactone + H}_2\text{O,}
\]

HDL Cholesterol

\[
\text{VLDL, LDL, HDL plasma} \rightarrow \text{VLDL, LDL, depleted plasma}
\]

Cholesterol ester + H2O \rightarrow Cholesterol + fatty acid

Cholesterol + H2O + O2 \rightarrow Cholesterol-4-en-3-one + H2O2

Triglycerides

\[
\text{Triglyceride + 3H}_2\text{O} \rightarrow \text{glycerol kinase}
\]

Glycerol + 3 fatty acid

Glycerol + ATP \rightarrow Glycerol-3-P + ADP

\[
\text{glycerophosphate oxidase}
\]

\[
\text{glucose oxidase}\]

\[
\text{Beta-D-Glucose + O}_2 \rightarrow \text{D-Gluco-1,5-Lactone + H}_2\text{O,}
\]

\[
\text{peroxidase}
\]

\[
\text{Quinoneimine dye + 4H}_2\text{O}
\]

\[
\text{Peroxidase (Horseradish)}
\]

\[
\text{2 H}_2\text{O}_2 + 4\text{-AAP + Disubstituted Aniline} \rightarrow \text{Quinoneimine dye + 4H}_2\text{O}
\]

\[
\text{Phosphotungstic acid}
\]

\[
\text{Peroxidase}
\]

\[
\text{2 H}_2\text{O}_2 + 4\text{-AAP + Disubstituted Aniline + Quinoneimine dye + 4H}_2\text{O}
\]

CHEMICAL COMPOSITION
Each Metabolic Chemistry Panel Test Strip contains the following active ingredients:

- Cholesterol Esterase (Microorganism)
- Cholesterol Oxidase (Microorganism)
- 4-aminoantipyrine
- Phosphotungstic acid
- 4-hydroxyacetone-P-O and
- 2-HPO
- N,N-disubstituted aniline
- Glycerol-3-Phosphate Oxidase (Microorganism)
- Glycerol Kinase (Microorganism)
- ATP (Microorganism)
- Lipoxygenase (Microorganism)

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.
- Use test strips 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.
- 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.

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 hand creams should be avoided before testing.
- Hands should be washed in warm water with antibacterial soap and rinsed thoroughly.
- If you wipe the finger 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.

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

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

* NCEP expected values for triglycerides require patient to be fasting (No food or drink except water for at least 9 hours.)

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.

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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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 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 for a Quality Control test.

EXPECTED VALUES

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 (2.79 mmol/L) or above 240 mg/dL (13.22 mmol/L) may indicate a serious medical condition. If your test result should fall below 50 mg/dL (2.79 mmol/L) or exceed 240 mg/dL (13.22 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: 70-110 mg/dL (3.9-5.8 mmol/L).

- 500 mg/dL and above (5.65 mmol/L) – very high
- 200-499 mg/dL (2.26-5.64 mmol/L) – high
- 150-199 mg/dL (1.70-2.25 mmol/L) – borderline high
- 100-149 mg/dL (1.11-1.71 mmol/L) – high normal
- 50-99 mg/dL (0.56-1.10 mmol/L) – low normal

MEASURING RANGE

Metabolic Chemistry Panel Test Strips will display numeric results in the following ranges:

- 40-60 mg/dL (2.22-3.33 mmol/L) – low
- 60-100 mg/dL (3.33-5.55 mmol/L) – normal
- 100-150 mg/dL (5.55-8.33 mmol/L) – borderline high
- 150-200 mg/dL (8.33-11.11 mmol/L) – high
- 200 mg/dL and above (11.11 mmol/L) – very high

LIMITATIONS OF THE PROCEDURE

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

1. PRESERVATIVES: Blood specimens 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 methyldopa decreased the results of HDL cholesterol and triglycerides. Studies were performed to test for substances that may interfere with these tests. The results are below.
3. INTERFERENCE: See Limitations Section.
4. MEASURING RANGE: See Limitations Section.

INTERFERENCE: See Limitations Section.

REFERENCES


INTERFERENCE: See Limitations Section.

REFERENCE

REF/CAT NO. DESCRIPTION
1708 CARDOCHECK P•A Analyzer
2400 Metabolic Chemistry Panel Test Strips, 15 count
2408 Metabolic Chemistry Panel Test Strips, 3 count
0721 PTS PANELS Multi-Chemistry Controls – Level 1 & Level 2
0722 PTS PANELS HDL Cholesterol Controls – Level 1 & Level 2

AVAILABILITY

The Metabolic Chemistry Panel Test Strips are supplied with the CardioChek P•A and PTS PANELS Metabolic Chemistry Test Strips. The following results were obtained:

Triglycerides Comparison

The Metabolic Chemistry Panel Test Strips compare well to automated laboratory methods.

2. PRECISION: Twenty replicates of various levels of whole blood were tested using the Metabolic Chemistry Panel Test Strips. The following results were obtained:

Glucose

<table>
<thead>
<tr>
<th>Sample</th>
<th>No. of Samples</th>
<th>Mean Glucose Conc. (mg/dL)</th>
<th>Std. Deviation (mg/dL)</th>
<th>Coefficient of Variation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>20</td>
<td>34.7</td>
<td>3.01</td>
<td>8.67</td>
</tr>
</tbody>
</table>

Triglycerides

<table>
<thead>
<tr>
<th>Sample</th>
<th>No. of Samples</th>
<th>Mean HDL Conc. (mg/dL)</th>
<th>Std. Deviation (mg/dL)</th>
<th>Coefficient of Variation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>20</td>
<td>86.2</td>
<td>5.78</td>
<td>6.71</td>
</tr>
</tbody>
</table>

STORAGE AND HANDLING

This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.