**CHEMICAL COMPOSITION**

Each cholesterol test strip contains the following active ingredients:

- Cholesterol Esterase (Microorganism) ≥ 0.75 IU
- Cholesterol Oxidase (Microorganism) ≥ 0.5 IU
- 4-aminoantipyrine + H2O2 ≥ 12 µg
- Peroxidase (Horseradish) ≥ 1 IU
- Substituted aniline derivatives ≥ 30 µg

Test strips are contained in a desiccated vial to control moisture. Molecular sieve is integrated into the vial.

**STORAGE AND HANDLING**

- Store test strip package in a cool, dry place at room temperature 68-86°F (20-30°C) or refrigerated at 35-46°F (2-8°C). Test strips must be brought to room temperature 68-86°F (20-30°C) before using. Do not freeze.
- Keep away from heat and direct sunlight.
- If a desiccant packet is included in the vial, do not remove or discard it.
- 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 in the original box that held the test strips.
- Store the test strips in the original vial. Do not combine with other test 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.

**WARNINGS AND PRECAUTIONS**

- For in vitro diagnostic use.
- PTS Panels cholesterol test strips can only be used in CardioChek brand 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- Out-of-date or expired test strips cannot be used in your test system.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. If you do not get all of the blood on the test strip, do not add additional blood to the same test strip. Test again with a new, unused 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.
- Users should adhere to Standard Precautions when handling or using this device. All parts of the system should be considered potentially infectious and capable of transmitting bloodborne pathogens between patients and healthcare professionals. For more information, refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007”, http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.
- The analyzer should be cleaned and disinfected after use on each patient. This test system may only be used for testing multiple patients when Standard Precautions and the manufacturer’s disinfection procedures are followed.
- Please refer to the analyzer User Guide for cleaning and disinfection instructions. This procedure is important to prevent the potential transmission of infectious diseases.
- Only auto-disabling, single-use lancing devices may be used with this device.

**ADDITIONAL CONSIDERATIONS**

- 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.
  - If you get a reading of “LOW”, “< __”, “HIGH”, “> ___” or any unexpected result, test again.
- See analyzer user guide troubleshooting section for additional help.
- To verify enough blood has been applied to the test strip, remove test 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.

**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 fingerstick, follow the steps below:

- Use of lotions and handcreams should be avoided before testing.
- Hands should be washed in warm water with antibacterial soap, 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 "DIRECTIONS FOR USE - 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.
TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL) or in millimoles per liter (mmol/L). The analyzer is preset to mg/dL, which is the appropriate unit in the United States and many other countries. Other countries use mmol/L. Select the units that are correct for your country. For instructions on how to change the units, please see the analyzer user guide. No calculation of results is necessary.

QUALITY CONTROL

Quality control tests are used to ensure that the total system (analyzer, test strips, ME/Mo Chip) is working properly. Users should 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. The CardioChek PA and CardioChek Plus professional analyzers are factory calibrated before they are packaged. Use the gray check strip supplied with the analyzer to verify that the analyzer’s electronics and optics are working properly. The check strip is NOT a quality control test.

CAUTION: If your quality control test result falls outside the control range shown on the control range card, DO NOT use the system to test blood. The system may not be working properly. If you cannot correct the problem, contact Customer Service for help.

EXPECTED VALUES

Blood cholesterol levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise. The expected or reference ranges recommended are as follows from the US National Cholesterol Education Program (NCEP) 2001 Guidelines:

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

A healthcare professional will discuss values that are specifically appropriate for a patient’s usual cholesterol concentration. An elevated cholesterol level is only one risk factor for heart disease. There are many others. A cholesterol level less than 200 mg/dL is desirable.

LEVELS OF CHOLESTEROL

1. Below 200 mg/dL is desirable.
2. 200-239 mg/dL is borderline high.
3. 240 mg/dL and above is high.

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

Cholesterol Education Program (NCEP) 2001 Guidelines:

1. Below 200 mg/dL (5.18 mmol/L) is desirable.
2. 200-239 mg/dL (5.18-6.20 mmol/L) is borderline high.
3. 240 mg/dL (6.21 mmol/L) and above is high.

A cholesterol level is only one risk factor for heart disease. There are many others.

PERFORMANCE CHARACTERISTICS

1. ACCURACY: A clinical study was performed by healthcare professionals who measured cholesterol levels on fresh capillary blood specimens from 125 persons. The results below show that the cholesterol test strips compare well to a reference cholesterol method that is correlated to the “Abell-Kendall Method.” The performance of the cholesterol test strips has been determined by a network laboratory (Cholesterol Reference Method Laboratory Network) to meet both accuracy and precision requirements recommended by the NCEP. This certification is issued through the Centers for Disease Control.

PTS Panels Cholesterol Test Strips vs. Reference Method

Number of patients = 125

<table>
<thead>
<tr>
<th>Mean Cholesterol Conc. (mg/dL)</th>
<th>Coefficient of Variation (%)</th>
<th>Mean Cholesterol Conc. (mmol/L)</th>
<th>Coefficient of Variation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>105</td>
<td>2.49</td>
<td>2.69</td>
<td>2.49</td>
</tr>
<tr>
<td>154</td>
<td>3.72</td>
<td>4.02</td>
<td>3.92</td>
</tr>
<tr>
<td>230</td>
<td>6.61</td>
<td>6.08</td>
<td>6.08</td>
</tr>
<tr>
<td>262</td>
<td>7.67</td>
<td>7.42</td>
<td>7.42</td>
</tr>
</tbody>
</table>

This test system will detect cholesterol levels from 100-400 mg/dL (2.59-10.36 mmol/L) and will display a number value for results in this range.

2. PRECISION: Twenty replicates of various levels of whole blood were tested for cholesterol. The following results were obtained:

- No. of Samples: 20, 20, 20, 20
- Mean Cholesterol Conc. (mg/dL): 105, 154, 230, 262
- Std. Deviation (mg/dL): 2.54, 3.72, 6.61, 7.67
- Coefficient of Variation (%): 2.42, 2.41, 2.88, 2.92

This means that the variation between strips is less than 3%.

3. INTERFERENCES: See LIMITATIONS section.

CLIA INFORMATION (US ONLY)

Complexity Categorization: Waived

USA: RX ONLY

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

AVAILABILITY

<table>
<thead>
<tr>
<th>REU/CAT NO.</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1708</td>
<td>CardioChek PA professional analyzer</td>
</tr>
<tr>
<td>2700</td>
<td>CardioChek Plus professional analyzer</td>
</tr>
<tr>
<td>1711</td>
<td>PTS Panels cholesterol test strips – 25 tests</td>
</tr>
<tr>
<td>2863</td>
<td>PTS Collect™ capillary tubes, 15µL – 25 count</td>
</tr>
<tr>
<td>0721</td>
<td>PTS Panels multi-chemistry controls – Level 1 &amp; Level 2</td>
</tr>
</tbody>
</table>

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.

1-877-870-5610 (Toll-free inside the USA)
+1-317-870-5610 (Direct)
+1-317-870-5608 (Fax)

E-mail: customerservice@ptsdiagnostics.com

PTS Panels test strips are manufactured in the United States by Polymer Technology Systems, Inc., Indianapolis, IN 46268 USA.

© 2017 Polymer Technology Systems, Inc.

PTS Panels, CardioChek, ME/Mo Chip and PTS Collect are trademarks of Polymer Technology Systems, Inc.

EXPLANATION OF SYMBOLS