INTENDED USE
PTS Panels® triglycerides test strips are intended to measure triglyceride in whole blood for use in the diagnosis and treatment of diabetes mellitus, nephrosis, liver obstruction and other diseases involving lipid metabolism, or varicose endocrine disorders. This testing system is intended for professional use.

SUMMARY
Triglycerides and cholesterol are the main types of fats that are transported in blood. Individuals with a high triglyceride level should consult a physician for advice.

PRINCIPLES OF THE TEST
Triglycerides test results are based on the instrument reading light reflected off a test strip that has changed color after blood has been placed on it. The darker the color, the higher the triglycerides level. The instrument converts this reading into a triglycerides level. Triglycerides levels vary significantly from day to day and are affected by diet. Triglycerides test results must be interpreted by a trained medical professional along with other factors such as HDL cholesterol, total cholesterol, diet, exercise, and family history.

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.
- Do not store the MEMo Chip in the test strip vial.
- Once the vial has been opened, strips are stable until expiration date if vial is properly capped.

WARNINGS AND PRECAUTIONS
- For in vitro diagnostic use.
- PTS Panels test strips can only be used in the CardioChek PA and CardioChek Plus professional analyzers.
- Use test strip as soon as you have removed it from the vial.
- 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.
- Do not store the MEMo Chip in the test strip vial.
- Once the vial has been opened, strips are stable until expiration date if vial is properly capped.

MATERIALS PROVIDED
- PTS Panels triglycerides 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 fingerstick (or venous blood collection supplies)
- Alcohol wipes and gauze
- Capillary blood collector or other precision pipet for blood collection and application

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 soap, rinsed, and dried thoroughly.
- Clean the finger 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 finger.
- Wipe away the first drop of blood with a clean piece of gauze.
- Gently, without force, apply pressure to the lancet 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.

DIRECTIONS FOR USE TESTING
1. Insert the MEMo Chip that matches the lot number on the test strip vial and press one of the buttons to turn on the analyzer.
2. Hold the test strip by the horizontal raised lines. Insert the opposite end of the test strip into the 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 15 µL of whole blood to the test strip blood application window.
4. In as little as 45 seconds, the result will appear on the display. Remove and discard test strip. Do not add more blood to a test strip that has been used.

*For best results, test in a fasting state (no food or drink, except water, for at least 12 hours).
**As an alternative, the test strip may be inserted into the analyzer within 10 seconds AFTER blood is applied to the test strip, when blood is applied to the strip directly from a finger. Touch a drop of blood hanging from the finger to the blood application window of the test strip. The blood drop must fill the entire window.

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 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.

![Diagram](attachment:image.png)
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, MEMO Chip) is working properly. Users should run controls when results are questionable or to comply with their own facility’s quality control requirements. Run a quality control test if you have not run a triglyceride test in the last 30 days. 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 you get one of these results, or an unexpected result for any results above this range will read “HIGH” or “>500 mg/dL (5.65 mmol/L).”

EXPECTED VALUES
Blood triglycerides levels will vary from time to time depending on food consumed, activity levels, health status, medication dosages, stress or exercise. A physician or healthcare professional will discuss “target values” (that is, highs and lows) specifically appropriate for each patient.

Triglycerides results around decision levels of 150 mg/dL (1.70 mmol/L) and 200 mg/dL (2.27 mmol/L) should be repeated. Triglycerides results of less than 50 mg/dL (0.56 mmol/L) (“low”) or greater than 500 mg/dL (5.65 mmol/L) (“high”) should be reported. In addition, at least two fasting measurements of triglycerides on separate occasions should be made before a medical decision is made, since a single reading may not be representative of a patient’s usual triglycerides. The expected or reference ranges recommended are as follows from the US National Cholesterol Education Program (NCEP) 2001 Guidelines are:

- Below 150 mg/dL (1.70 mmol/L) - desirable
- 150 - 199 mg/dL (1.70-2.27 mmol/L) - borderline high
- 200 - 499 mg/dL (2.26-5.64 mmol/L) - high
- 500 mg/dL (5.65 mmol/L) and above - very high

MEASURING RANGE
This test system will detect triglycerides levels from 50-500 mg/dL (0.56-5.65 mmol/L) and will display a number value for results in this range. Results below this range will read, “LOW” or “<50 mg/dL (0.56 mmol/L).” Results above this range will read “HIGH” or “>500 mg/dL (5.65 mmol/L).”

IMPORTANT: If you get one of these results, or an unexpected result for any test, test again with a new unused test strip.

LIMITATIONS OF THE PROCEDURE
1. 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.
2. METABOLITES: This test system is specific for triglycerides. Reducing substances such as vitamin C (ascorbic acid) may falsely decrease the test result.
3. HEMATOCRIT: No hematocrit effect was seen between 30 and 50% HCT.
4. ELEVATED LIPIDS: No interference was found for total cholesterol results up to 400 mg/dL.
5. BILIRUBIN AND URIC ACID: Up to 20 mg/dL do not interfere.
6. DRUG INTERFERENCES: Dopamine and methyldopa falsely decrease the test results. Statins gemfibrozil and simvastatin (Zocor and Lopid) did not interfere. Acetaminophen, Ibuprofen, and Salicylate do not interfere.
7. HAND LOTIONS/COSMETICS: Contamination of the blood sample with cosmetics or hand lotions (most contain glycerol) may give falsely high results.

PERFORMANCE CHARACTERISTICS
1. ACCURACY: A clinical study was performed at three sites. Triglycerides levels were measured on fresh capillary blood specimens from 111 persons by healthcare professionals. The PTS Panels triglyceride test strips compared favorably to the triglyceride method run at a Cholesterol Reference Method Laboratory Network (CRMLN) laboratory.

PTS Panels Triglycerides Test Strips vs. CRMLN Reference Method
Number of patients = 111
triglycerides concentration range: 66-481 mg/dL
slope = 0.96
y-intercept = 2.8
r = 0.97

2. PRECISION:
   a. Within-run precision: Twenty replicates of three levels of whole blood were tested for triglycerides. The following results were obtained:
      No. samples 20 20 20
      Mean triglycerides conc. (mg/dL) 137 208 424
      SD upper CI 8.86 9.00 22.87
      Std. Deviation (mg/dL) 7.07 7.18 18.25
      CV upper CI 6.47% 4.33% 5.39%
      Coefficient of variation 5.16% 3.45% 4.30%

   b. Total Imprecision: Total imprecision was calculated at the two critical levels of triglycerides (~200 and 400 mg/dL) using whole blood run by 59 to 60 different persons at three different sites.
      No. samples 59 60
      Mean triglycerides conc. (mg/dL) 198 373
      SD upper CI 4.75 17.72
      Std. Deviation (mg/dL) 4.08 15.35
      Upper CI for Coeff. of variation 2.40% 4.73%
      Coefficient of variation 2.06% 4.17%

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>REF/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>1716</td>
<td>PTS Panels triglycerides 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, MEMO Chip and PTS Collect are trademarks of Polymer Technology Systems, Inc.

EC REF
MOSS GmbH
Schiffgraben 41
30175 Hannover, Germany

EXPLANATION OF SYMBOLS
- Use-by
- Batch code
- Manufacturer
- Temperature limitation
- In vitro diagnostic medical device
- Keep away from sunlight
- Catalog number
- Keep dry
- Consult instructions for use
- Caution
- This product fulfills the requirements of European Directive 98/79/EC on in vitro diagnostic medical devices
- Contains sufficient for <n> tests
- Authorized representative in the European Community
- Prescription required (USA only)