pts panels®

Triglycerides

Test Strips

For professional use with CardioChek® PA and CardioChek® Plus analyzers

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 various 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 triglycerides level should consult a physician for advice. Triglycerides may be high in persons with diabetes, kidney, liver or heart disease. Individuals with elevated triglycerides may also be at higher risk for heart disease. Test in a fasting state (no food or drink, except water, for twelve hours). Fasting triglycerides levels may vary significantly from one day to the next 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.

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 the 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 as little as 45 seconds.

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 result and displays the result. This procedure is based on the "Trinder Method" for the determination of triglycerides.

Triglycerides

$$\text{Triglyceride} + 3H_2O \xrightarrow{\text{lipoprotein lipase}} \text{Glycerol} + 3\ \text{fatty acid}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow[\text{Mg}]{\text{glycerol kinase}} \text{Glycerol-3-}PO_4 + \text{ADP}$$

$$\text{Glycerol-3-}PO_4 + O_2 \xrightarrow{\text{glycerophosphate oxidase}} \text{Dihydroxyacetone-}PO_4 + H_2O_2$$

$$2H_2O_2 + \text{4-AAP} + \text{N, N-disubstituted aniline} \xrightarrow{\text{peroxidase}} \text{Quinoneimine dye} + 4H_2O$$

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

CHEMICAL COMPOSITION

Each PTS Panels triglycerides test strip contains the following active ingredients:

N,N-disubstituted aniline	> 50 µg
Glycerol-3-Phosphate Oxidase (Microorganism)	> 1.5 I.U.
Peroxidase (Horseradish)	> 6 I.U.
Lipoprotein Lipase (bacterial)	> 4.5 I.U.
Glycerol Kinase (bacterial)	> 2.0 I.U.
4-aminoantipyrine	> 40 µg
ATP (bacterial)	> 50 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.
- Keep the test strips stored in the original vial. Do not combine with other 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.
- 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. 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.
- Keep out of reach of children under the age of 3 years.
- Users should adhere to Standard Precautions when handling or using this device. All parts of the system should be considered potentially infectious and are 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.

SPECIMEN COLLECTION AND PREPERATION

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:

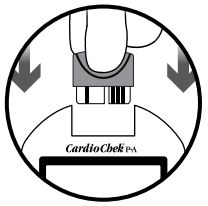
- **Use of lotions and handcreams should be avoided before testing.**
- Hands should be washed in warm water with soap, rinsed and dried thoroughly.
- Clean the fingertip with alcohol. Be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, auto-disabling, single-use lancet 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.

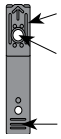
DIRECTIONS FOR USE - TESTING

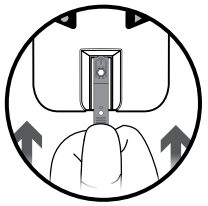
IMPORTANT: Read all instructions carefully before testing.
Test patient in a fasting state.*

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.

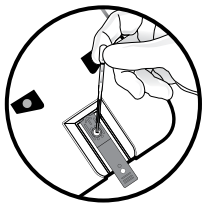


2. Hold the test strip by the end with the horizontal raised lines. Insert the opposite end of the test strip into the analyzer. Push the test strip in as far as it will go.**

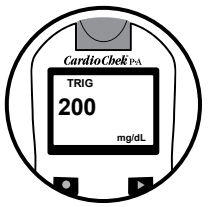




3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 15 µL of whole blood to the test strip blood application window.



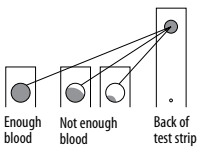
4. In as little as 45 seconds, the result will appear on the display. Remove and discard test strip. Do not add more blood to a test strip that has been used.



*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. Insert the test strip into the analyzer. In as little as 45 seconds, the result will appear on the display.

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.



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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 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 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 400 mg/dL (4.52 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 repeated. In addition, at least two fasting measurements of triglycerides on separate occassions 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:[9]

- Below 150 mg/dL (1.70 mmol/L) - desirable
- 150 - 199 mg/dL (1.70-2.25 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 approximately 400 mg/dL cholesterol.
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 triglycerides test strips compared favorably to the triglycerides 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	15.55
Upper CI for Coeff. of variation	2.40%	4.75%
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

REF/CAT NO.	DESCRIPTION
1708	CardioChek PA professional analyzer
2700	CardioChek Plus professional analyzer
1716	PTS Panels triglycerides test strips – 25 tests
2863	PTS Collect™ capillary tubes, 15µL – 25 count
0721	PTS Panels multi-chemistry controls – Level 1 & Level 2

REFERENCES

1. Diabetes Care, Management of Dyslipidemia in Adults with Diabetes, Vol. 22, Supplement 1, January, 1999.
2. Am. J. Cardiol, 1998;81(4A):18B-25B.
3. Data on file, Polymer Technology Systems, Inc., Indianapolis, IN 46268.
4. Clinical Diagnosis and Management by Laboratory Methods, Eighteenth Edition, John Bernard Henry, Editor,. W.B. Saunders Company, Philadelphia, 1991.
5. NCCLS Proposed Guideline EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
6. Textbook of Clinical Chemistry, Norbert W. Tietz, Editor, W.B. Saunders Company, Philadelphia, 1986.
7. NCCLS Tentative Guideline EP7-T. Interference Testing in Clinical Chemistry. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
8. Handbook of Lipoprotein Testing, Nader Rifai, G. Russell Warnick and Marek H. Dominiczak, Editors, AACC Press, 1997.
9. NCCLS: Evaluation of Precision Performance of Clinical Chemistry Devices;' Approved Guideline, 1999:19(2):EP5-A
10. National Cholesterol Education Program. ATP III Guidelines At-A-Glance Quick Desk Reference. National Institutes of Health. National Heart, Lung and Blood Institute. NIH Publication No. 01-3305, May 2001

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)
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E-mail: customerservice@ptsdiagnostics.com

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

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CE

EXPLANATION OF SYMBOLS

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