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PTS PANELS™ Triglycerides Test Strips for use with CardioChek™ Brand Analyzers

INTENDED USE

PTS PANELS Triglycerides Test Strips provide a quantitative measurement of triglycerides in fingerstick whole blood. This testing system is intended for in-home (self-testing) or 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.

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. 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.

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 a minute.

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 results. This procedure is based on the "Trinder Method" for the determination of triglycerides.

MATERIALS PROVIDED

- PTS PANELS Triglycerides Test Strips
- MEMo Chip (contains lot-specific test strip information)
- Instructions

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek brand 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 Triglycerides Test Strip contains the following active ingredients:

N,N-disubstituted aniline	≥ 50 µg
Glycerol-3-Phosphate Oxidase (Microorganism)	≥ 1.5 I.U.
Peroxidase (Horse radish)	≥ 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

Each vial contains: silica gel and/or molecular sieve: not more than 5 g.

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.
- Keep the desiccant stored in the vial. Do not remove or discard.
- 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.
- Keep the test strips stored in the original vial. Do not combine with other 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.

PRECAUTIONS

- For *in vitro* diagnostic use. Intended for self-testing.
- PTS PANELS Test Strips can only be used in the CardioChek brand 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 once. 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.
Test patient in a fasting state.*

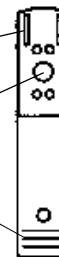
1. Insert the MEMo Chip that matches the lot number on the test strip vial and press one of the buttons to turn the analyzer ON.

- 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.

Ribs that guide the strip into the analyzer

Blood application window

Hold strip by this end.



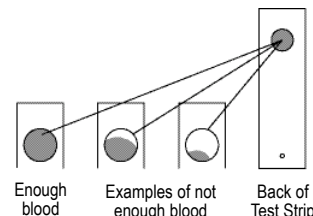
3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 15 µL of whole blood to the test strip blood application window.
4. In about a minute, the result will appear on the display. Remove and discard strip. **DO NOT** add more blood to a test strip that has been used.

*For best results (Fasting State - No food or drink, only water, for at least 12 hours.)

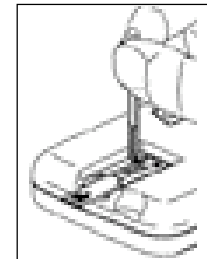
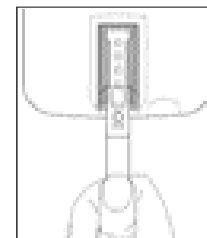
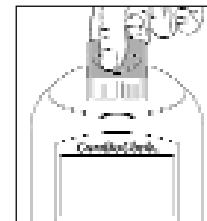
**As an alternative, the test strip may be inserted into the analyzer within 10 seconds AFTER blood is applied to the strip, when blood is applied to the strip directly from a finger. Touch a drop of blood hanging from the finger to the blood application window of the test strip. The blood drop must fill the entire window. Insert the strip into the analyzer. In about a minute, read result.

ADDITIONAL CONSIDERATIONS

1. 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.
2. If you get a reading of "LOW", "< ___", "HIGH", "> ___" or any unexpected result, test again.
3. See analyzer User Guide Troubleshooting section for additional help.
4. To verify enough blood has been applied to the test strip, remove 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.



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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 analyzer is preset to US units by the manufacturer. No calculation of results is necessary. To change to INTL (mmol/L) units, please see the analyzer User Guide.

QUALITY CONTROL

Please refer to the analyzer User Guide for the proper procedure and materials to be used to perform Quality Control tests. Quality Control tests are used to ensure that the system (analyzer, strips, and 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.

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 occasions should be made before a medical decision is made, since a single reading may not be representative of a patient's usual triglycerides. Never make any medical decisions based on your results. Always contact your healthcare professional for advice.

The expected values or reference ranges (for fasting adults) recommended by the US National Cholesterol Education Program (NCEP) 2001 Guidelines are:⁹

- Below 150 mg/dL (Below 1.70 mmol/L) - Normal triglycerides
- 150 - 199 mg/dL (1.70-2.25 mmol/L) - Borderline-high triglycerides
- 200 - 499 mg/dL (2.26-5.64 mmol/L) - High triglycerides
- 500 mg/dL and above (5.65 mmol/L and above) - Very high triglycerides

MEASURING RANGE

The triglycerides 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. If the display reads "LOW" or "<" (less than measuring range), the triglycerides level is below 50 mg/dL (0.56 mmol/L). Results above 500 mg/dL (5.65 mmol/L) will read "HIGH" or ">" (greater than measuring range). If a "LOW", "HIGH", "<" or ">" result is displayed, always test again.

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: Sample hematocrits between 30% and 50% HCT do not interfere with this test. Hematocrits above 50% HCT will decrease the results. In one study, a sample with a 55% HCT decreased the result by 15%.
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 methyl dopa falsely decrease the test results. Statins gemfibrozil and simvastatin (Zocor and Lipid) did not interfere. Acetaminophen, Ibuprofen, and Salicylate do not interfere.
7. 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 Triglycerides Test Strips compared favorably to the triglycerides method run at a Cholesterol Reference Method Laboratory Network (CRMLN) laboratory.

PTS PANELS Triglycerides 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.

AVAILABILITY

REF/CAT NO.	DESCRIPTION
1716	PTS PANELS Triglycerides Test Strips - 25 Tests
1717	PTS PANELS Triglycerides Test Strips - 6 Tests
1789	PTS PANELS Triglycerides Test Strips - 3 Tests
730/1709	CardioChek Analyzer
1708	CardioChek P•A Analyzer
0721	PTS PANELS Multi-Chemistry Controls - Level 1 & Level 2

CLIA INFORMATION (US only)

Complexity Categorization: Waived

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CUSTOMER SERVICE

Customer Service is available to answer questions regarding the CardioChek brand analyzers and PTS PANELS Test Strips. Outside Customer Service hours, please contact your healthcare professional.

(877) 870-5610 (8 a.m. – 5 p.m. EST, M-F toll-free inside the USA)

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per IVDD 98/79/EC

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Explanation of Symbols

	Use By/Expiration date	REF	Catalog number
			Consult instructions for use
	Batch Code/Lot number		Manufacturer
	For in vitro diagnostic use		Store at/Temperature limitation
	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.		