

PTS PANELS™ LDL Cholesterol Test Strips

for use with CardioChek™ P•A Test Systems

INTENDED USE

PTS PANELS LDL Cholesterol Test Strips provide a quantitative measurement of LDL (low density lipoprotein) cholesterol in whole blood. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This system is intended for professional use.

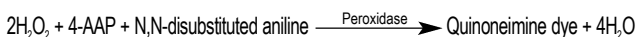
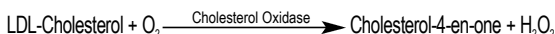
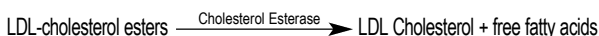
SUMMARY

Low density lipoproteins (LDL) are also sometimes called "bad cholesterol". Elevated LDL cholesterol is a risk factor for coronary artery disease because it clogs the arteries and reduces blood flow. The National Cholesterol Education Program Adult Treatment Panel (ATP III) lists elevated LDL cholesterol as a primary criterion for treatment.

To measure LDL with this system, the MEMo Chip™ provided with each package of test strips 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. A test strip is then inserted into the analyzer and blood applied to the strip. LDL test results are displayed in about two minutes.

PRINCIPLES OF THE TEST

LDL Cholesterol test results are based on a reading of light reflected off a test strip that has changed color after blood is applied. The intensity of the color is directly proportional to the concentration of LDL cholesterol in the sample. The analyzer converts this reading into a LDL cholesterol result and displays it. This test, which selectively measures LDL cholesterol, is an enzymatic colorimetric test based on the "Trinder Method" for the determination of cholesterol. In the presence of oxygen, cholesterol is oxidized by cholesterol oxidase to cholesterol-4-en-one and hydrogen peroxide. In the presence of peroxidase, hydrogen peroxide reacts with 4-aminoantipyrine and N,N-disubstituted aniline to form a blue dye.



MATERIALS PROVIDED

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

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek P•A analyzer
- Quality Control materials
- Lancets for fingerstick (or venous blood collection supplies)
- Alcohol wipes and/or gauze
- Capillary Blood Collector / Capillary Tube or other precision pipet for blood collection and application

CHEMICAL COMPOSITION

Each LDL Cholesterol Test Strip contains the following active ingredients:

Cholesterol Esterase (Microorganism)	≥ 0.75 I.U.
Cholesterol Oxidase (Microorganism)	≥ 0.5 I.U.
4-aminoantipyrine	≥ 12 µg
Peroxidase (Horseradish)	≥ 1 I.U.
Substituted aniline derivatives	≥ 30 µg

Also: MOPS (3-morpholinopropane sulfonic acid) buffer, MES (2-(N-Morpholino) ethanesulfonic acid) buffer, surfactants, polyanions, nonionic surfactants, PEG derivatives, modified cyclic sugars, and protecting agents.

Each vial contains not more than 5 g 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 use. Do not freeze.
- Keep away from heat and direct sunlight.
- Do not remove or discard the desiccant packet in the vial.
- 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.
- 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.
- PTS PANELS LDL Cholesterol Test Strips can only be used in a CardioChek P•A 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 below:

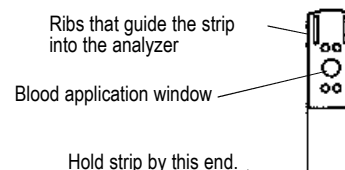
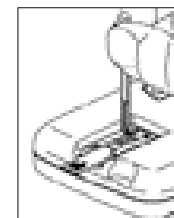
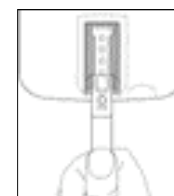
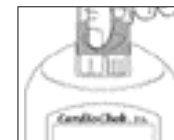
- Use of lotions and handcreams should be avoided before testing.
- Hands should be washed in warm water with antibacterial soap, rinsed and dried thoroughly.
- If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, disposable lancet 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

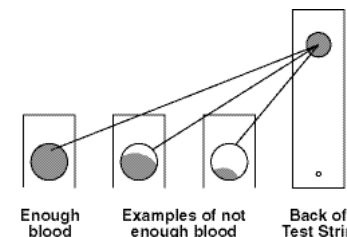
IMPORTANT: Read all instructions carefully before testing.

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 opposite the blood application window. Insert the opposite end of the strip into analyzer. Push the 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 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.



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 analyzer.
2. If you get a reading of "<_" or ">_" 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 at least monthly or with each new lot of test strips, when results are questionable or to comply with their own facility's quality control requirements.

EXPECTED VALUES

LDL cholesterol levels may 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.⁷

LDL Cholesterol Expected Values

- Below 100 mg/dL (2.59 mmol/L) - Optimal
- 100-129 mg/dL (2.59-3.35 mmol/L) - Near optimal/above optimal
- 130-159 mg/dL (3.36-4.12 mmol/L) - Borderline high
- 160-189 mg/dL (4.13-4.91 mmol/L) - High
- 190 mg/dL (4.92 mmol/L) and above - Very high

At least two measurements of LDL cholesterol 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 LDL cholesterol concentration. Results around decision points should be followed with a repeat measurement. Elevated results should be confirmed by follow-up testing in a clinical laboratory. An elevated LDL cholesterol level is only one risk factor for heart disease and should not be used as the sole basis of medical decisions.

MEASURING RANGE

PTS PANELS LDL Cholesterol Test Strips measure LDL cholesterol levels from 50-200 mg/dL (1.29-5.18 mmol/L) and will display a numeric value for results in this range. If the display reads "< ___" (less than measuring range), the LDL cholesterol level is below 50 mg/dL (1.29 mmol/L). Results above 200 mg/dL (5.18 mmol/L) will read "> ___" (greater than measuring range). If a "<" or ">" result is displayed, always test again. Samples with LDL values > 200 mg/dL (5.18 mmol/L) should not be diluted.

A linearity study covering the range of 48-244 mg/dL (1.24-6.32 mmol/L) had a correlation coefficient of 0.973 with the regression line of $y = 0.8909x + 13.24$, with an average recovery of 103.3%.

LIMITATIONS OF THE PROCEDURE

1. PRESERVATIVES: Blood samples preserved with Fluoride or Oxalate should not be used for testing with this system. EDTA and Heparin do not interfere with the test. Fingertick whole blood is the specimen of choice.
2. 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.
3. HEMATOCRIT: Hematocrit values above 57% may incorrectly lower the results. Hematocrit lower than 35% may incorrectly increase the result.
4. Ascorbic acid up to 3 mg/dL, acetaminophen up to 20 mg/dL, Ibuprofen up to 40 mg/dL and Salicylate up to 50 mg/dL do not interfere. Bilirubin up to 10 mg/dL, hemoglobin up to 500 mg/dL, uric acid up to 20 mg/dL and triglycerides up to 500 mg/dL* do not interfere. HDL cholesterol up to 85 mg/dL** does not interfere.
* Triglycerides above 500 mg/dL may increase the LDL result.
** HDL cholesterol above 85 mg/dL may increase the LDL result.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician or practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

PERFORMANCE CHARACTERISTICS

1. ACCURACY: A clinical study was performed by healthcare professionals who measured LDL cholesterol levels on fresh capillary blood specimens from 128 non-fasting persons. The results below show that the PTS LDL Cholesterol Test Strips compare well to a commercially available direct LDL cholesterol method that is certified as traceable to the Center for Disease Control's Cholesterol Reference Method Laboratory Network accuracy base. The PTS PANELS LDL Test Strips have not been tested or certified by the Cholesterol Reference Method Laboratory Network (CRMLN).

PTS PANELS LDL Cholesterol vs. Direct LDL Method

Number of patients = 128

slope = 0.9348

y-intercept = +9.51

r = 0.90

Range of samples tested: 53 to 244 mg/dL LDL

Bias at 100 mg/dL LDL = +2.99%

Bias at 130 mg/dL LDL = +0.80%

Bias at 160 mg/dL LDL = -0.6%

2. PRECISION:

a. Within-Run

Laboratory professionals tested twenty replicates of various levels of LDL cholesterol in whole blood. The following results were obtained:

No. of Samples	20	20	20
Mean LDL Conc. (mg/dL)	79.8	113.6	151.6
Std. Deviation (mg/dL)	3.79	6.11	7.38
Coefficient of Variation (%)	4.75	5.38	4.87

b. Total Precision⁶

A ten day total precision study testing three levels of control material gave the results listed below:

No. of Days	10	10	10
Mean LDL Conc. (mg/dL)	96.8	140.5	171.3
Within-Run S.D. (mg/dL)	2.56	5.49	7.84
Within-Run CV (%)	2.65	3.91	4.58
Total S.D. (mg/dL)	4.03	5.96	9.02
Total C.V. (%)	4.16	4.24	5.26

3. INTERFERENCES: See LIMITATIONS section.

AVAILABILITY

REF/CAT NO.

1753

1754

1708

0721

DESCRIPTION

PTS PANELS LDL Cholesterol Test Strips – 25 Tests

PTS PANELS LDL Cholesterol Test Strips – 6 Tests

CardioChek P•A Analyzer

PTS PANELS Multi-Chemistry Controls – Level 1 and Level 2

CLIA INFORMATION (US only)

Complexity Categorization: Waived

Results of Untrained User Study

An "untrained user" study was conducted in which participants were given only the test instructions and asked to perform testing of three (3) samples in random order. The samples consisted of control material with LDL concentrations at three target levels of 78 mg/dL, 108 mg/dL, and 134 mg/dL. The participants were not given any training on the use of the test. A total of 60 participants were enrolled from 3 sites, representing a diverse demographic (educational, age, gender, etc) population.

Tables below present the summary of the performance:

	Level 1	Level 2	Level 3
N	60	60	60
Target conc. (mg/dL)	78	108	134
Mean (mg/dL)	79.1	110.3	131.1
95% CI (mg/dL)	(78.2; 80.0)	(108.8; 111.8)	(129.4; 132.8)
SD (mg/dL)	3.7	5.9	6.8
CV (%)	4.7%	5.3%	5.2%
Observed Range	67 - 96	95 - 126	116 - 152

Percent of Results in the Range:

Mean ± 15% of Mean 98.3% (59/60)

95%CI: 91.2% to 99.9% 100% (60/60)

95% CI: 94.0% to 100% 100% (60/60)

REFERENCES

1. Data on file, Polymer Technology Systems, Inc., Indianapolis, IN 46268.
2. Clinical Diagnosis and Management by Laboratory Methods, Eighteenth Edition, John Bernard Henry, Editor., W.B. Saunders Company, Philadelphia, 1991.
3. NCCLS Proposed Guideline EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
4. NCCLS Tentative Guideline EP7-T, Interference Testing in Clinical Chemistry. Villanova, PA: National Committee for Clinical Laboratory Standards, 1986.
5. National Cholesterol Education Program. Report of expert panel on detection, evaluation, and treatment of high blood cholesterol in adults. National Heart, Lung and Blood Institute, NIH, Bethesda, MD. Arch. Int. Med., 148:36-69 (1988).
6. NCCLS. Evaluation of Precision Performance of Clinical Chemistry Devices: Approved Guideline. 1999:19(2):1-43.EP5-A.
7. National Cholesterol Education Program Adult Treatment Panel III (ATP III). National Institutes of Health. National Heart, Lung and Blood Institute. NIH Publication No. 01-3670, May 2001.

CUSTOMER SERVICE

Customer Service is available in the US to answer questions regarding the CardioChek P•A analyzer 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)

(317) 870-5610, FAX 1 (317) 870-5608

E-mail inforequest@cardiochek.com

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In Europe, contact:
AUTHORIZED EUROPEAN REPRESENTATIVE
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MDSS GmbH
D-30163 Hannover
Germany

Explanation of Symbols

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