PS-002591E Rev. 2 05/13

PTS PANELS™ Creatinine Test Strips

for use with CardioChek P•A™ Analyzer

INTENDED USE

PTS PANELS Creatinine Test Strips are intended to measure creatinine in whole blood. Creatinine measurements are used in the diagnosis and treatment of renal (kidney) diseases and in the monitoring of renal dialysis. This test is designed for use by healthcare professionals.

SUMMARY

Creatinine Test Strips measure creatinine in whole blood. 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 within eight minutes.

PRINCIPLES OF THE TEST

Results of the Creatinine Test Strips are based on reading light reflected off a Test Strip that changes color after blood has been placed on it. The darker the color, the higher the creatinine level. The instrument converts the reading into a creatinine concentration and displays the result.

Creatinine is measured by a set of five coupled enzyme reactions. First creatinine is converted into sarcosine by the sequential action of three different enzymes. Sarcosine is then enzymatically oxidized to produce hydrogen peroxide in a concentration equal to the sample creatinine concentration. Hydrogen peroxide then forms color through the oxidative coupling of substituted aniline with MBTH. The resulting color of the quinoneimine dye is read by the analyzer.

creatinine —(creatinine deiminase)→ N-methylhydantoin

N-methylhydantoin —(NMHase)→ N-carbamoylsarcosine

N-carbamoylsarcosine —(CSHase)→ sarcosine

sarcosine —(sarcosine oxidase)→ glycine + formaldehyde + H_2O_2

H_2O_2 + MBTH + substituted aniline —(peroxidase)→ quinoneimine dye

MATERIALS PROVIDED

- PTS PANELS Creatinine 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 or other precision pipet for blood collection and application

CHEMICAL COMPOSITION

Each Creatinine Test Strip contains the following active ingredients:

Substituted aniline derivatives	≥ 150 µg
CSHase (Arthrobacter)	≥ 0.5 I.U.
Creatinine Deiminase (Microorganism)	≥ 4 I.U.
NMHase (Arthrobacter)	≥ 0.3 I.U.
Sarcosine Oxidase (Microorganism)	≥ 2 I.U.
Peroxidase (Horseradish)	≥ 10 I.U.
MBTH	≥ 3 µg

Each vial contains not more than 5 g silica gel desiccant.

STORAGE AND HANDLING

- Store Test Strip package in a refrigerator at 35-46°F (2-8°C). Bring 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 Test Strips can only be used in the 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 the 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 use. 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:

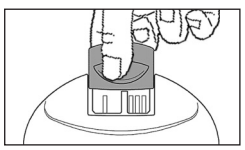
- Use of lotions and handcreams should be avoided before testing.
- Hands should be washed in warm water with antibacterial soap and rinsed and dried thoroughly.
- If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
- Use a sterile, disposable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

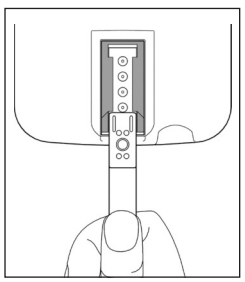
TESTING

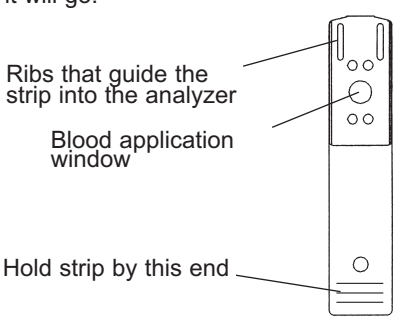
Be sure to read all instructions carefully before testing.

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.

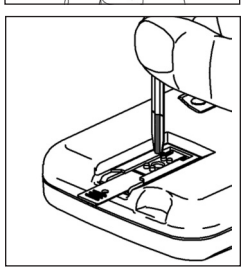


2. Hold the Test Strip by the end with the horizontal raised lines. Insert the opposite end of the strip into analyzer. Push the strip in as far as it will go.





3. When APPLY SAMPLE appears on the display, use a capillary blood collector or pipet to apply 20 µL of whole blood to the Test Strip blood application window.



4. Within eight minutes, the Creatinine result will appear on the display. Remove and discard strip. DO NOT add more blood to a Test Strip that has been used.

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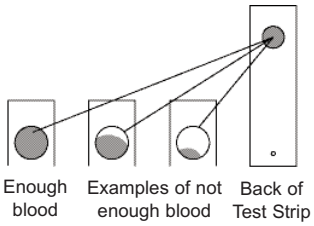
ADDITIONAL CONSIDERATIONS

1. If you do not get a result; make sure:
   – Enough blood was added to Test Strip to completely fill plastic well around white reaction area.
   – 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 "<" 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.



TEST RESULTS

Results are displayed in either milligrams per deciliter (mg/dL) or in micromoles per liter (µmol/L). The mg/dL measurement is a US version, while µmol/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 (µmol/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.

EXPECTED VALUES

The expected or reference range for creatinine is 0.5-1.5 mg/dL (44-133 µmol/L)[6].

MEASURING RANGE

The Creatinine test system will detect creatinine from 0.2-10 mg/dL (17.7-885 µmol/L) and will display a numeric result for results in this range. Results below or above this range will read "<___" (less than measuring range), or ">___" (greater than measuring range). If a "<" or ">" result is displayed, always test again.

LIMITATIONS OF THE PROCEDURE

1. PRESERVATIVES: EDTA and Heparin in blood collection tubes had no effect on the results of the Test Strip.
2. DRUGS: Dopamine above 3.5 mg/dL decreased the results of the creatinine test.
3. METABOLITES: Ascorbic acid (Vitamin C) up to 3 mg/dL did not interfere.
4. HEMATOCRIT: Hematocrit values between 32% and 47% had no effect on the results.
5. 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.

PERFORMANCE CHARACTERISTICS

1. ACCURACY: Laboratory professionals used the Creatinine test system and a commercially available automated creatinine reagent to test creatinine on 115 samples from 87 persons. The subjects in this study were from three sites, including two dialysis clinics which allowed for pre- and post-dialysis samples to be collected. The results of the Creatinine Test Strips in comparison to the commercially available method are listed below:

   n = 115 samples
   sample range <0.2 mg/dL to >10 mg/dL
   Number of sites = 3
   Slope = 0.93
   y-intercept = 0.49
   correlation coefficient (r) = 0.97

This shows that the PTS PANELS Creatinine test system compares well to the reference method results.

2. PRECISION: Three laboratory professionals tested three levels of whole blood for creatinine on multiple analyzers. The following results were obtained:

No. of Samples (n)	20	20	20
Mean Creatinine Conc. (mg/dL)	1.19	3.46	6.00
Std. Deviation (mg/dL)	0.20	0.33	0.41
Coefficient of Variation (%)	–	9.69	6.77
Mean Creatinine Conc. (mg/dL)	1.34	3.39	6.51
Std. Deviation (mg/dL)	0.20	0.30	0.46
Coefficient of Variation (%)	–	8.77	7.05
Mean Creatinine Conc. (mg/dL)	1.38	3.48	6.54
Std. Deviation (mg/dL)	0.16	0.24	0.45
Coefficient of Variation (%)	–	6.77	6.94

3. INTERFERENCES: See LIMITATIONS section.

AVAILABILITY

REF/CAT NO. US/EU	DESCRIPTION
1720	PTS PANELS Creatinine Test Strips – 25 Tests
1708	CardioChek P•A Analyzer
0774	20 µL Capillary Blood Collectors

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. NCCLS Evaluation of Precision Performance of Clinical Chemistry Devices: Approved Guideline. 1999:19(2):1-48.EP5-A.
6. Tietz, NW: Textbook of Clinical Chemistry, W.B. Saunders Co., Philadelphia, PA 1986 pp. 1271-1279, 1820-1821.
7. Young, DL, et. Al., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Wash., D.C., 1990.

CUSTOMER SERVICE

Customer Service is available 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)
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CardioChek brand analyzer and PTS PANELS Test Strips are manufactured in the US by Polymer Technology Systems, Inc. Indianapolis, IN 46268

CE

AUTHORIZED EUROPEAN REPRESENTATIVE
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Explanation of Symbols

	Use By	REF	Catalog number
			Consult instructions for use
LOT	Batch Code		Manufacturer
IVD	In vitro diagnostic medical device		Temperature limitation
CE	This product fulfills the requirements of the European Directive 98/79 EC for in vitro diagnostic medical devices.	EC REP	Authorized European Representative