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.

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:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substituted aniline derivatives</td>
<td>≥ 150 µg</td>
</tr>
<tr>
<td>CSHase (Arthrobacter)</td>
<td>≥ 0.5 I.U.</td>
</tr>
<tr>
<td>Creatinine Deiminase (Microorganism)</td>
<td>≥ 4.1 I.U.</td>
</tr>
<tr>
<td>NMHase (Arthrobacter)</td>
<td>≥ 0.3 I.U.</td>
</tr>
<tr>
<td>Sarcosine Oxidase (Microorganism)</td>
<td>≥ 2 I.U.</td>
</tr>
<tr>
<td>Peroxidase (Horseradish)</td>
<td>≥ 10 I.U.</td>
</tr>
<tr>
<td>MBTH</td>
<td>≥ 3 µg</td>
</tr>
</tbody>
</table>

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:

1. Use of lotions and handcreams should be avoided before testing.
2. Hands should be washed in warm water with antibacterial soap and rinsed and dried thoroughly.
3. If you wipe the fingertip with alcohol, be sure that the alcohol dries completely before sticking the finger.
4. Use a sterile, disposable lancet to puncture the side of the fingertip.
5. Wipe away the first drop of blood with a clean piece of gauze.
6. Gently, without force, apply pressure to the fingertip to accumulate a drop of blood.
7. Excessive squeezing of the finger may alter test results.
8. See the “TESTING” section for information on how to apply the blood to the Test Strip.
9. 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.
2. PRECISION: Three laboratory professionals tested three levels of whole thereference method results. This shows that the PTS PANELS Creatinine test system compares well to

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:

<table>
<thead>
<tr>
<th>n</th>
<th>Number of samples</th>
<th>Mean Creatinine Conc. (mg/dL)</th>
<th>C.V. %</th>
<th>Std. Deviation (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>115</td>
<td>3</td>
<td>1.34</td>
<td>6.51</td>
<td>0.39</td>
</tr>
<tr>
<td>20</td>
<td></td>
<td>1.38</td>
<td>6.54</td>
<td>0.49</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>1.38</td>
<td>6.54</td>
<td>0.49</td>
</tr>
</tbody>
</table>

3. INTERFERENCES: See LIMITATIONS section.

AVAILABILITY

REF/CAT NO. DESCRIPTION
US/EU

1720 PTS PANELS Creatinine Test Strips – 25 Tests
1708 CardioChek P•A Analyzer
0774 20 µL Capillary Blood Collectors

REFERENCES


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)
(317) 870-5610, FAX (317) 870-5608
E-mail informquest@cardiochek.com

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

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AUTHORIZED EUROPEAN REPRESENTATIVE

per IVD 98/79/EC
MDSS GmbH
D-30163 Hannover
Germany

Explanation of Symbols

Use By/Expiration date

Catalog number

Consult instructions for use

Batch Code/ Lot number

Manufacturer

For in vitro diagnostic use

Store at/Temperature limit

This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.