

CardioChek[®] ChekMate[™] Strips

For use with the CardioChek[®] PA Analyzer and CardioChek[®] Plus Test System

INTENDED USE

The CardioChek ChekMate[™] strips are dry strips that mimic the use of the PTS Panels[®] test strips to check the CardioChek analyzer system optics, calibration, and result handling algorithms.

SUMMARY

The CardioChek ChekMate[™] is an assayed, two level, dry strip system. To check analyzer operation, it is recommended that ChekMate strips be run once each day of analyzer use. Both Level 1 and Level 2 ChekMate strips will report four (4) results. These results (C1 RED, C2 RED, C3 RED, C1 GREEN) correspond to a specific optical reading for each chemistry test "window" and are reported as % reflectance. **These values should not be compared to values obtained with PTS Panels test strips.**

Quality Control

CardioChek ChekMate should be used in conjunction with liquid PTS Panels Quality Controls to check the performance of the entire CardioChek test system consisting of the CardioChek analyzer, MEMo Chip[®], and PTS Panels test strips. **ChekMate strips should not be used as a replacement for liquid quality control material, but rather as one component of your facility's quality assurance program.** ChekMate strips do not assess the functionality of the test strips. Liquid PTS Panels Quality Controls should be run as directed in the package insert. It is recommended that the liquid PTS Quality Controls be run whenever a new lot of PTS Panels test strips are received or as required by local accrediting and regulatory bodies. Please refer to the liquid PTS Panels Quality Controls package inserts for instructions on how to run liquid quality controls.

PRECAUTIONS

- For in vitro diagnostic use.
- Handle the ChekMate strips with care; do not drop.
- Do not store or operate in direct light.
- The strips should always be stored in the original container when not in use to protect from light and from accidental scratching.
- Never touch the blue membrane which is the read area of the strip.
- Do not expose strips to high humidity, extreme heat, cold, dust or dirt.
- Recommended usage is 500 uses or 18 months.

STORAGE & HANDLING

Store in a cool dry place at room temperature of 68-80°F (20-27°C) and 20-80% relative humidity (RH). Always store in the original container when not in use to protect from light and from accidental scratching. Do not freeze.

HOW TO USE

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE TESTING

Materials Provided:

- ChekMate MEMo Chip[®] with USE CODE #0001
- ChekMate[™] LEVEL 1 and LEVEL 2 strips

Materials Required, but NOT Provided:

- CardioChek[®] PA analyzer or
- CardioChek[®] Plus test system

ChekMate Test Procedure:

1. Insert the ChekMate MEMo Chip.
 2. Press either button to turn the analyzer ON. USE CODE 0001 will display on the analyzer.
 3. Insert the LEVEL 1 ChekMate strip into the analyzer.
 4. Wait for results to be displayed.
- NOTE:** The value displayed is a reflectance value for the analyzer and will have units of % reflectance. This value should not be compared to values obtained with PTS Panels test strips.
5. Press and release the NEXT button to cycle through the results and read each test window.
 6. Record results on the ChekMate Results sheet.
 7. Compare the results to the LEVEL 1 acceptable ranges printed on the ChekMate Result sheet or visit www.ptsdiagnostics.com to get a list of the LEVEL 1 acceptable ranges.
 8. Remove Level 1 ChekMate strip and press ENTER.
 9. Repeat steps 3 – 7 with the ChekMate LEVEL 2 strip and LEVEL 2 acceptable ranges.

EXPECTED RESULTS

Results are displayed as the following readings: C1 RED; C2 RED; C3 RED; C1 GREEN. These correspond to each chemistry test "window" and are reported as % reflectance. **These values should not be compared to values obtained with PTS Panels test strips.** All results for the ChekMate strips should be within the ranges specified on the ChekMate Result sheet or listed at www.ptsdiagnostics.com. Users may also track their own results and define a narrower acceptance limit based upon the trend for each device as test results accumulate. If test results are outside the specified range, re-test. Should unexpected results be observed, suspect strip damage and replace immediately. If the results remain outside of the specified ranges, contact PTS Diagnostics Customer Service at: **+1-877-870-5610 (Toll-free inside the U.S. and Canada).** RX Only



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Use by

REF Catalog number



Lot number



Manufacturer



In vitro diagnostic medical device



Temperature limitation



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



Consult instructions for use



Authorized representative in the European Community