

ChekMate

Strips

For professional use with CardioChek® PA and CardioChek® Plus analyzers

INTENDED USE

The 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 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

Liquid PTS Panels Quality Controls should also be used in addition to ChekMate strips to check the performance of the entire CardioChek test system, consisting of a CardioChek PA or CardioChek Plus 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 their package insert. This includes running liquid PTS Quality Controls whenever a new lot of PTS Panels test strips are received, to comply with your facility’s quality control requirements or as required by local accrediting and regulatory bodies. Please refer to the liquid PTS Panels Quality Controls package inserts for complete 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
- Do not use after expiration date on package, or 500 uses (whichever comes first).

STORAGE AND HANDLING

Store in a cool dry place at room temperature of 20-27°C (68-80°F) 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.

MATERIALS PROVIDED

- ChekMate MEMO Chip with USE CODE #0001
- ChekMate LEVEL 1 and LEVEL 2 strips

MATERIALS NEEDED BUT NOT PROVIDED

- CardioChek PA analyzer or CardioChek Plus analyzer

HOW TO USE

IMPORTANT: Read instructions carefully before testing.

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 is in units of % reflectance. This value should not be compared to values obtained with PTS Panels test strips.

5. Press and release the Next button, if necessary, to cycle through the results and read each test window.
6. Record results on the ChekMate Results sheet included in the ChekMate kit.
7. Compare the results to the LEVEL 1 acceptable ranges printed on the ChekMate Range card 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 Range card 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 analyzer as test results accumulate.

If test results are outside the specified range, re-test.

If the results remain outside of the specified ranges, please contact PTS Diagnostics Customer Service (M-F, 6 a.m. - 9 p.m. US EST) or your local authorized dealer.

1-877-870-5610 (Toll-free inside the USA and Canada)

+1-317-870-5610 (Direct)

+1-317-870-5608 (Fax)

E-mail: customerservice@ptsdiagnostics.com

USA: RX ONLY















Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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EXPLANATION OF SYMBOLS

	Use by		Manufacturer
	Batch code		Temperature limitation
	<i>In vitro</i> diagnostic medical device		Keep away from sunlight
	Catalog number		Keep dry
	Consult instructions for use		Caution
	Humidity limitation		Prescription required (USA only)
	This product fulfills the requirements of European Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices		Authorized representative in the European Community