PT/INR MONITORING IS AT HAND

WITH NEW DIRECT CLOT DETECTION TECHNOLOGY

INTRODUCING
Coag-Sense™ Prothrombin Time (PT)/INR Monitoring System

For testing in office or for patient self-testing at home

Coag-Sense

Coag-Sense PT/INR System Helps Improve

A Breakthrough in PT/INR Testing

- **First system with Direct Clot Detection Technology**
  - Micro-mechanical process offers superb accuracy and precision
- **Barcoding on each test strip**
  - Validates strip outdate—no calibration code input or chip required
- **Internal verification**
  - Performs a system self-check each time a strip is inserted
- **Displays PT results in less than 1 minute**
  - Calculates actual PT time without look-up table or curve-fitting algorithm
  - Allows for immediate patient consultation

Simple, accurate sample collection

- **Requires a small sample size**
  - Just one drop (10 µL) of blood
- **Uses unique micropipette or transfer tubes**
  - Allows steady transfer of sample to test strip
  - Reduces strip waste

A more direct approach to INR testing

- **Measures actual time required for clotting**
  - The only portable monitoring system that directly detects clotting endpoint—a system that emulates the WHO reference method
- **Allows greater confidence in results**
  - The patented technology of direct clot detection delivers accurate and precise (CV 2.5%) results
  - Reportable range 0.8–8.0 INR

For *in vitro* diagnostic use

To perform a CLIA-waived test, a certificate of waiver (COW) is required.

Consistency of INR Results

More frequent testing benefits patients[1]

- **Recommendations for improved testing**
  - 2008 Joint Commission safety goals call for reduced likelihood of patient harm due to anticoagulation therapy[2]
  - Warfarin black box warning calls for more frequent patient testing[3]

Extending your control from office to home

- **Consistency of monitoring between your office and their home**
  - Same system provides consistent results; may help patients become more compliant under your supervision
- **Convenience of portable, stable tabletop design**
  - Combined with micropipette sampling method, helps patients with limited motor skills steadily apply fingerstick sample
- **Independent Diagnostic Testing Facility (IDTF) supervision**
  - Coordinates patient's home testing results; reports results to you; can help improve testing adherence, insurance adjudication, and ordering supplies
  - Reduces burden on you, freeing you to manage more complex patient cases
- **Reimbursable**
  - Medicare covers weekly home PT/INR monitoring for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism

For *in vitro* diagnostic use

Professional Intended Use: The Coag-Sense Prothrombin Time (PT)/INR Monitoring System is an *in vitro* diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by health care professionals at the point of care to monitor patients who are on warfarin-type (coumarin) anticoagulation therapy. The device is not intended to be used for screening purposes.

Coag-Sense PT/INR System:

PT/INR MONITORING IS AT HAND

- For use in office
- Micropipette stabilizes sample collection
- Directly detects clot formation
- Improved confidence in INR results
- For patient self-testing at home

Cleared for home use	Yes
Cleared for professional use	Yes
Sample size	1 drop (10 µL) capillary blood minimum
Sampling method	21g lancet; micropipette/transfer tube
Device specifications	Portable
Size	3 in (7.6 cm) x 6.5 in (16.5 cm) x 5.75 in (14.5 cm)
Weight	1.2 lb (0.5 kg) with batteries
Test strips packaging	Individually pouched in boxed quantities of 12 and 50
Storage	Non-refrigerated, up to 24-month outdate
Tracking	Barcoded
Heparin sensitive	Yes
Clot detection principle	Direct; measures actual time required for clotting
INR range	0.8–8.0
ISI	~1.0
Prothrombin time (PT)	8–80 seconds
Analysis time	<1 minute
QC	External
Memory	100 tests
Barcoded test strips	Yes
Power source	4 AA batteries/AC adapter (included in P
Warranty	1 year with immediate replacement

For *in vitro* diagnostic use

Self-Testing Intended Use: The Coag-Sense Self-Test PT Monitoring System is an in vitro diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and international normalized ratio (INR) units. It uses fresh capillary whole blood. It is intended for use by properly selected and suitably trained patients or their caregivers on the order of the treating doctor. Patients should be stabilized on warfarin-type (coumarin) anticoagulation therapy prior to self-testing with the Coag-Sense Self-Test PT Monitoring System. It is not intended to be used for screening purposes.

References:
1. Oral anticoagulation patient self-testing: Consensus guidelines for practical implementation. *Managed Care.* 2008;17(suppl 9):1-8.
2. 2008 National Patient Safety Goals. The Joint Commission. Available at: www.jointcommission.org/PatientSafety/National Patient SafetyGoals/08_amb_npsgs.htm. Accessed November 2009.
3. New labeling stresses bleeding risk from Coumadin. U.S. Food and Drug Administration. FDA Patient Safety News Web site. www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=58. Accessed March 25, 2010.

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