

Coag-Sense®

Prothrombin Time (PT)/INR Monitoring System

Quick Reference Guide



PST

Getting Started and Setting Up the Meter

1. Gather test supplies such as test strips, lancets and sample transfer tubes.
2. Warm your hands to increase circulation.
3. Wash your hands with warm soapy water and completely dry them.
4. Place the meter on a flat, non-vibrating surface.

Performing a ProThrombin Time Test

Activity

1. Turn the meter on by pressing and holding the POWER button on the right side of the meter. Press TEST.
2. Confirm that the Patient Strip Lot # is correct by matching with pouch. If blank or incorrect press CHANGE then touch the NFC chip (located on the bottom front right corner of the test strip kit) to the NFC target rings on meter case. If the test strip kit box with NFC chip is not available then manually enter the lot # and Barcode # from the patient test strip pouch and Press CONTINUE.
3. Insert the black plastic plunger into the end of the glass capillary tube with the red stripe. Your meter includes tubes with the plungers pre-loaded. Use care to avoid hitting white plug. The meter will beep to let you know it is ready for a sample and display the message "APPLY SAMPLE". The sample application area will flash green indicating where the sample should be applied. You have 2.5 minutes to apply the sample to the strip.

Display/Visual Aid



Intended Use: The Coag-Sense Self-Test 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 properly selected and suitably trained patients or their caregivers on the order of the treating physician. Patients should be stabilized on warfarin-type (coumarin) anticoagulation therapy prior to self-testing. The device is not intended to be used for screening purposes.

Activity

Display/Visual Aid

4. Remove the cap from the one-time-use 21g lancet, place it against the skin, and push down **firmly** against the finger to lance the surface of skin.

Note: smaller gauge diabetes lancets should not be used.

5. The blood should bleed freely. If it doesn't, gently squeeze the finger to get it started. Lower your hand below your heart if necessary to produce a "bead"-sized drop of blood.

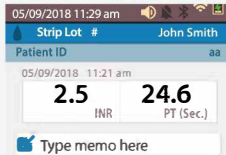
6. Approach bead of blood with transfer tube horizontal. Touch tip to bead of blood and let capillary action fill until blood flow stops at white plug. Squeeze finger to generate additional blood if required to completely fill to white plug.

7. Insert transfer tube tip into sample application well of test strip, **touching tip down** at flashing green light in front of wheel. Depress black plunger completely to dispense the blood. **You must apply blood to the test strip within 15 seconds of lancing the finger.**

The meter will know that you have added the sample and the display will then read: "TESTING, PLEASE WAIT". Testing time is patient's actual Prothrombin time.

8. When testing is complete, the meter beeps once and the results (INR and PT seconds) appear on the screen.

Record the results. Remove the test strip and properly dispose along with the sample transfer tube and lancet. Turn off the meter.



NOTE: Read Self-Test User's Manual for complete instructions for use, indications, warnings, precautions and troubleshooting tips. If any error messages are displayed, refer to the "Troubleshooting" section of the User Manual or call CoaguSense Technical Service at 1-866-903-0890

For In Vitro Diagnostic Use

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