Memorial Home Care Services Document

COAG-SENSE (PT2) PT/INR

PURPOSE:

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 International Normalized Ratio (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 (Coumadin) anticoagulation therapy. The device is not intended to be used for screening purposes.

Oral anti-coagulation medication is prescribed to patients with acute and chronic conditions including, but not limited to: congestive heart failure, atrial fibrillation, prosthetic heart valve, myocardial infarction, joint replacement, deep vein thrombosis, pulmonary embolism, thrombotic stroke, coronary artery disease, venous thromboembolism and cancer.

The rate at which blood clots is measured in units is called International Normalized Ratio (INR). It is very important for patients to stay within their individual target INR range. If the INR is too low, the risk of blood clots increases. If the INR is too high, the risk of hemorrhaging increases. The patient's physician will determine the most appropriate INR range for the patient, depending upon the patient's indication and how they respond to the oral anticoagulants.

The Coag-Sense PT/INR Monitoring System uses a modified version of the one-stage Prothrombin time (PT) test. After a drop of blood is applied to the test strip, it is drawn into the test area containing the reagent and is mixed by a rotating wheel that starts the coagulation process. When the blood clots, it gets picked up in the wheel and obstructs a beam of light. The results are then reported on the meter display in PT seconds and INR units.

SPECIMEN:

Testing should be performed using fresh capillary whole blood. The drop of blood must be a minimum of 10 µL and collected by a 21 g auto-disabling single-use lancet.
See procedure section for more information on sample collection

MATERIALS:

- Coag-Sense Meter
- Coag-Sense Patient Test Strips
- Near Field Communication (NFC) card
- Coag-Sense Low and High Control Strips
- Control Activation Solution
- Sample Transfer Tubes
- Alcohol wipe and gauze
- 21 gauge lancets
- Puncture resistant SHARPS container
- Disposable gloves

Meter Storage and handling

Operating Temperature	18°C to 32°C (65°F to 90°F)
Operating Humidity	10% to 85% (without condensation)
Storage Temperature	0°C to 50°C (32°F to 122°F)
Storage Humidity	20% to 80%

Reagent Storage and handling

- Store the test strips, the control strips and control activation solution in their box at room temperature or in the refrigerator (2-27°C, 35- 80°F). If refrigerated all components must be brought to room temperature before use.
- When stored properly, an unopened test strip, control strip or control activation solution can be used until the expiration date printed on the test strip pouch or control activation solution tube.
- Throw the test strips or control activation solution away if they are past their expiration "Exp." date.
- Once a test or control strip pouch has been opened, the strip should be used within 10 minutes.
- Only use test materials from the same test kit together, no mix and matching.

QUALITY CONTROL:

Controls should be tested immediately upon receipt of each new lot number and ran on every device. There are 2 low control strips, 2 high control strips and a control strip activation solution shipped with each test strip kit.

Running Quality Control

1. Turn the meter ON by press and holding the ⏻ (POWER) button on the right side of the meter.
2. Successful login directs the user to the Home screen.
3. Press the Control icon on the display.
4. Select from the following two options as applicable; Low Control Test or High Control Test.
5. Proceed with testing if the strip is from the same lot as displayed on the screen. Otherwise, follow the steps below (a-c)
    a) Scan the NFC tag from the box against the NFC Tag scanner on the meter.
    b) The Lot # (six-digit number) and Barcode # (eight-digit number) will auto populate.
    c) If box NFC tag information is not available, you may manually enter the Lot # and Barcode # using the keypad on the touchscreen into the respective fields.
6. Press the forward button to continue.
7. Open a Control strip foil pouch at the notched end and take the test strip out.

8. The meter screen should display “Please Insert Strip”.
9. While holding the meter steady with one hand, hold the test strip from the rounded end and insert the test strip into the meter with the Bar Code facing down and the wheel end first.
10. The meter warms the strip for 25 seconds with a screen display of “Please Wait Until Warmup Is Complete”.
11. The meter beeps once and screen display is “Apply Control Solution”. The green sample target light will start flashing at the sample application well.
12. Open the control activation solution and hold at an angle to allow insertion of the transfer tube. Insert transfer tube into control activation solution. Let capillary action fill until solution flow stops at white plug.
13. Apply it to the sample application well on the Control strip. The green light will now turn off. The screen display shows “Testing Please Wait”.
14. When testing is complete the meter will beep and the result of Pass/Fail will appear with PT seconds displayed on the screen along with the date and time of testing.
15. Record the results on the QC log.
16. Repeat the process for the other control strip.
17. Expected control ranges are printed on the outside of the test strip kit. In case of error, review the Troubleshooting section in User’s Manual, repeat the test and if error persists, call the point of care office at 509-574-5847 or CoaguSense Technical Service at 866-903-0890.

QUALITY ASSURANCE:

Coag-Sense user instructions recommends testing one set of controls (High and Low) per new Lot# of Patient Test Strip Kits immediately upon receipt of shipment. QC is to be ran on each instrument used for patient testing. The meter does not require any calibration.

The meter performs a self-check when it is first powered ON and every time a test strip is inserted. If there are any problems detected during self-check, an error message is displayed on the touchscreen.

The Coag-Sense is only to be operated by staff (RN and LPN) that are competent, have completed initial training, and annual training thereafter. The Clinical Manager is responsible for supervising the waived testing.

CALIBRATION:

No calibration testing required by manufacturer

PROCEDURE:

1. Always observe safety and universal/standard precautions.
2. Identify the patient using 2 patient identifiers per policy.
3. Turn the meter ON by press and holding the ⏻ (POWER) button on the right side of the meter.

4. Press the Login icon. Enter login credentials.
5. Successful login directs the user to the Home screen.
6. Press the Test icon on the display.
7. Strip lot confirmation screen displays the lot information of the strip that was last recorded.
8. Proceed with testing if the strip is from the same lot as displayed on the screen. Otherwise, follow the steps below (a -c)
    a) Scan the NFC tag from the box against the NFC Tag scanner on the meter.
    b) The Lot # (six-digit number) and Barcode # (eight-digit number) will auto populate.
    c) If box NFC tag information is not available, you may manually enter the Lot # and Barcode # using the keypad on the touchscreen into the respective fields.
9. Press the forward button to continue.
10. Manually enter the patient ID into the field. Then press the forward arrow icon.
11. The meter screen should display “Please Insert Strip”. Open a test strip foil pouch at the notched end and take the test strip out.
12. While holding the meter steady with one hand, hold the test strip from the rounded end and insert the test strip into the meter with the bar code facing down and the wheel end first.
13. The meter warms the strip for 25 seconds with a screen display of “Please Wait Until Warmup Is Complete.”
14. The meter beeps once, and screen display is “Apply Sample”. The green sample target light will start flashing at the sample application well. This screen will display for 2.5 minutes
15. Prepare the sample transfer tube by verifying the plunger is in the end of the capillary tube with red stripe, use care to avoid hitting the white plug in the tube.
16. Perform a finger stick following instructions below and produce a large drop of blood on the finger using gentle, repetitive pressure. NOTE: Do not use milking technique to collect the drop of blood.
    - Warm the patient’s hands to increase circulation. For fingerstick blood testing, increasing the flow of blood in the finger will help you obtain a good drop of blood.
    - Wash the patient’s hands with warm soapy water or wipe the finger with an alcohol pad.
    - Dry patient’s hands completely as alcohol can effect results.
    - Use a 21g 1.8 mm depth single-use auto-disabling lancet. Smaller gauge/shallow depth lancets (i.e. diabetes 23g lancets) should not be used.
    - The quality of fingerstick and the sample delivery technique are important to the test results. If there is a question about the sample or sample collection, obtain a new strip, repeat the fingerstick on a different finger, and test again.
17. Hold the Sample Transfer Tube between your thumb and forefinger with the tube in the horizontal position, touch the tip to the bead of blood, let capillary action fill the

tube until blood reaches the white plug (avoid air bubbles). Squeeze finger to produce additional blood if required to completely fill the tube.

18. Depress plunger until blood exits the tube and fills the sample application well on the test strip. The green light will now turn off. The screen display shows "Testing Please Wait".
19. When testing is complete the meter will beep, and the result of PT/INR are displayed on the screen along with the date and time of testing.
20. If the INR >8.0 the screen will say "no clot detected" and a lab INR will need to be ordered. If the INR is <0.8 the screen will say "clot time too short" and you will have to start the process over with a fresh finger stick from a different finger. If a different error message appears, see User's Manual for trouble shooting action.
21. Press the check mark icon to return to home screen.
22. Record the result in the medical record.
23. Turn off the meter by holding down the power button
24. Dispose of all testing materials following proper infection control guidelines.

RESULT REPORTING:

Result INR directly to the patient's record. If you need to pull the result from the instrument memory, see procedure notes section.
Do not result a patient result unless QC is acceptable.

MAINTENANCE:

When the power is off and the USB cable is not connected, the meter housing can be cleaned and disinfected by wiping all exposed surfaces with bleach wipes for a contact time of 1 minute to pre-clean blood and other body fluids. Caution should be taken to not spill fluids inside the meter through the test strip port or data transmission ports. The meter should be allowed to air dry before use.

REFERENCE RANGES:

	INR result
Normal range:	0.8 – 1.1
Anticoagulant Therapy	2.0 – 3.0
Reportable Range	0.8 to 8.0
Critical value range:	$\geq$ 4.5

PROCEDURE NOTES:

Reading results in meter memory

The Coag-Sense meter stores up to 2,000 patient test results and 500 control test results, along with the respective date and time of the test performed. The memory can be accessed by pressing the results icon on the home screen. When the memory has reached maximum storage capacity, the oldest result is automatically deleted and gets replaced with the most recent result. This meter records all test results, i.e. patient tests, control. Memory is not lost if there is a break in power for any length of time.

LIMITATIONS OF PROCEDURES:

- The Coag-Sense PT/INR system has not been evaluated and tested clinically in pediatric patients or in patients with the following medical conditions; Anemia, Polycythemia, Cancer, Antiphospholipid Antibody Syndrome, Severe Liver disease, Scleroderma, Reynaud's Disease.
- This test system is not recommended for patients who have recently taken or are currently taking any type of Heparin anticoagulants or Low Molecular Weight Heparin or any direct thrombin or Factor Xa inhibitor.
- The Coag-Sense PT/INR system is designed to use fresh capillary whole blood.
- The drop of blood must be a minimum of 10 ul.
- The quality of the blood sample can affect PT test results. A blood sample of poor quality can produce unreliable results.
- Hematocrit ranges between 15 – 60% will not affect test results.
- In-vitro studies show no significant effect in samples containing up to 20 mg/dL of bilirubin and 500 mg/dL of hemoglobin (hemolysis). No significant effect was seen in samples containing up to 3000 mg/dL of triglycerides (lipemia).
- Differences in reagents, instruments, and pre-analytical variables can affect prothrombin time results. These factors should be considered when comparing results from different test methods.
- If you need to repeat a test, use a different finger for the fingerstick, since blood may have started to clot on the first finger, which may cause unreliable results.
- If there is a bubble or an air pocket showing in the blood sample in the collection tube, start the test over. Use a new fingerstick (using a different finger and collection tube) or results may be unreliable.

REFERENCES:

Policies & Procedures For Coag-Sense® PT/INR Monitoring System (PT2)
Coag-Sense Professional User's manual
Joint commission standard WT.01.01.01
Joint commission standard WT.02.01.01
Joint commission standard WT.03.01.01
Joint commission standard WT.04.01.01

DOCUMENT REVIEW:

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