FHN

Procedure Title:	Coag-Sense Prothrombin Time (PT)/INR

Date Revised/Reviewed	By (signature)	Summary of Revisions	Reviewed by Laboratory Director	Date Approved
4/19/23	C. Engbert	New procedure		

Coag-Sense Prothrombin Time (PT)/INR

PRINCIPLE:

The Coag-Sense PT/INR system uses direct clot detection technology to directly determine prothrombin time. Each test strip contains a rotating spoked wheel which draws sample into a reaction well containing thromboplastin. The wheel spokes mix the sample with the reagent and rotate across a light beam. As the sample transforms into a solid clot, it is picked up by the spokes interupting the light beam. This elapsed time from when the sample is applied to the test strip to when the clot is detected is the actual prothrombin time. No curve fitting algorithms or look-up tables are used.

SPECIMEN REQUIREMENTS:

Patient Preparation:

- Warm the patient's hand to increase circulation
- Wipe the finger with alcohol. Wipe with gauze to dry completely

Specimen Type and Collection Method:

- Fresh capillary blood
- 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.
- Lance the fleshy part of the fingertip just slightly left or right of the center. Press lancet firmly against finger.
- For better blood flow, you may have the patient hold their hand below their heart. If necessary, squeeze the finger from the sides to open the wound for proper blood flow to produce a pea sized drop.

EQUIPMENT, REAGENTS, AND SUPPLIES:

Equipment or Instrumentation:

- Coag-Sense meter

Reagents or Media:

- Coag-Sense test strips

Reagent Performance Parameters:

- INR value: 0.8 – 8.0

Storage Requirements:

- Coag-Sense meter
  - 32^{o}F to 122^{o}F (0^{o}C to 50^{o}C)
    - Operating Temperature: 65^{o}F to 90^{o}F (18^{o}C to 32^{o}C)
  - 20%-80% humidity
    - Operating Humidity: 10% to 85% (without condensation)
- Coag-Sense test strips
  - 2 – 27^{o}C (35 – 80^{o}F)

Special Supplies:

- 21g Lancet device (Single use, auto disabling)
- Sample Transfer Tubes
- Sterile alcohol prep pads
- Gauze square and Band-Aids
- Biohazard waste container (SHARPS)

Warnings and Precautions:

- This device is for in vitro diagnostic use and is not intended to be used for screening purposes.

- This test system is not recommended for patients who have recently taken or are currently taking any type of Heparin anticoagulants. The system should also not be used to monitor patients on direct oral anticoagulants (DOACs) including Factor Xa and Direct Thrombin inhibitors.

CALIBRATION:
The meter does not require the running of controls for any calibration.

INSTRUMENT MAINTENANCE:
Cleaning and Disinfecting:

- Cleaning and disinfecting should occur after each use of the meter and when the meter is visibly soiled.
    - To Clean: Use a damp cloth, wipe the surface of the meter.
    - To Disinfect: Use the Super Sani-Cloth BLEACH Germicidal Wipes (orange container), wipe surface for a contact time of 1 minute and allow to air dry
    - Do NOT clean/disinfect the meter where the test strip is inserted.

QUALITY CONTROL:
QC Material:

- Low and High control strip
- Control strip activation solution

Frequency of Performance:

- Immediately upon receipt of each new lot or new shipment.

Acceptable Limits:

- Acceptable limits can be found on the Control Strip Kit box

Corrective Action:

- If control test fails, repeat the test with a new strip. If the control test continues to FAIL, please contact the Point of Care Coordinator or Coag-Sense Technical Support for assistance.

Recording QC Data:

- Record QC results on the appropriate log sheet.

QC Procedure:

1. Turn the meter ON by press and holding the (POWER) button on the right side of the meter.
    a. Note: The message field on the first screen will display errors encountered during self-check if any.
2. Press the Login icon. Enter your employee ID.
3. Successful login directs the user to the Home screen. Press the Control icon on display icon.
4. Select from the following two options as applicable;
    a. Low Control Test or
    b. High Control Test.
5. Strip lot confirmation screen displays the Lot information of the strip that was last recorded. Proceed with testing if the control strip is from the same lot.
    a. Otherwise, press Change and scan the NFC tag (located on the bottom right corner of test strip kit box) against the NFC Tag scanner on the meter, the Lot # (six-digit number) and Barcode # (eight-digit number) will auto populate.
    b. If box with NFC tag information is not available, you may manually enter the Lot # and Barcode # using the keypad on the touchscreen into the respective fields.
    c. Note: Ensure the strip expiration date on the strip packaging has not passed.
    d. Press the forward button.
6. Open the packaging of the selected control strip by tearing the notched end.

7. Holding the round end, gently push the strip completely into the meter. The strip fits snuggly when pushed all the way toward the back wall of the strip insertion area.
8. Insert the black plastic plunger into the end of the glass capillary tube with the red stripe. Use care to avoid hitting white plug.
    a. Note: Do not apply the control activation solution until the warm-up is complete and the meter display shows 'Apply Control Solution'.
9. 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.
10. The meter beeps once and displays "Apply Control Solution" when it is ready for the control strip activation solution.
11. Rest hand on the meter or counter top to steady. 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 activation solution.
    a. Note: You now have up to 2 ½ minutes to apply the activation solution to the control strip.
12. When the control activation solution is properly applied and detected, the flashing green light will turn off, and the meter displays 'Testing Please Wait'.
    a. Note: If this screen is not displayed within 8 seconds not enough solution was applied. Remove the strip. Retest with a new control strip. DO NOT attempt to add more solution to the strip.
13. When testing is complete, the Pass/Fail results are displayed in PT units. Date and Time are also displayed.
    a. Note: Control test results only display PT seconds, this is to avoid confusing control strip INR results with patient test strip INR results.
14. Repeat Steps 3-13 for 'High control strip.'
15. Once the controls have been successfully tested, remember to remove and discard the control strips.
16. Record results on QC Log and logout of the instrument.
17. You can now proceed to testing patient blood samples. If you are not going to test, turn off the meter by pressing and holding the POWER button. The opened control activation solution may be used until the expiration date.

PROCEDURE:

1. Turn the meter ON by pressing and holding the (POWER) button on the right side of the meter.
    a. Note: The message field on the first screen will display errors encountered during self-check if any.
2. Press the Login icon. Enter your employee ID.
3. Successful login directs the user to the Home screen. Press the Test icon on display screen.
4. Patient Strip lot confirmation screen displays the Lot information of the strip that was last recorded. Proceed with testing if the test strip is from the same lot.
    a. Otherwise, scan the NFC tag against the NFC tag scanner on the meter, the Lot # (six-digit number) and Barcode # (eight-digit number) will auto populate.
    b. If NFC tag information is not available, you may manually enter the Lot # and Barcode # using the keypad on the touchscreen into the respective fields.
    c. Press the forward button.
    d. Note: Make sure the expiration date on the strip packaging has not passed.
5. Enter patient's Account Number (A number)
    a. Press the forward button.
6. Open the packaging of the test strip by tearing the notched end.
7. Holding the round end, gently push the strip completely into the meter. The strip fits snuggly when pushed all the way toward the back wall of the strip insertion area.
8. The meter warms the strip (for 25 seconds) to operating temperature. The display shows a countdown in seconds.
    a. Note: Do not apply test sample until the warm-up is complete and the meter display shows 'Apply sample.'
9. While the meter is warming up, get ready to perform a fingerstick:

a. Have patient wash hands with soap and warm water. Dry completely. If using an alcohol wipe, the finger must be wiped dry with gauze (air drying is insufficient to remove residual alcohol in time)
    i. Note: Residual alcohol or water will affect results. Be certain that finger is completely dry.
b. Choose a site near the top of one of the middle fingers to lance.
    i. Note: Avoid the more sensitive area in the center. Avoid any calluses or scars.
c. Remove the cap from the single use lancet. Place it against the skin. Holding the body of the lancet, push down firmly against the finger to lance the surface of the skin. Do not lance finger until meter displays "APPLY SAMPLE." A minimum of 10µl of collected blood sample is required.
    i. Note: The blood should flow freely. If it doesn't, gently squeeze the finger to get it started. Lowering the patient's hand and arm so that the fingertip is below the heart helps the blood drop form.
    ii. WARNING: Squeezing the fingerstick site excessively (milking) releases interstitial "tissue layer" fluid that cause unreliable results.
d. When ready to collect the drop of blood, hold the Sample 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.
e. Once you have collected the sample, IMMEDIATELY put it into the sample well on the test strip. See 'Performing a PT Test' section of this manual.
    i. WARNING: If there is a bubble or an air pocket present in the blood sample in the transfer tube, start the test over with a fresh fingerstick on a different finger.
    ii. WARNING: Place the meter on a stationary, level surface for testing. DO NOT move the meter or allow it to vibrate during the test. Unreliable results may occur. Wear gloves and follow all applicable hygiene and safety procedures.

10. When the warm-up is complete, the meter beeps (if sound is turned ON) the screen displays a 'Apply Sample' message.
    a. Note: You now have up to 2 ½ minutes to perform a fingerstick and apply the sample to the test strip.
11. IMMEDIATELY after collecting the patient sample, place the tip of the sample transfer tube at a 45º angle into the sample well on the test strip in front of the wheel where you see the flashing green light. Gently touch the tip down onto the sample well. Depress the plunger completely to dispense blood sample.
    a. Note: Discard the sample transfer tube in a biohazard container.
12. When the sample is detected, the meter displays a 'Testing Please Wait' message.
    a. Note: If this screen is not displayed within 8 seconds not enough blood sample was applied. DO NOT attempt to add more sample. Stop the test and retest with a new strip and fingerstick.
13. When testing is complete, the meter beeps (if sound is turned ON). The results (INR and PT seconds) are displayed on the screen along with the date and time of the test.
    a. Note: Memo field allows user to make notes along with the results. Upon clicking the Check mark icon, the main screen is displayed.
    b. Note: Refer to the "Troubleshooting" section of the operator's manual if the meter displays messaging, like for example: CLOT TIME TOO SHORT or NO CLOT DETECTED.
14. Remove the test strip and dispose in a biohazard collection container.
    a. Note: Repeat the test if the results seem unusually low or high. If the results still seem unusual after a second test, contact Technical Support.
15. Record results on patient log sheet and in patient chart.
    a. Note: The meter stores about 2000 patient test results in memory with the time and date stamp. Refer to "Reviewing the Memory" in this manual for more information.
16. Logout of the meter
17. Turn the meter OFF by pressing and holding the POWER button when you are finished testing.

REPORTING RESULTS:

Reference Intervals:

- Normal
  - INR 0.9 – 1.2
  - PT 9.5-13.5 seconds
- Below Therapeutic INR
  - Under 2.0
  - Under 2.5*
- Therapeutic INR
  - 2.0-3.0
  - 2.5-3.5*
- Above Therapeutic
  - Above 3.0
  - Above 3.5*

*patient with mechanical heart valve

Reporting Abnormal Results:

- Results of greater than 8.0 must be reported in the patient chart as >8.0
- Any result of greater than 4.5 should be repeated. If result is still greater than 4.5, a venous specimen must be drawn and sent to the main lab for confirmation.

Result Entry:

- All results are to be reported on the appropriate log sheet, and also in the patient chart.

LIMITATIONS OF PROCEDURE:

Reportable range: 0.8 – 8.0 INR units

- 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 Coag-Sense PT/INR system should not be used if the patient is on heparin or Low Molecular Weight Heparin or any direct thrombin or Factor Xa inhibitor.
- 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.

COMPETENCY REQUIREMENTS:

- Staff new to testing will be required to complete at minimum a return demonstration and assigned quiz.
- Existing staff will be required to complete an annual quiz AND one of the following:
  - Quality Control test
  - Return demonstration
  - Proficiency Test or blind sample

REFERENCES:

Coag-Sense Prothrombin Time (PT)/INR Professional Test Strip Kit Freemont 2018
Professional User's Manual Coag-Sense Prothrombin Time (PT)/INR Monitoring System Fremont 2019