Clinical Laboratory Department POLICY AND PROCEDURE

POLICY NUMBER: 1332
VERSION: 2

SUBJECT: Coagulation: Use of the CoaguChek XS Plus System

PURPOSE

The CoaguChek XS Plus System measures blood-clotting time (prothrombin time, or PT) using blood from the fingertip for people who are taking anticoagulation medications, such as Coumadin® or warfarin. The CoaguChek XS Plus System quantitatively measures prothrombin (blood-clotting) time (PT/Quick value/INR). INR is a measure of the rate at which blood clots. A low INR can increase the risk of blood clots, while a high INR can increase the risk for internal bleeding. The CoaguChek XS Plus System is CLIA waived.

PRINCIPLE

The CoaguChek XS PT Test, used as directed with the CoaguChek XS Plus meter, will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. In simple terms, blood works with the chemicals in the test strip to make a small electric current in the test strip that measures blood clotting time.

In 1983, the World Health Organization (WHO) adopted this calibration system and made recommendations for its implementation to allow all thromboplastins of varying sensitivity in any laboratory for oral anticoagulant control to be calibrated against a reference thromboplastin of human brain with an ISI of 1.0.

POLICY

Testing with the CoaguChek XS Plus System will be used to monitor oral anticoagulant therapy and/or treatment in assessing a patient's health. Only a certified operator may perform a test with the CoaguChek XS Plus System.

EQUIPMENT, MATERIALS AND STORAGE REQUIREMENTS

The Operating Environment for the instrument is 15°C to 32°C (59°F to 90°F) with a relative humidity between 10 and 85% with no condensation.

TEST STRIP STORAGE AND HANDLING

- Store the test strips in their container with the cap tightly closed.
- Store the test strips at room temperature (2°C to 30°C)
- When stored properly, the test strips can be used until the expiration date printed on the test strip container.
- When you are ready to test, open the test strip container and remove one strip from the container. Immediately close the container. Make sure it seals tightly.
- Use the test strip within 10 minutes after removing it from the container.
- Do not open a vial of test strips or touch a test strip with wet hands or gloves. This may damage the test strips.

CODING THE METER WITH THE TEST STRIP CODE CHIP

The test strip code chip provides the meter with important information that it needs to perform the coagulation test. The chip contains information about the test method, the lot number and the expiration date.

• The test strip code chip is required when a new test strip container is opened to store the lot information about the test strips in the meter.
• The CoaguChek XS Plus meter stores the data from up to 60 code chips.
• Use the test strip code chip that was supplied with each new test strip container before you perform the first test from that lot.
• Always compare the code number you see on the display with the number that is printed on the test strip container you are using. If the two code numbers do not match, insert the correct code chip in the slot in the meter.
• Protect the code chip from moisture and equipment that produces magnetic fields.

1. Before each test, make sure the correct code chip is in the meter.
2. The 3-number code on the test strip container must match the 3-number code on the code chip.
1. Be certain the meter is OFF.
2. Remove the old code chip if there is one inserted in the meter. Store the code chip with appropriate strip lot.
3. Insert the code chip into the code chip slot in the meter with the printed side facing UP until it snaps into place.

PROCEDURE:

QUALITY CONTROL TESTING

The CoaguChek XS Plus system performs many types of quality control tests independently:
• A check of the electronic components and functions every time the meter is turned on.
• A check of the expiration date and lot information on the test strip.
• A quality control function is incorporated into the test strip.
• A two-level, on-board quality control test and patient result determination within a single test chamber.

LIQUID QUALITY CONTROL TESTING

Coagulation: Use of the CoaguChek XS Plus System

• If you are using test strips from a new unopened container, you will need to change the test strip code chip. (The meter recognizes only those test strips that match the test strip code chip.)
NOTE: The meter automatically checks to see if you have the right test strip code chip. The 3 digit code on the test strip container must match the number on the test strip code chip before a test can be run.
• The CoaguChek XS Plus meter displays the control range and the result. The reading is automatically saved in the memory of the CoaguChek XS Plus meter.
• Acceptable CoaguChek PT Controls ranges are displayed on the meter when each Quality Control test is run.
• The system is working properly and all handling has been done correctly when the test results obtained are within the acceptable control range.
•If quality control testing results are within the acceptable control ranges, it is appropriate to proceed with patient testing.

UNACCEPTABLE CONTROL RESULTS
• An out of range result is indicated by an arrow. An arrow pointing up means the result is too high. An arrow pointing down means the result is too low. To resolve out of range results or error messages, check for the following:
• Controls may be expired or stored improperly.
• The control may not have been used within 30 minutes of reconstitution.
• You may not be doing the test correctly. Repeat the control test, using a new test strip.
• Make sure you run the test within 10 minutes of removing the test strip from its container.

• If you follow all these guidelines and your results are still unacceptable, call the POCT coordinator.
• QC must be performed at least once a week, when problems with a patient result are suspected, when troubleshooting the system, if the meter is dropped, or if there are any indications that the meter is not working properly. Both levels of QC must fall within the acceptable assay range printed on each control solution package insert.

LIQUID CONTROL STORAGE AND HANDLING
• Exercise the normal precautions required for handling all laboratory reagents.
• Store controls in refrigerator at 2° to 8°C. DO NOT FREEZE.
• Unopened, lyophilized controls that are stored in the refrigerator are good until the expiration date.
• Discard any outdated controls.
• Controls are stable for 30 minutes after adding the diluent.

PREPARING A LIQUID QUALITY CONTROL
1. Gather Supplies
2. Insert the quality control code chip into the meter. This tells the meter the acceptable ranges for this box of controls.

3. Remove the screw cap and rubber stopper from the quality control bottle. Label the bottle with the date and time that you reconstitute it.
4. Using scissors, cut off the tip of the dropper at the end of the stem. Hold the dropper a safe distance from your face.
CAUTION: To avoid loss of diluent, hold the dropper by the stem; do not squeeze the bulb of the dropper while cutting the tip.
5. Invert the dropper and place the tip into the bottle.
6. Gently squeeze the bulb to dispense all of the contents of the dropper over the dried material. Do not allow the dropper to touch the dried material.
IMPORTANT: Make sure you dispense ALL the diluent.
7. Remove the dropper from the bottle. DO NOT discard the dropper. Replace the cap first and gently swirl the bottle to dissolve the quality control. Do not shake or invert the quality control. Make sure that all control material is completely dissolved before you test it.
8. Use the reconstituted quality control within 30 minutes from the time the diluent is added.

LIQUID QUALITY CONTROL TESTING

1. Place the meter on a flat surface, free of vibrations or hold it in your hand so it is roughly horizontal. Do not move the meter during testing.
2. Check the date and time on the meter to confirm it is correct.

3. When you are ready to test, remove one test strip from the container and immediately close the container. Make sure it seals tightly.
IMPORTANT: Do not open a container of test strips or touch a test strip with wet hands or gloves. This may damage the test strips.
4. Use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test.
5. Hold the test strip so the lettering is facing upward.
6. Slide the test strip into the test strip guide in the direction indicated by the arrows.
7. Slide the test strip as far as you can into the meter. This turns the meter ON. A beep tone indicates that the meter has detected a test strip (provided the beeper is turned on in the settings).
8. Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests.
9. Touch CONTROL TEST.
10. The meter automatically checks to see if you have the right test strip code chip. The three digit code on the test strip container must match the number on the test strip code chip before the test can be run.
11. If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now.
12. Select the code already stored for your current control solution, or touch NEW CODE to use a new control solution.
13. If you are using a new control solution, remove the code chip from the meter and insert the code chip that came with the control solution instead.
14. Select level for this control test measurement. (L1 or L2)
15. The hourglass symbol shows that the test strip is warming up.

16. The dropper symbol flashes to indicate that the meter is ready to perform the test and is waiting for the control solution to be applied. A 180second countdown begins.
17. When the meter is ready for the sample, gently swirl the control bottle once or twice to mix
18. Draw control solution into the dropper and put one drop of the liquid on the top of the target area (clear area of the test strip). DO NOT add more control. DO NOT touch or remove the test strip while the test is in progress.
19. The flashing dropper symbol changes to an hourglass symbol when the meter detects a sufficient sample. You hear a beep tone when you have applied enough control solution. The dropper symbol disappears and the test starts.
20. You must WAIT for results—this takes about one minute.
21. The result of the quality control is displayed. It is automatically saved to memory.
22. The acceptable range of results for the liquid control is displayed below the current result.
23. If any control remains in the dropper after you dose the test strip, return the remaining control material to the control bottle. Save extra control until after the test result is obtained, in case the control test needs to be repeated.
24. Record the result. After you verify the validity of the control result, discard the test strip, dropper and the reconstituted bottle of quality control.
25. If the quality control test fails, an up arrow (too high) or down arrow (too low) flashes on the display.
Comments MUST be added to any failed QC result. To add a comment, touch the small empty "word bubble." Select the desired predefined comment(s) from the display list or touch "Custom" to enter your own comment using the keypad. Once you have selected the desired comment(s) touch the ✓ to return to the results.
26. If you need to repeat a test, use a new test strip.
27. Remove the quality control code chip and store it with the opened box of controls. Reinsert the test strip code chip if necessary.
28. Turn the meter OFF.

PATIENT PREPARATION

• Before performing the test, the operator identifies the patient with at least two unique identifiers, and explains to the patient the purpose and steps of the procedure.
• Observe universal precautions.
• Operators must wash hands before and after testing.
• Operators must wear disposable gloves when collecting blood samples or performing tests.
• Have patients wash hands with warm soapy water prior to testing. Allow to dry completely. Do not use products containing alcohol.
• Dispose of used test strips, lancets, and venipuncture supplies in the appropriate designated biohazard or sharps containers.

PATIENT TEST

1. Prepare the lancet device or venipuncture supplies according to the manufacturer's instructions.

2. Confirm that there is an order in Cerner, or that there is a current written protocol order for the test being performed.
3. Place meter on a flat surface, free of vibrations. Do not move the meter around during testing.
4. Take a test strip out of the container. Close the container tightly.
5. Hold the test strip so the lettering "CoaguChek XS PT" is facing upward.
6. Slide the test strip into the test strip guide in the direction indicated by the arrows.
7. Slide the test strip in as far as it will go. This turns the meter ON. A beep tone indicates that the meter has detected the test strip.
8. Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests.
9. Check that the date and time are correct.

• If a lockout is displayed instead of PATIENT TEST, you must run a quality control before you can perform a test. When the meter is in lockout status, a test cannot be performed.

10. Choose your name from the list, then enter your password/employee number when prompted.
11. Touch the ✓ to log on and move to the main menu.
12. Touch PATIENT TEST.
13. Enter Patient FIN number and the ✓ .
14. An hourglass symbol indicates the test is warming up.
15. Confirm that the code number displayed on the meter matches the number on the test strip container.

• The meter automatically checks to see if you have the right test strip code chip. The 3 digit code on the test strip vial must match the number on the test strip code chip before a test can be run.

16. The blood drop symbol flashes to indicate that the meter is ready to perform the test and is waiting for blood to be applied. The 180-second countdown begins.

• DO NOT "perform finger stick" until the flashing drop of blood appears on the display. Strip must be used within ten minutes of removing it from the container.

17. Identify the sample target area on the test strip.

• Massage the finger from its base DO NOT MILK THE FINGER.

When the meter displays the flashing test strip and blood drop symbols, with the hand still down, stick the side of finger with a lancet.

DO NOT wipe away the first drop of blood. Apply the first drop of blood to the top or side of the target area within 15 seconds of puncture. Hold the blood drop to the test strip until you hear a beep.

Avoid getting air bubbles into the sample.

18. Apply the blood directly to the semicircular, transparent sample application area of the test strip.
19. You hear a beep tone when you have applied enough blood. The blood drop symbol disappears and the test starts.

Note: DO NOT add more sample. DO NOT touch the test strip or move the meter until the result is displayed.

20. The meter automatically performs a two-level, on-board quality control test on the test strip before it displays the test result. "QC" appears in the display.
21. You must WAIT for results—this takes about one minute

22. Results will automatically upload to Cerner after the meter has been docked. Do NOT enter the results manually into Cerner as this will result in a double entry.
4. After the test results are displayed, a strip and arrow symbols appear on the screen, prompting you to remove the strip. If you need to add a comment to the result, you must do so BEFORE you remove the test strip from the meter. Once the strip is removed, the meter automatically returns to the Main Menu and a comment can no longer be added. To add a comment, touch the small empty "word bubble." Select the desired predefined comment(s) from the display list or touch "Custom" to enter your own comment using the keypad. Once you have selected the desired comment(s) touch the ✓ to return to the results. A comment MUST be entered for all results >3.9 (Critical Results).

25. Remove the test strip from the measurement chamber.
26. The device must be kept powered on and have an operator logged in before it can be placed on the dock.
27. Dispose of all biohazardous material in the appropriate designated biohazard or sharps container.
Note: Use a new finger stick from the opposite hand and a new test strip if you must retest. DO NOT add more blood to the first test strip.

PROCEDURES FOR ABNORMAL RESULTS

1. The Department of Health Services has adopted the standardized expected range of 0.9 – 1.1.
2. Whole blood INR values ≤0.8 indicate excessive blood coagulation activation, possibly due to specimen collection or processing, and should be repeated. Results will be reported as "<0.8".
3. Whole blood INR results > 3.9 should be repeated. If upon repeat, the result is still >3.9, testing must be repeated at the HD main lab site for confirmation. Results will be reported as ">3.9.
4. The Department of Health Services has adopted a critical value of >3.9. Critical resulting protocol must be followed. A note must be entered into the CoaguChek meter for each and every occurrence of a critical result.

PROCEDURAL NOTES

1. If the meter displays a message other than a result, refer to the Error Messages section of this document.
2. If a < 0.8 INR or > 8.0 INR is displayed, the test result could not be measured or the result may be outside the measuring range for the particular lot of test strips. Repeat the test with a new strip and a new finger stick.
Note: In rare cases, an error message can occur in patients with long coagulation times (> 8 INR). If this error message appears again when the test is repeated, the result must be checked using another method.
3. If the meter displays an unusual test result (other than an error message), check the following items:

- Check that the correct code chip is in the meter. The 3-number code on the test strip container must match the 3-number code on the code chip.

• Check that the meter is set up with the correct date and time. The expiration date of the strips is programmed into the code chip, and is compared to the date on the meter. Therefore, it is important that the date and time be programmed correctly on the meter.
4. Debris on the test strip guide can cause problems with results.

LIMITATIONS

• The results are unaffected by heparin concentrations up to 0.8 U/mL.
• The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL.

• Certain drugs may affect results by interfering with warfarin pharmacology. The potential effect of a drug interaction with warfarin or the effect of underlying diseases (e.g. liver disease, congestive heart failure) must be considered when interpreting a result.
• Changes in the patient's diet can cause unusually low or high results.
• Any unusual result can be followed up with inquiries to define the cause of the unusual result. If the result does not match the clinical symptoms, repeat the patient test to rule out procedural error.
• The CoaguChek XS Plus System should not be used for patients being treated with any direct thrombin inhibitors –including Hirudin, lepirudin, Bivalirudin and Argatroban.
• The CoaguChek XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used
• The blood drop must be a minimum of 8 µL in volume. Low sample volume will cause an error message.
• Never add more blood to test strip after test has begun or perform another test using the same fingerstick
• When a patient is on intravenous infusion therapy, do not collect sample from arm receiving the infusion line.
• Hematocrit ranges between 25-55% do not significantly affect test results. A "c" by patient test result may indicate hematocrit outside range. HCT should be checked.
• Testing performed with the following in vitro spiked samples or native blood samples (Triglycerides) indicated no significant effect on test results:
• Bilirubin up to 30 mg/dL
• Lipemic samples containing up to 500 mg/dL of triglycerides
• Hemolysis up to 1000 mg/dL
• The results are unaffected by heparin concentrations up to 0.8 U/mL.
• The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL.
• Clopidogrel up to 20 mg/dL
• Fondaparinux up to 5 mg/L
• The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values. A comparison to an APA-insensitive laboratory method is recommended if the presence of APAs is known or suspected.

MAINTENANCE

CLEANING AND DISINFECTING THE METER

• Wear disposable gloves when cleaning and performing preventive maintenance.

• The outside of the meter must cleaned after each patient using only 70% alcohol.

- Do not wipe off the alcohol as it must remain on the meter housing for a contact time of >1 minute.
- The meter must be powered off and the test strip guide must remain tightly closed while cleaning the housing. Make sure that no liquid enters the meter.

• The test strip guide and cover must be cleaned weekly or more often if necessary using either 70% alcohol or water.

- With the meter powered off, use your thumbnail to open the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter.
- Rinse the test strip cover with water or wipe it clean with 70% alcohol.
- Hold the meter upright with the test strip guide facing down
- Clean the easily accessible areas with a cotton swab. Ensure the swab is only damp, not wet with 70% alcohol or water.
- Let the inside of the test strip guide dry for at least 10 minutes.
- Close the test strip guide cover and make sure it snaps into place.

RECALLING PATIENT TEST RESULTS STORED IN MEMORY

Review the following steps to recall patient test results that are stored in memory.
Turn the meter on by pressing the ON/OFF button.
1. Wait until the main menu is displayed.
2. Touch MEMORY.
3. Select PATIENT RESULT.
Display patient result memory
Review the following steps to display all test results for patients, sorted chronologically or by patient ID.
1. Touch the ↑ or ↓ to display the entry of choice.
2. Touch the entry you want to open. The entry is displayed. When you touch the Individual symbol, results for the selected patient are displayed.

INSTRUMENT DOWNTIME

During instrument downtime, patient samples will be run in the main (Lancaster) laboratory.

ERROR MESSAGES AND CORRECTIVE ACTION

The meter continually checks its systems for unexpected and unwanted conditions. Depending on the circumstances, a message may appear on the display of the meter. These messages are marked with either an "i" icon for a status message or an "x" icon for an error message. All messages are accompanied by a description of the error and a possible solution. Take the action suggested on the screen to resolve the problem. If the error disappears, you may continue using the meter. If the problem persists, contact the laboratory.

REFERENCES

CoaguChek XS Plus Policies and Procedures Manual, 2007-2013 Roche Diagnostics. All rights reserved. 05021499001(04)

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