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Title: Point of Care - Coaguchek XS Plus INR Test Procedure		
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TITLE: CoaguChek® XS Plus System - INR

PRINCIPLE:

The CoaguChek XS Plus System measures blood-clotting time (prothrombin time, or PT) for people who are taking anticoagulation medications, such as Coumadin® or warfarin. The CoaguChek XS Plus System measures blood-clotting time using blood from the fingertip or whole blood from a vein (nonanticoagulated venous whole blood).

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 patient's physician will determine the best INR range for that patient, depending on why the patient is taking anticoagulants and how the patient reacts to them. The doctor will also determine how often the patient needs blood testing.

The system includes the CoaguChek XS Plus meter, CoaguChek XS PT test strips and optional liquid CoaguChek XS Pro PT Controls. The meter guides you through the test step by step using the symbols and instructions in the display. Each box of test strips has its own code chip that you insert into the meter. The code chip contains lot-specific information about its test strips, such as the expiration date and calibration data. Controls are made available to assist with regulatory compliance requirements as applicable to this facility.

Clinical Laboratory Improvement Amendments 1988 (CLIA '88) Requirements

As of September 2012, the CoaguChek XS Plus System is CLIA waived.

Principle of Operation

Use

The CoaguChek XS PT Test strip, used as directed with the CoaguChek XS Plus meter, provides accurate blood PT values.

Test 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.

WHO reference

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. [1]

If you have questions, please contact Concord Hospital Point of Care at ext 4645 or 4343, or call Roche Diagnostics Technical Service Center at 1-800-428-4674, available 24 hours a day, 365 days a year.

SPECIMEN:

Specimen requirement: 8 ul fresh capillary whole blood from finger stick or a drop of venous blood from a syringe (after expelling 4 drops).

Specimen Handling Conditions:

All body fluids should be handled as if capable of transmitting infectious diseases. Use standard precautions when in contact with such materials. Refer to Laboratory Infection Control Policy.

REAGENTS AND SUPPLIES:

Test Strip Storage and Handling

PURPOSE

The following policy is intended to help trained operators with correct strip handling and storage.

Ingredients

Each CoaguChek XS PT test strip contains reagent (human recombinant thromboplastin 1.5 U), stabilizers, preservatives, and additives.

POLICY—Test Strip Storage and Handling

- Strips are intended for in vitro diagnostic use only.
- Exercise normal precautions when handling laboratory reagents. Follow your facility's infection control guidelines.
- Store the test strips in their container with the cap closed.
- You can store the test strips at room temperature or in the refrigerator (36°F to 86°F or 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.
- Dispose of the test strips if they are past their "Use By" date.
- 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.
- Close the container tightly.

Coding the Meter with the Test Strip Code Chip

PURPOSE

The following procedures provide instructions for matching the code chip to the test strip lot and changing 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.

POLICY—Coding the Meter with the Test Strip Code Chip

- 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.
- Leave the code chip in the meter to protect the electrical contacts in the meter from becoming dirty.
- Each code chip belongs to a particular lot of test strips. Only remove the code chip when you are testing with test strips taken from a new pack (with a new code chip).
- Protect the code chip from moisture and equipment that produces magnetic fields.

PROCEDURE—Matching Code Chip to Test Strip

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.
3. To install the code chip, follow the instructions below. Have the code chip ready.

PROCEDURE—Inserting the Test Strip 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.
    - 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.
    - If the code chip is missing or incorrectly inserted, error messages appear in the display. (Please refer to the chapter *Error Messages* in the *CoaguChek XS Plus System User Manual*.)

CALIBRATION:

Calibration and Calibration Verification

PURPOSE

The following policy provides information on calibration for the CoaguChek XS Plus System.

Definitions:

Calibration is the process of "setting" the instrument to provide correct answers. This is usually done by analyzing known standards supplied by the manufacturer.

Linearity testing defines the limits of accuracy, which is known as the reportable range. This is usually tested with another series of known standards with a wide range of values.

Calibration verification was introduced by CLIA '88 and is defined as, "The assaying of calibration materials in the same manner as patient sample to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the reportable range for patient test." (CFR 42 Section 493.1217). This calibration verification process determines the reportable range so it replaces the concept of linearity testing.

POLICY—Calibration and Calibration Verification

CoaguChek XS Plus System users are already in compliance with CLIA '88 calibration requirements because the code chip supplied with each box of test strips automatically calibrates the meter for that particular lot of strips. The code chip provides specific performance characteristics information to the meter so it is calibrated for use with its corresponding specific lot of test strips and controls.

The manufacturer establishes the performance characteristics based on testing of specimens from donors on warfarin therapy. Each code chip is verified to show that it will produce expected results. In addition, every time the meter is turned on, it goes through a series of self-diagnostic checks.

Roche Diagnostics tests extensively to be sure calibration data provides analytical values that correspond to established reference methods. The CoaguChek XS Plus System calibration is traceable to the WHO International Reference Preparations.

The CoaguChek XS Plus System cannot be adjusted externally to fit a certain linearity curve.

QUALITY CONTROL:

Quality Control Testing

Your 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.

PURPOSE

The following policies and procedures provide instructions for performing and documenting liquid quality control testing. Roche Diagnostics has made available liquid quality controls for the CoaguChek XS Plus System. These controls are made available to assist with regulatory compliance requirements as applicable to this facility. These instructions should be read thoroughly before using the liquid controls.

Ingredients

Each control bottle contains non-human plasma with varied levels of coagulation factors, stabilizers, and preservatives. Each diluent-filled dropper contains a calcium chloride solution with preservatives.

POLICY—Liquid Quality Control Testing

- Read control instructions thoroughly before using the controls.
- Both levels of liquid quality control must be performed: weekly and with changes in test strip lot numbers and with new shipments of the same lot number of test strips, or as needed to trouble shoot unusual patient results or error codes.
- 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. To install the test strip code chip, follow the instructions in the *CoaguChek XS Plus System User Manual.*

- Refer to the *CoaguChek XS Plus System User Manual* for more details about the components and procedures of the CoaguChek XS Plus System
- 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 XS Pro PT Controls ranges are displayed on the meter when each Quality Control test is run. These ranges must be recorded along with the QC result you obtain on the QC log sheet.
- The system is working properly and all handling has been done correctly when the test results obtained are within the acceptable control range.
- If a quality control test result is within the acceptable control range, 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. Carefully follow the instructions in the User Manual.
- 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 Point of Care Testing Specialists at the hospital (Michelle Labbe x4645 or Suzanne Chute x4643) or Roche Diagnostics Technical Service at 1-800-428-4674.

POLICY— Liquid Control Storage and Handling

- Wear disposable gloves when collecting handling test strips and performing QC procedures
- For in vitro diagnostic use. Do not take internally.
- Exercise the normal precautions required for handling all laboratory reagents.
- Store controls in refrigerator at 36°F to 46°F (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.

POLICY—Documenting Liquid Quality Control Testing Results

- Liquid quality control records are retained 4 years, as required for State of NH laboratory licensure.
- All quality control results, along with any corrective action to restore that result to the acceptable range, are recorded on a quality control log. This log includes the test strip lot number and expiration dates, control solution lot number and expiration dates, meter serial number, control ranges, operator identification, and date and time the test was performed.
- The liquid quality control log is reviewed for completeness and any trends that indicate potential problems. Such trends include: gradual drifting of values, sudden shifts in control values while using the same lot of strips, and differences in operator performance.
- The liquid quality control log is reviewed at least quarterly.
- An audit trail links the liquid control test with the appropriate CoaguChek XS Plus meter, test strip lot, and control solution lot used for quality control testing. Quality control testing information is also traceable to patient test results.

PROCEDURE—Preparing a Liquid Quality Control

1. Gather Supplies
    - CoaguChek XS Plus meter
    - CoaguChek XS PT Test strip(s) with matching test strip code chip
    - CoaguChek XS Pro PT Controls: Level 1 and/or 2 with matching quality control code chip
    - Diluent dropper(s): one for each control to be run
    - Scissors
2. Insert the quality control code chip into the meter. This tells the meter the acceptable ranges for this box of controls.
3. Wearing gloves, 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 a few times to dissolve the quality control. Do not shake or invert the quality control. Allow the bottle to sit for one minute. 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.

PROCEDURE—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. When you are ready to test, put on gloves and remove one test strip from the container then 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.

3. Use the test strip within 10 minutes of removing it from the container. Hold the test strip so the lettering is facing upward.
4. Slide the test strip into the test strip guide in the direction indicated by the arrows.
5. 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).
    - For alternative ways of turning on the meter, please refer to the *CoaguChek XS Plus System User Manual.*
6. Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests. The meter takes 4 AA batteries that are not rechargeable.
7. Check that the date and time are correct. You must correct any wrong entries as described in *Meter setup/Setting the date* of the *CoaguChek XS Plus System User Manual* before proceeding with the test.
8. Enter your OPERATOR ID.
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.

Note: When you first run your control, the QC TEST screen will not display. This screen will display the next time you use the control.

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 180-second countdown begins.
    - You must apply the control sample within this time. Otherwise, you will receive an error message.
17. When the meter is ready for the sample, gently swirl the control bottle once or twice to mix the control solution. DO NOT mix the solution with the dropper.
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 (provided the beeper is turned on). 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. (Reconstituted liquid control solution must be discarded after 30 minutes).
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.
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. Re-insert the test strip code chip if necessary.
28. Turn the meter OFF.
29. Both levels of liquid QC must be performed and they both must pass in order to perform patient testing.

PATIENT TESTING:

Patient Preparation

PURPOSE

The following policy and procedure provides instruction for preparing a patient for testing on the CoaguChek XS Plus System.

POLICY—Patient Preparation

- Before performing the test, the operator explains to the patient the purpose and steps of the procedure.
- Observe standard precautions based on the compliance program of this facility.
- Exercise precautions required for handling all blood specimens and laboratory reagents.
- Operators must wash hands before and after testing.
- Operators must wear disposable gloves when collecting blood samples or performing tests.
- If possible, have patients wash hands prior to testing.
- Dispose of used test strips in the appropriate designated biohazard trash and the lancets in a sharps container.

PROCEDURE—Patient Preparation

1. Explain the purpose and steps of the testing procedure to reassure the patient.
2. Wash your hands and put on disposable gloves prior to testing.
3. Collect blood sample following the procedure in the *Specimen Collection and Handling* section below.

Specimen Collection and Handling

PURPOSE

The following policies and procedures provide instructions for collecting, handling, and rejecting patient test specimens.

POLICY—Specimen Collection and Handling

- The CoaguChek XS Plus System test may be performed with fresh capillary whole blood from a finger stick or a drop of fresh venous blood from a syringe (after expelling 4 drops).
- 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.
- The test strip must be used within **10 minutes** of removing from it from the container.
- The meter should display the flashing test strip and blood drop symbols prior to sample collection.
- Capillary sample must be applied to the strip within **15 seconds** of the fingerstick.
- Venous blood must be used immediately.
- Minimum sample size is 8 µL of blood.

POLICY—Rejecting Specimens

- Plasma or serum CANNOT be used as a testing sample.
- Sample size CANNOT be less than 8 µL.
- Venous sample CANNOT be collected in a syringe containing anticoagulant.
- Sample must be USED IMMEDIATELY after collection.
- Glass tubes or glass syringes CANNOT be used (only use plastic).
- Additional blood sample CANNOT be added to the test strip once testing has begun.
- When a patient is on intravenous infusion therapy, sample CANNOT be collected from arm receiving the infusion line.
- See the package insert for additional limitations to the procedure.

POLICY—Blood Application

- Apply directly from the finger to the test strip or use the CoaguChek Capillary Tubes/Bulbs (REF 11621173001).
- Read the testing instructions in the *CoaguChek XS Plus System User Manual* and the *CoaguChek XS Plus PT Test Insert* before collecting the sample.

PROCEDURE—Sample Collection

- CoaguChek XS Plus meter
- CoaguChek XS PT Test strips and matching code chip
- CH approved Lancet
- Alcohol wipe or soap and water
- Gauze or cotton ball
- Bandages

1. Prepare lancet device according to manufacturer's instructions. Set it aside until finger stick is needed.
2. If using the CoaguChek Capillary Tubes/Bulbs (REF 11621173001), prepare capillary collection device by firmly inserting the capillary tube into the capillary bulb. Set aside until needed
3. Warm the hand. Have the patient hold it under his or her arm, use a hand warmer, or wash with warm water.
4. Have the patient let that arm hang down by his or her side before lancing a finger.
5. Massage the finger from its base DO NOT MILK THE FINGER.
6. Clean the selected finger with alcohol wipe or use soap and warm water. Allow to air dry completely. It is acceptable to wipe the area dry with a clean gauze.
7. 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.
    - DO NOT puncture the finger until the flashing test strip and blood drop symbols appear on the meter screen.
8. Immediately after lancing, massage gently along the side of the finger to obtain a large blood drop without pressing or squeezing too hard.
9. While the flashing test strip and blood drop symbols appear on the display, apply the first drop of blood (within 15 seconds) as outlined in *Testing a Patient Sample.*
    - Hold the blood drop to the strip until the meter beeps (providing beeper is set to ON).
    - DO NOT apply a second drop or disturb the strip while testing.
10. If using the CoaguChek Capillary Tubes/Bulbs, touch the capillary tube to the blood drop. Keep tube level and allow it to fill halfway by capillary action. Put finger over hole in the capillary bulb. Hold capillary tube directly over sample target area. While the test strip and blood drop symbols are flashing on the display, apply the sample within 15 seconds of the puncture as outlined in *Testing a Patient Sample.*
11. If using venous blood, engage the safety device on the needle and remove from syringe, disposing in a sharps container. Expel 4 drops of blood on

absorbent pad then add the 5th drop to the sample target area while the test strip and blood drop symbols are flashing on the display.

Note: Avoid getting air bubbles into the sample. Do not touch the bulb during sample collection. If blood gets into the capillary bulb during sample collection, discard the bulb.

12. Clean the Coaguchek XS Plus meter in accordance with instructions at the end of this procedure.

Testing a Patient Sample

Note: Medical staff and other persons using the CoaguChek XS Plus meter to perform tests on more than one patient must be aware that any object coming into contact with human blood is a potential source of infection (See: Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline -Third Edition; CLSI document M29-A3, 2005). Refer to the user manual for guidance on the cleaning and disinfection of the meter system. Meter cleaning instructions are also at the end of this procedure.

PURPOSE

The following policy and procedure provides instructions for testing a patient sample.

POLICY—Testing a Patient Sample

- Only a trained operator may perform a test with the CoaguChek XS Plus System.
- Tests are performed with the CoaguChek XS Plus System only in response to written or electronic requests from an authorized person.
- Oral requests are permitted only if the facility obtains written authorization for testing within 30 days.
- Because of the hazards of handling blood products, wear disposable gloves when collecting specimens and performing test procedures.
- Observe and use standard precautions for all blood specimens. Handle at Biosafety Level 2 as recommended for any potentially infectious material in the Centers for Disease Control/National Institutes of Health manual, Biosafety in Microbiological and Biomedical Laboratories, 1999.
- Refer to this facility's infection control procedures for proper disposal of blood-contaminated items in compliance with OSHA and CDC regulations for standard precautions.

PROCEDURE—Testing a Patient Sample

1. Prepare the lancet device according to the manufacturer's instructions.
2. Place meter on a flat surface, free of vibrations. Or hold it in your hand horizontally until you see the test result. Do not move the meter around during testing.
3. Take a test strip out of the container. Close the container tightly.
4. Hold the test strip so the lettering "CoaguChek XS PT" is facing upward.
5. Slide the test strip into the test strip guide in the direction indicated by the arrows.
6. 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 (provided the beeper is turned on in the settings).
    - For alternative ways of turning on the meter, please refer to the *CoaguChek XS Plus System User Manual*.
7. Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests.
8. Check that the date and time are correct. Correct any wrong entries as described in the *CoaguChek XS Plus System User Manual*.
    - If a lockout (OP. or QC Lockout) is displayed instead of PATIENT TEST, you must run a quality control before you can perform a test. (Refer to *Quality control* in the User Manual.) When the meter is in lockout status, a test cannot be performed.
9. Enter your operator ID.
10. Touch ✓ [OK] to log on and move to the main menu.
11. Touch PATIENT TEST.
12. Select or enter Patient ID.
13. Touch ✓ [OK]. An hourglass symbol indicates the test is warming up.
14. 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.
15. 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 count down begins.
    - DO NOT "perform finger stick" until the flashing drop of blood appears on the display. Strip must be used within **10 minutes** of removing it from the container.
16. Identify the sample target area on the test strip.
17. Collect the finger stick as outlined below.

- *Finger stick sample* – 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 (provided the beeper is set to ON).
- *Using the Plastic Capillary Tube* – Touch the CoaguChek Capillary tube to the blood drop. Keep tube level and allow it to fill halfway by capillary action. Put finger over hole in the capillary bulb. Hold capillary tube directly over sample target area and expel sample within 15 seconds.

Note: Use the **first** drop of **capillar**y blood. Avoid getting air bubbles into the sample.

- *Venous blood* – Expel 4 drops of blood from syringe, then use the test strip while the test strip and blood drop symbol are flashing on the meter display.

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 (provided the beeper is turned on). 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. Following a successful outcome of the quality control test, a check mark appears after “QC.”
22. You must WAIT for results—this takes about one minute
23. The result is displayed in the unit of measure you chose when setting up the meter. It is automatically saved to memory.
24. Read and record results.
25. After the test results are displayed, a strip and arrow symbols appear on the screen, prompting you to remove the strip. If you would like to add a comment to the result, you must do so BEFORE you remove the test strip from the meter.
26. Remove the test strip from the measurement chamber.
27. Turn meter OFF.
28. Dispose of all biohazardous material in the appropriate designated biohazard trash. Lancets must be disposed of in a biohazard sharps container.
29. Clean the meter between patients in accordance with instructions at the end of this procedure.

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.

Interpreting Test Results

PURPOSE

The following policies and procedures assist you with interpreting test results. Before interpreting the result, please also read the test strip package insert carefully.

POLICY—Interpreting Test Results

Any unexpected results should always be followed up with an immediate call to the attending physician. A Panic Value is a PT INR result that is above or below the Immediate Follow-up Values set by the physician. Panic Values should always be followed up with an immediate call to the physician.

Expected Results:

- The CoaguChek XS Plus meter displays test results in units equivalent to laboratory plasma measurements.
- Results may be displayed in three ways (we will use INR only):
    - International Normalized Ratio (INR=(PT/Mean Normal PT))
    - INR/SEC (Seconds)
    - INR/% Quick (a unit used mainly by healthcare professionals in Europe).
- Each lot of test strips is calibrated to a reference lot that is traceable to the WHO International Reference Preparations. Normal INR levels vary from person to person.
- For the purpose of providing universal INR results, the Mean Normal Prothrombin Time (MNPT) has been established as 12 seconds and the ISI for the system has been established as 1.0.
- The physician must determine the best INR level depending on the reason for anticoagulant treatment and how each individual responds to treatment (based on Prothrombin Time).
- Each physician should establish expected values for his or her patient population or individual patients.
- Differences in reagents, instruments, and pre-analytical variables can affect prothrombin time results. These factors should be considered when comparing different prothrombin time test methods.[1] Experience comparing results obtained using the CoaguChek XS Plus System to those obtained using common clinical laboratory reagents shows that the CoaguChek XS Plus System correlates well with

the following clinical laboratory reagents: Dade Innovin, Ortho Recomboplastin, and Dade Thromboplastin C+.

Note: It's possible other clinical laboratory reagents may not consistently correlate with the CoaguChek XS Plus System as well as the recommended list above.

Unusual Results:

- 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.

PROCEDURE—Interpreting Test Result

1. If the meter displays a message other than a result, refer to the *Error Messages* section of the *CoaguChek XS Plus System User Manual*. Repeat error messages may indicate a problem in measuring the INR. If repeat error messages occur, such as **Error 6**, consider the possibility of an interference or high INR value. Use another method for testing (send patient for blood draw for PTINR).
2. The *Coagucheck XS Plus* has been verified and approved for use at this facility for INR results from 0.8 to 6.0.
    - INR Results above 6.0 should be repeated. Repeat the test with a new strip and a new finger stick. If the result is still above 6.0, we recommend that the patient have blood drawn for PTINR.
3. **If any INR result is accompanied by "c", you must consider this result inaccurate due** to decreased or increased hematocrit (<25% or >55%). The patient must be sent for a blood draw for PTINR and **hematocrit**.
4. 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 and send the patient for a blood draw for PTINR and /or emergent care as necessary.

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.

5. 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.

6. **Debris on the test strip guide can cause problems with results.** Clean the meter as recommended in the *CoaguChek XS Plus System User Manual*.
    - Do not use a spray to clean the guide or any part of the meter.
    - Do not let liquid enter the meter
7. See the test strip package insert for the measurement range of the system and Limitations of Procedure.

Documenting Test Results

PURPOSE

The following policy and procedure provides instructions for documenting test results. The test result is displayed in the unit of measure you chose when setting up the meter. It is automatically saved to memory. If the memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved. In the memory display, you can scroll through additional results or return to the main menu.

POLICY—Documenting Test Results

Concord Hospital Anticoagulation Clinics:

- Test requisitions, test authorizations, QC, and test results are retained for a minimum of 4 years as required for State of New Hampshire laboratory licensure.
- Patient results are immediately entered into Hospital Information System (HIS) after again verifying the patient identification. Results are only entered into HIS by the nurse performing the test. The date, time, and nurse's identification are all documented in the HIS.
- Linking the patient test with the appropriate CoaguChek XS Plus meter and test strip lot number creates an audit trail. This is accomplished by recording the meter serial number on the QC log along with the date and time of changes in test strip lot numbers, then pulling a report from the HIS and matching the date and time of patient visit with the test strip lot number in use and meter serial number on the QC log.

Walk-In Urgent Care Center at Horseshoe Pond (HSP WIUCC) and New Hampshire Oncology & Hematology (NHOH)**:**

- Test requisitions, test authorizations, QC, and test results are retained for a minimum of 4 years as required for State of New Hampshire laboratory licensure for HSP WIUCC and 2 years as required by the College of American Pathologists for NHOH.

- Patient results are manually recorded on the point of care testing Coaguchek XS Plus log sheet, and manually entered directly into Laboratory Information System (LIS).
- Linking the patient test with the appropriate CoaguChek XS Plus meter and test strip lot number creates an audit trail. This is accomplished by recording the meter serial number on the QC log sheet as well as on the patient result log sheet.

PROCEDURE—Documenting Test Results

1. The *Coagucheck XS Plus* has been verified and approved for use at this facility for INR results from 0.8 to 6.0.
2. Results above 6.0 should be repeated with a new strip and a new fingerstick. If the result is still above 6.0, the laboratory at Concord Hospital recommends that the patient be sent for a blood draw for PTINR to confirm the result.
3. If any INR result is accompanied by "c", you must consider this result inaccurate due to decreased or increased hematocrit (<25% or >55%). The patient must be sent for a blood draw for PTINR and hematocrit. Results with "c" cannot be documented/ reported.
4. 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. If repeat results are still questionable, another method for testing INR must be used. This can be accomplished by having the patient's blood drawn for a PTINR.

Limitations of the Method

PURPOSE

The following are limitations of the CoaguChek XS Plus System. Refer to the *CoaguChek XS Plus PT Test* S*trip Insert* for the most current information.

LIMITATIONS

- 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
- Use only plastic syringes without anticoagulants or additives. Glass tubes or syringes must not 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 finger stick

- 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.[3]
- In rare cases, **patients with long clotting times (>8 INR) may receive an error message on the meter display**. If this error message appears again when the test is repeated, the result must be checked using another method.

Cleaning the Meter

PURPOSE

The following policies and procedures provide instructions for cleaning and disinfecting the CoaguChek XS Plus meter.

POLICY—Cleaning and Disinfecting the Meter

Concord Hospital's Cleaning & Disinfecting of Reusable Shared Patient Care Equipment and Roche Diagnostic's manufacturer's guideline are used when cleaning and performing preventive maintenance.

After each patient test, and prior to the next patient entering the room, or if the meter looks dirty, the outside of the meter housing and the test strip guide (blue piece) are cleaned.

The outside of the meter housing is wiped clean with an approved product after each patient test, before the next patient enters the room.

The Test Strip guide (Blue piece) is cleaned with an approved product when the blue test strip appears dirty, before the next patient enters the room.

- Do not use sprays of any sort.
- Ensure that swab or cloth is only damp, not wet.
- Wear disposable gloves when cleaning and performing preventive maintenance.

The CoaguChek XS Plus meter may potentially be infectious. It should therefore be decontaminated before disposal.

Follow the procedures outlined below to clean and disinfect the meter and test strip guide. Failure to follow these procedures may cause malfunction of the meter.

PROCEDURE - Cleaning/disinfecting the METER HOUSING (the OUTSIDE of the meter)

- Use only the following items for cleaning/disinfecting the CoaguChek XS Plus meter housing for a contact time of >1 minute:
  - 70% isopropyl alcohol
  - Super Sani-Cloth® Germicidal disposable wipes EPA#9480-4 (Container has a purple top).
  - **NOTE: Do not use any other disinfectants/cleaning solutions on the meter housing. Do not use peroxide.**
- Ensure that the blue test strip guide cover remains tightly closed while cleaning the housing.

1. With the meter powered off, wipe the meter's exterior clean.
   - Using an approved Super Sani-Cloth Germicidal wipe or 70% alcohol wipe, apply cleaning agent for a contact time of >1 minute (refer to the corresponding product labeling
   - Do not let liquid accumulate near any opening. Make sure that no liquid enters the meter.
2. With a lint-free tissue, dry the meter.
   - Wipe away residual moisture and fluids after cleaning the housing.
   - Ensure the meter is completely dry before performing a test.

PROCEDURE - Cleaning/disinfecting the meter TEST STRIP GUIDE (Blue piece)

- Use only 70% isopropyl alcohol (alcohol swab) to regularly clean and disinfect the CoaguChek XS or CoaguChek XS Plus test strip guide.
- **Do not use any other cleaning/disinfecting solutions on the test strip guide. Use of other cleaning/disinfecting solutions could result in damage to the meter. Do not use peroxide.**

1. With the meter powered off, wearing gloves, 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. Then rinse the cover with water or wipe it clean.

2. To clean the test strip guide:

   - Wearing gloves, hold the meter upright **with the test strip guide facing down.**
   - Clean the easily accessible areas with a cotton swab dampened by an alcohol swab
     - Ensure the swab is only damp, not wet.
     - Apply 70% alcohol for a contact time of >1 minute (refer to the corresponding product labeling
     - Wipe away residual moisture and fluids.

Caution: Do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide.

3. Let the inside of the test strip guide **dry for at least 10 minutes**.

4. Close the test strip guide cover and make sure it snaps into place.

HISTORICAL APPROVAL:

PATHOLOGIST APPROVAL: Gary York, MD DATE: 6-4-2013

REFERENCES

[1] Loeliger EA, van den Besselaar AMHP and Lewis SM., "Reliability and Clinical Impact of the Normalization of the Prothrombin Times in Oral Anticoagulant Control." Thromb Haemostas, 1985; 53: 148-154.
CoaguChek XS Plus Operator's Manual; 05021464001 (07) 2016-04. Roche Diagnostics Indianapolis IN 50457
Coaguchek XS Pro PT Test (Strips) Product Insert v 8.0 Roche Diagnostics Indianapolis In 50457
CoaguChek XS Pro PT Controls; Product Insert v 7.0 11-2017 Roche Diagnostics Indianapolis In 50457
Cleaning & disinfection of Reusable Shared Patient Care Equipment 4.2.1 to 4.2.4; Concord Hospital Policies & Procedure manual; v.4 July 1 2016

DISTRIBUTION

Anticoagulation Clinic at Concord Hospital
Concord Hospital Walk In Urgent Care Center

RESPONSIBLE DEPARTMENT/UNIT

Point of Care Testing Department, Concord Hospital Laboratory.

APPROVAL

Initiated by: Amber Lundell, MT (ASCP) Date: May 9, 2013
Adopted (date): June 10, 2013
Reviewed (date): _____
Revised (date): _____