



INR Point of Care CoaguChek® XS Plus	Attachments <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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INR Point of Care Testing Procedure
 Test Procedure (Pages 3-4)
 Quality Control (Page 4-5)
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PURPOSE/PRINCIPLE

To provide direction for performing the International Normalized Ratio (INR) using the CoaguChek XS Plus analyzer for the monitoring the long-term use of warfarin.

POLICY

All staff performing this testing will follow the approved techniques outlined in this procedure.

HealthPartners family of care uses single-use needle and devices for all phlebotomy and blood collection procedures. Should it be necessary to re-stick a patient, a new, single-use needle or device will be used.

HealthPartners family of care will clean the outside of a POCT meter with an approved disinfectant wipe after each patient test for meters that come into direct contact with patients in accordance to HPMG policy and CDC requirements.

Reagent/Materials

- CoaguChek XS Plus Analyzer
- CoaguChek XS PT Test strips
- CoaguChek XS Plus PT Controls

Storage/Handling

Test strips

- Store at room temperature, or in the refrigerator (2-30°C) in the original container, with lid tightly closed until manufacturer expiration date.
- Strips **must** be used within 10 minutes of removal from the container.
- Do not open a vial or touch a test strip with wet hands or gloves as this may damage the test strips.

Controls

- Unopened, lyophilized controls are stable at 2-8°C until the manufacturer expiration date.
- Controls are reconstituted using the diluent supplied
- Controls are stable for 30 minutes after reconstitution
- Do NOT freeze

Specimen

- Minimum sample size is 10 µL of whole blood obtained by fingerstick.
- **Do NOT wipe away the first drop of blood** – it is critical that the test be performed using the first drop of blood


PROCEDURE

Coding the Meter with the Test Strip Code Chip

- The test strip code chip is required with each new lot of test strips so that the meter can read and store the lot information about that particular lot of test strips.
- Before each test, make sure 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.
- Leave the code chip in the meter to protect the electrical contacts in the meter from becoming dirty
- Protect the code chip from moisture and equipment that produces magnetic fields
- The CoaguChek XS Plus meter stores the data from up to 60 code chips.

NOTE: The XS Plus meter will store up to 100 test results with the dates and times. When the memory is full, the oldest test result will be removed when a new test is performed.



Inserting the Test Strip Code Chip:

- Insert the code chip into the code chip slot with the printed side facing UP until it snaps into place.
- Verify the code number displayed on the meter matches the code number on the strip container.
- Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal
- Power the meter on by pressing the  button for approximately 1 second. 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 User Manual).

Collecting the Specimen

- Clean the selected finger with alcohol wipe. Allow to air dry completely.
- When the meter displays the flashing test strip and blood drop symbols, stick the middle 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.
- Immediately after lancing, massage gently along the side of the finger to obtain a good blood drop without pressing or squeezing too hard.
- 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 the Performing a Test section of this procedure.
- Hold the blood drop to the strip until the meter beeps (provided the beeper is set to ON).
- DO NOT apply a second drop or disturb the strip while testing.

Performing a Test: XS PLUS meter

- Place meter on a flat surface, free of vibrations or hold it in your hand so the meter is roughly horizontal. Do not move the meter during testing.
- Turn meter ON by pressing the  button for approximately 1 second
- Select Patient Test
- Enter Patient ID then select 
- The test strip icon will prompt you to insert a test strip. Take a test strip out of the container. Close the container tightly.

The test strip must be used within ten minutes of removing it from the container

- Hold the test strip so the lettering “CoaguChek XS PT” is facing upward.
- Slide the test strip into the test strip guide in the direction indicated by the arrows as far as it will go.
- A beep tone indicates that the meter has detected the test strip
- Confirm that the test chip code number displayed on the meter matches the number on the test strip container.
- The hourglass icon shows that the test strip is warming up. When the warming up process is complete, a further beep indicates that you can now apply blood.
- The blood drop icon 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 obtain sample until the flashing drop of blood appears on the display. However, you must apply the drop of blood to the test strip before the countdown ends.
- Collect the sample by fingerstick or venipuncture with an anticoagulant-free syringe.
- **DO NOT wipe away the first drop of blood.**
- Apply the **first drop of blood** to the semicircular, transparent sample application area on top of the test strip within 15 seconds of puncture. Hold the blood drop to the test strip until you hear a beep.
- The blood drop symbol disappears and the test starts.
- DO NOT add more sample to the test strip. DO NOT touch the test strip or move the meter until the result is displayed.
- After the test results are displayed, document result on the patient label, remove and discard strip.
- Turn off the meter.
- After each patient test, clean the outside of the meter with an approved disinfectant. Allow the meter to dry before testing. DO NOT get moisture in the code key slot or test strip guide.

Reporting Results

- Refer to the Beaker result entry procedure.
- INR results are reported to one decimal position. (ie. 2.3 etc)
- INR results ≥ 4.0 and < 0.8 are not linear on the CoaguChek.
 - Enter the INR results into the Beaker as > 3.9 or < 0.8
 - Once result is verified, it reflexes to a venipuncture Protime/INR. Labels will print
 - Collect venipuncture specimen and send STAT to Regions per usual protocol
 - Notify Centralized INR Hotline (952-883-1002) the result is > 3.9 or < 0.8 ; Result to be Verified by venipuncture INR/Protime
 - Document the call in Beaker per protocol using the Protime, Whole Blood MPI number.
- Stable anticoagulation therapeutic range is 2.0-3.0
- Stable anticoagulation therapeutic range for patients with a mechanical heart valve is 2.5-3.5


Quality Control Testing

- External controls must be run once per month AND with changes in lot numbers of the test strips.
- The system performs internal quality control tests: a check of the electronic components and functions, the expiration date and lot information on the strip and a two level, onboard quality control test is performed every time the meter is turned on and a test is run.

Preparing a Liquid Quality Control

- Insert the quality control code chip into the meter. This tells the meter the acceptable ranges for this box of controls.
- Remove the screw-cap and rubber stopper from the quality control bottle. Label the bottle with the date and time that you reconstitute it.
- Using a 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.**
- Invert the dropper and place the tip into the bottle.
- 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.**
- 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. Let the bottle sit undisturbed for one minute.
- Use the reconstituted quality control within 30 minutes from the time the diluent is added.

Liquid Quality Control Testing

- 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.
- Turn the meter on by pressing the  button for approximately 1 second.
- Select Control test
- The test strip icon will prompt you to insert a test strip. Take a test strip out of the container. Close the container tightly.
 - **The test strip must be used within ten minutes of removing it from the container**
- Hold the test strip so the lettering "CoaguChek XS PT" is facing upward.
- Slide the test strip into the test strip guide in the direction indicated by the arrows as far as it will go.
- A beep tone indicates that the meter has detected a test strip.
- Select the code already stored for your current control solution, or touch NEW CODE to use a new control solution.

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.

- Confirm that the test chip code number displayed on the meter matches the number on the test strip container.
- Select level for this control test measurement. (L1 or L2)
- The hourglass icon shows that the test strip is warming up. When the warming up process is complete, a further beep indicates that you can now apply control.
- The dropper icon 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.
- 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.
- Draw control solution into the dropper and put one drop of the liquid on the top of the semicircular transparent sample application area on the top of the strip. DO NOT add more control or touch or remove the test strip while the test is in progress.
- The flashing dropper icon changes to an hourglass icon and a beep tone indicates when the meter detects a sufficient sample.
- The result of the quality control is displayed. It is automatically saved to memory.
- The acceptable range of results for the liquid control is displayed below the current result.
- 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 just in case the control test needs to be repeated.
- Record the result in Beaker. Update acceptable range in Beaker under QC material if needed. After you verify the validity of the control result, discard the test strip, dropper and the reconstituted bottle of quality control.
- If the quality control test fails, an up arrow (too high) or down arrow (too low) flashes on the display.
- If you need to repeat a test, use a new test strip.
- Remove the quality control code chip and store it with the opened box of controls. Re-insert the test strip code chip if necessary.
- Turn the meter OFF.

Corrective action when a control fails to perform as expected

- Verify use of correct control, confirm the test strip chip code displayed on the meter matches the test strip lot number on the container and all expiration dates are acceptable.
- Remix and repeat
 - If acceptable – document corrective action, record results and proceed with patient testing
 - If repeat failure – document corrective action and proceed to step 3.
- Open a new control, mix and test
 - If acceptable – document corrective action, record results and proceed with patient testing
 - If repeat failure – document corrective action and proceed to step 4.
- Open a new container and/or lot of test strips
 - If acceptable – document corrective action, record results and proceed with patient testing
 - If repeat failure – document corrective action and proceed to step 5.
- Contact your laboratory supervisor.

Limitations

- The CoaguChek XS Plus System should not be used for patients being treated with direct thrombin inhibitors including Hirudin, Lepirudin, Bivalirudin, and Argatroban.
- The CoaguChek XS Plus System should not be used for patients who are on Low Molecular Weight Heparin therapy either alone or in combination with warfarin. The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL. The results are unaffected by heparin concentrations up to 0.8 U/mL.

Note: Patients who are on Low Molecular Weight Heparin therapy should not have their INR tested using a point-of-care meter; regardless of the brand or manufacturer. INR testing for these patients should be performed with a specimen collected by venipuncture and sent to the main laboratory.

- Patients with anti-phospholipid antibodies, such as Lupus antibodies, can potentially lead to prolonged clotting times. The CoaguChek Plus System should not be used to monitor INR values for patients with anti-phospholipid antibodies. These patients should be drawn and their INR sent to Regions for testing.
- In the event that an ERROR 7 message is displayed, repeat the test. If this error message appears again, then draw the patient and send the INR to Regions for testing.
- Hematocrit ranges between 25-55% do not significantly affect test results.
- For patients whose INR test results were sent to Regions for testing due to a critical value or other error results, these patients may resume having their INR test results performed on the CoaguCheck XS Plus meter at the next time their INR test results are to be tested.
- Error 6 Messages: Roche has confirmed the potential for an undetected elevated INR result with the CoaguChek XS meters. In *rare* cases, instead of a value, an "ERROR 6" message is displayed. The meter is functioning properly by displaying this error message and not a result. High INR values are associated with an increased risk of bleeding, therefore, if an "ERROR 6" is displayed, the following action should be taken:
 - Repeat testing using a different finger for the specimen collection
If a numerical result displays, follow usual protocol
If "ERROR 6" message displays again, testing by alternate method is required.
 - If available, release standing order for PT from Epic. If no standing order available, place an order for PT in the lab computer system.
 - Collect a venipuncture specimen and send STAT to Regions per usual protocol
 - Notify Centralized INR hotline (952-883-1002) "due to error code, result will be verified by venipuncture INR/Protime
 - The Protime, Whole Blood test must be credited.

Cleaning and Disinfecting the Meter Exterior

Do Not spray anything on the meter and do not immerse it in liquid. Ensure the cloth or swab is only damp, not wet, to protect against moisture entering the meter.

- Use an approved disinfectant wipe to clean the exterior of the meter
- Ensure the blue test strip guide remains tightly closed while cleaning the meter exterior.
- Ensure the meter has been powered off.
- Apply the cleaning solution for a contact time of at least 1 minute.
- With a fresh, dry cloth or lint-free tissue, wipe away residual moisture from the meter exterior.
- Allow the wiped areas to dry for at least 10 minutes before performing a test.

Cleaning and Disinfecting the Test Strip Guide

- Use an approved disinfectant wipe
- With the meter turned OFF, open the cover of the test strip by pressing upwards from the front (e.g. using your thumbnail).
- Move the cover safely away from the meter. Then rinse the COVER with an approved cleaning agent.
- Let the cover dry for at least 10 minutes.
- Hold the meter upright with the test strip guide facing down.
- Clean the easily accessible white areas with a moistened cotton swab.
- Ensure the swab is only damp, not wet.
- Wipe away residual moisture and fluids
- With the cover off, let the test strip guide dry for at least 10 minutes.
- Reattach the test strip guide cover to the housing. Make sure that the cover is properly closed. You still hear it snap in to place.

Maintenance Notes

- Make sure that no liquid enters the meter.
- Do not insert any objects in the test strip guide. Doing so may damage the electrical contacts behind the test strip guide.
- Contact Roche Diagnostics Point of Care Technical Service at 1-800-428-4674 if:
 - Error 4 appears when turning on the instrument the first time after cleaning/disinfecting, or
 - Error 8 appears during the first measurement after cleaning/disinfecting.

DEFINITIONS

COMPLIANCE

Failure to comply with this policy or the procedures may result in disciplinary action, up to and including termination.

ATTACHMENTS

OTHER RESOURCES

Internal: CoaguChek XS Plus Manual, Package Inserts
CoaguChek XS Manual, Package Inserts

Other: For assistance contact the Regional Clinic Laboratory Supervisor or call Roche Diagnostics Point of Care Technical Service Center at 1-800-428-4674.

ENDORSEMENT Laboratory Administration

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