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THE RICHLAND HOSPITAL and Clinics

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Owner	Dana Wilson: Laboratory Director
Area	Laboratory

INR Meter: Point of Care Testing Policy and Procedure

INR METER: COAGUCHEK XS SYSTEM

METHOD:

CoaguChek XS Meter – CLIA Waived *(Richland Hospital Nursing Department POCT Certificate of Waiver CLIA ID Number 52D1083369)*

PRINCIPLE:

The CoaguChek PT Test provides an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin present in the test strip to make a small electric current that measures blood clotting time.

The CoaguChek XS quantitatively measures prothrombin time, displaying the result as the International Normalized Ratio (INR).

PURPOSE:

The CoaguChek XS System provides a rapid test method to measure blood clotting time (prothrombin time or PT) for people who are taking anticoagulation medications, such as Coumadin or warfarin. Blood clotting time must be monitored for those on anticoagulation medications to ensure that the patient's medication dosage is correct.

MATERIALS:

- CoaguChek XS System Meter
- CoaguChek XS PT Test Strips with matching code chip

- Lancet device
- Alcohol wipe
- Gauze
- Bandage
- Liquid control solutions

REAGENTS:

- CoaguChek XS PT Test Strip: impregnated with human recombinant thromboplastin
- CoaguChek XS Pro PT Controls, Levels 1 and 2: lyophilized non-human plasma with varied levels of coagulation factors, stabilizers and preservatives.
- CoaguChek XS Pro PT Control Diluent: Calcium Chloride solution with preservatives.

TEST STRIP STORAGE AND HANDLING:

- Store test strips at 2°C- 30°C (36°F – 86°F)
- 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 making sure it seals tightly.
- Do not open a vial of test strips or touch a test strip with wet hands or gloves. This may damage the test strip.
- Close the container tightly.
- Use the test strip within **10 minutes** after removing it from the container.
- Dispose of the test strips if they are past their "Use By" date.

OPERATING CONDITIONS:

- Room temperature must be 15°C - 32°C (59°F – 90°F).
- Relative humidity must be < 85%, without condensation.
- Meter must be kept horizontal during testing. Place on a level, vibration-free surface or hold it so it is roughly horizontal.

TESTING PERSONNEL:

INR METER TESTING BY NON-LABORATORY PERSONNEL

Purpose: To outline the extent to which waived testing will be used by the Richland Hospital when operating under the CLIA (Clinical Lab Improvement Ammendment) Certificate issued to the Richland Hospital Nursing Department.

Policy:

A. The CoaguChek XS System INR Meter *(Clia Waived)* is performed at the Richland Hospital INR

Clinic under the Richland Hospital Nursing Department POCT CLIA Certificate of Waiver license (CLIA ID Number 52D1083369).

B. Any waived testing performed outside of the Richland Hospital Laboratory, by non-laboratory staff, must be approved by the Laboratory Director.

C. The Laboratory Director must review and approve all procedures, competencies and policies regarding waived testing annually.

D. It is the responsibility of the Laboratory Director to resolve any competency and or non-compliance issues for INR Meter testing.

E. Once INR Meter testing staff have passed an initial competency established by the Laboratory, the INR Meter testing personnel may use a designated trainer or validator to complete annual competency for all nursing staff performing INR Meter waived testing. Documentation of each annual competency must be forwarded to the Laboratory Director.

F. The Laboratory Director will review all Quality Control and Patient testing results, assist with the necessary follow up, and maintain the Competency Testing records.

G. Quality Control: Two levels of Control Material (Level 1 and Level 2) are run on the CoaguChek XS System Meter with each new lot/shipment and every 30 days.

H. All waived testing is to be used as a tool to make decisions regarding patient care. A particular test may be used definitively when the value meets the criteria established for that test, or the test may serve as a screening tool only, which must be confirmed by testing performed by the Clinical Laboratory staff.

SPECIMEN:

Fresh capillary blood from the fingertip. Obtain specimen using the standard capillary collection method. **DO NOT WIPE AWAY THE FIRST DROP OF BLOOD.** Testing is performed on the **first drop** of blood from the finger. Minimum volume is 8uL.

QUALITY CONTROL

EXTERNAL QUALITY CONTROLS

- CoaguCheck XS Pro PT Control – Level 1 and Level 2
- Store at 2°C – 8°C. *Controls are stored in the Richland Hospital Laboratory.*
- External controls are run with each new lot/shipment **and** every 30 days.
- External controls may also be run when the tech feels it is necessary to validate the performance of the meter.
- Record the results on the "Coaguchek XS External QC Log".

INTERNAL CONTROLS:

The meter has the following built-in quality control functions:

- A check of the electronic components and functions every time the meter is powered on.
- A check of the test strip temperature while a test is in progress.

- A check of the expiration date and lot information on the test strip based on the code chip data.
- A two level, onboard quality control test is automatically performed within the test chamber as part of every blood test.
- ***When the quality test runs, the letters QC flash on the meter's display. When the quality control test completes, a checkmark (√) appears following the letters QC. If the quality test fails, the meter displays an error message and the test cannot be performed. Consult the User Manual for Error Message guidance.***

EXTERNAL CONTROL TESTING PROCEDURE:

A. **CONTROL PREPARATION:**

1. 1.Open a bottle of lyophilized control.
2. Using a scissors, cut off the flared tip of the dropper **at the end of the stem.** NOTE: Hold dropper vertically by the stem, to avoid loss of diluent.
3. Transfer the entire contents of the dropper to the bottle. NOTE: Do not touch the dropper to the dried material or the sides of the bottle. DO NOT discard the dropper. It will be used in running the control test.
4. Replace the cap. Gently swirl bottle. **DO NOT** shake or invert the bottle. Let stand for minimum of one minute.
5. Control solution **MUST** be used within 30 minutes of reconstitution.

B. **PERFORMING THE CONTROL TEST:** (perform steps 2 through 12 for each level)

1. Insert Strip Code Chip (**not** QC Code Chip) and turn on the meter.
2. Remove one test strip.
    a. Close container immediately.
    b. Test strip **must** be used within 10 minutes.
3. Insert test strip into the instrument in the direction of the arrows until it stops. The meter powers on.
4. The Strip Code Chip number flashes on the display. Confirm that the Strip Code Chip number matches the number on the test strip container. *If the numbers are different, make sure you are using the code chip that came with the test strips you are using.*
5. An hourglass symbol appears as the meter warms up, which takes about 30 seconds. **DO NOT ADD QC SAMPLE YET!** During this time, gently swirl the QC material but do not invert to mix. When the meter is warmed up, a flashing test strip appears and the meter begins a countdown. You have 180 seconds to apply the QC.
6. Apply the control.
    a. Once the flashing test strip has appeared on the meter, using the dropper used for reconstitution, apply a drop of control to the target area
    b. An hourglass symbol will appear, indicating the test is in progress.
    c. Return unused control solution to the bottle in case repeat testing is needed.

7. Record result on the CoaguChek XS External QC Log. Assess acceptability of the control value obtained by comparing the obtained result to the acceptable QC range according to the CoaguChek XS Pro PT Controls Package Insert. This range is also indicated on the CoaguCheck XS External QC Log. *A result will not appear if the internal QC is not acceptable.*
   NOTE: Both levels of external controls must be within acceptable range before performing patient testing.
8. Remove test strip and shut meter off.

PATIENT TESTING PROCEDURE:

A. **INSERT STRIP CODE CHIP:** Note: Meter must be OFF.
   1. Verify that the code number on the test strip container and the test strip code chip match.
   2. With the code number facing up, insert the code chip into the code chip slot until it snaps into place.
   3. NOTES:
      a. Each box of test strips comes with its own code chip. The code chip provides the meter with information such as the lot number and expiration date of the teststrips.
      b. Each time a new lot of test strips is opened, install the new code chip.
      c. Leave the code chip in the meter to protect the electrical contacts in the meter from becoming dirty.
      d. Protect the code chip from moisture and equipment that produces magnetic fields.

B. **PERFORM PATIENT TEST:**
   1. Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.
   2. Power the meter on by pressing the power button.
   3. Enter operator ID. Touch the green "check" to enter.
   4. Select <Patient Test>
   5. Enter Patient's name
   6. Insert Test Strip in direction of arrows, until it stops (audible beep).
      An hourglass symbol appears. **DO NOT ADD SAMPLE YET!**
      Make sure the code number on the display is the same as the number that is printed on the test strip container in use.
   7. When a strip and a blood drop appear on the screen, **perform the fingerstick.**
   8. **Apply the first drop of blood** to the target area of the test strip. This must be done within 180 seconds.
      When the sample is detected, there will be an audible beep and an hour glass will reappear on the screen. The hour glass indicates the testing, alone with an internal

QC check, is in progress.

9. INR results will appear on screen when testing is complete. NOTE: Results will not appear if the internal QC check is not acceptable.
10. Record patient results.
11. Remove test strip and discard in biohazard container. Discard lancet in biohazard sharps container. Shut off the meter.

NORMAL/REFERENCE RANGE:

INR Normal range: 0.8-1.2

INR Therapeutic Range: Low to Moderate Intensity Anticoagulation: 2.0-3.0

Moderate Intensity Anticoagulation: 2.5-3.5

Critical INR value: >4.5 or greater

REPORTABLE RANGE: INR: 0.8 - < 4.0

All INR results > 4.0 must be confirmed by collecting a venous sample for PT/INR testing at The Richland Hospital Laboratory.

LIMITATIONS OF PROCEDURE:

A. Patient's hematocrit must be between 25 and 55%.
B. Patient must be on a stable dose of coumadin.
C. Testing cannot be performed on patients being treated with any direct thrombin inhibitors.
D. The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies can potentially lead to elevated INR values. A comparison to an APA-insensitive laboratory method is recommended if the presence of APAs is known or suspected.

TROUBLESHOOTING:

Refer to troubleshooting section of the CoaguChek XS Plus Operator's Manual.

CLEANING/DISINFECTING THE METER HOUSING:

MUST BE DONE AFTER EVERY PATIENT TEST

*** Use only 70% isopropyl alcohol.**

A. With the meter powered off, wipe the meter housing thoroughly with 70% isoprophyl alcohol (alcohol wipe). Avoid the meter test strip guide (measurement chamber).
B. Ensure that the blue meter test strip guide cover remains tightly closed while cleaning the housing.
C. Let the disinfectant sit on the meter for a least one minute.

D. Make sure that no liquid enters the meter or accumulates near any opening.

E. With dry cloth or lint-free tissue, wipe away any residual moisture and fluids after cleaning the housing.

F. Allow wiped areas to dry for at least 10 minutes before performing a test.

CLEANING THE METER TEST STRIP GUIDE AND COVER:

MUST BE DONE, AT A MINIMUM, EVERY 30 DAYS

Use only 70% isopropyl alcohol.

A. Test Strip Guide Cover

   a. With the meter powered off, remove the test strip guide cover. (Use your thumbnail to open the cover of the test strip guide by pressing the front edge upward).

   b. Wipe clean with 70% alcohol (alcohol wipe).

   c. Allow to dry for at least 10 minutes before re-attaching it.

B. Test Strip Guide

   a. Hold the meter upright with the test strip guide facing down.

   b. Using a lint-free cotton swab moistened (damp, not wet) with 70% alcohol, clean the easily accessible white areas of the test strip guide.

   c. Let the disinfectant sit for a least one minute.

   d. With dry cloth or lint-free tissue, wipe away any residual moisture and fluids.

   e. With the cover off, let the test strip guide dry for at least 10 minutes.

   f. Re-attach the test strip guide cover to the housing. Make sure that the cover is properly closed. You will hear it snap into place.

REFERENCES:

CoaguChek XS Operator's Manual, Roche Diagnostics, Indianapolis, IN. 2012.

CoaguChek XS PT Test package insert. Roche Diagnostics, Indianapolis, IN. 03/2019.

CoaguChek XS Pro PT Controls package insert. Roche Diagnostics, Indianapolis, IN. 11/2017.

All Revision Dates

09/2023

Attachments

CoaguCheck XS Meter External QC Log.xls

CoaguCheck XS Meter Patient Test Log.xls

Approval Signatures

Step Description	Approver	Date
Medical Director of the Laboratory (aka Clinical Services Advisor)	Kathryn Swartz: Mail Fowarding kswartz@meriter.com	09/2023
	DeAnna Beve Caspers: Vice President of Professional Services	09/2023
	Dana Wilson: Laboratory Director	09/2023