**LOURDES HOSPITAL**

**169 Riverside Drive**

**Binghamton, New York 13905**

**LAB MANUAL**

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**SUBJECT: CoaguChek XS Protime Procedure ORIGIN DATE: 7/18/11**

**REVIEWED: 6/11/2021 REVISED: 6/6/2017**

**REGULATORY REFERENCES: NYS, CAP, JACHO**

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**PRINCIPLE:** Blood coagulation is one of the body’s protective responses. Certain diseases require oral anticoagulants to prevent clots from forming within the body. Patients on warfarin, a commonly used anticoagulant, must be carefully monitored to ensure their anticoagulation therapy is maintained within the therapeutic range. The CoaguChek XS performs a modified version of the one stage Prothrombin Time (PT) test using fresh whole blood obtained with a fingerstick. . The CoaguChek XS PT Test Strip uses a human recombinant thromboplastin with a 1.0 ISI and a peptide substrate. The enzyme thrombin (factor IIa) cleaves the peptide substrate, generating an electrochemical signal. The system converts this signal into INR by means of an algorithm and the monitor then displays the result.

Onboard Quality Control enables the CoaguChek XS System to automatically check for meter performance, proper strip chemistry and test strip mishandling with each patient test.

**CERTIFICATION**:

Registered Nurses may be certified to perform protime testing using the CoaguChek XS. Nursing staff will be certified by the Roche Representative or a designated trainer on initial hire, at 6 months and then yearly during their annual competency with a written test and a hand on demonstration of their ability to run both QC and patients.

**LIMITATIONS**:

* Do not use the CoaguChek XS System for testing patients with known anti-phospholipid antibodies such as Lupus
* Do not use the CoaguChek XS System for testing patients being treated with direct thrombin inhibitors including Hirudin, Lepirudin, Bivalurudin and Argatropban.
* The CoaguChek XS System uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used.
* The blood sample must be at least 8 uL. Low sample volume will cause an error message.
* Only plastic tubes with no additives may be used for sampling
* Never add more blood to the test strip after the test has begun or perform another test using the same fingerstick site.
* Do not collect a sample from an arm receiving intravenous infusion therapy.
* In rare cases, patients with long clotting times (>8 INR) may receive an “ERROR 7” message on the meter display. If this error message appears again when the test is repeated, check the patient with a venipuncture sent to the laboratory.

**REAGENTS, MATERIALS AND STORAGE REQUIREMENTS:**

**Test Strips**

* CoaguChek XS System Test Strips, 48 test strips per package, (Ref: 04625315160).
* Use only with the CoaguChek XS System
* For in vitro diagnostic use only.
* Infection control precautions are exercised when handling laboratory reagents.

**Storage and Stability**:

* Store strips in the original container with the cap tightly closed at room temperature 36o to 86o F until ready to use. When stored properly the test strips can be used until the date printed on the test strip container. Discard test strips that exceed the date printed on the container.
* The open date is written on each vial of strips when opened.
* Strips must be used within 10 minutes of removal from the container.

**Batteries:**

* Four AAA alkaline-manganese batteries-should last for approximately 60 tests. Replace all four batteries when only one battery segment is displayed in the battery symbol when the meter is turned on.

 **SPECIMEN TYPE:**

 A drop of fresh, whole capillary blood collected by fingerstick is used to perform a Protime/INR test on the CoaguChek XS. Whole blood collected via venous puncture using only plastic syringes or tubes without anticoagulants or additives is also acceptable for testing. Glass tubes or syringes are not to be used. When collecting any type of sample, follow universal blood collection precautions

 **COLLECTION**

The purpose of the test and the steps of the procedure should be explained to the patient prior to performing the test. The operator must be wearing gloves during the procedure and immediately after removing the gloves, wash their hands. UNIVERSAL PRECAUTIONS shall be observed for all blood specimens.

**IDENTIFICATION** and **LABELING** the patient will be identified using 2 identifiers, patient name and date-of-birth.

**QUALITY CONTROL**

The CoaguChek XS System has a number of built in quality control functions that control the entire anylytical process. Patient results will not be displayed if the QCcheck fails. Because of these advanced features liquid control material is not needed.

* A check of the electronic components and functions each time the meter is turned on.
* A check of the test strip temperature while a test is in progress.
* A check of the expiration date and lot information of the test strip carried out by the code chip.
* A two level on board quality control test located within the same single test chamber where patient results are determined.

Each test strip will run a Quality Control first with each blood test. While the quality control runs, the letters QC flash on the meter display. When the quality control test is complete a checkmark (√) appears following the letters QC. **The internal control must be documented as acceptable for each patient test in Standing Stone.**

* If the quality control test passes the meter will go on to run the patient test.
* If the quality control test fails the meter will display an error message and will not run the patient test. Refer to the Error Messages section in the CoaguChek User manual for explanation and direction on follow up. If unable to resolve quality control failures, call Roche Technical Service Center at 1-800-428-4674.

**TEST PERFORMANCE**:

Patient Testing

1. Make sure all your supplies are ready and the meter is on a flat surface, do not move the meter during testing.
2. Remove one test strip from the container, recap the container tightly. Holding the test strip so the lettering “CoaguChek XS PT” is facing up, insert the test strip into the meter strip guide in the direction of the arrows as far as it will go.
3. The meter will power on and display the strip code number. Confirm that the number displayed is the same as the number on the test strip container being used, the date and time are correct and there is at least one bar showing on the battery symbol.
4. An hourglass appears for about 30 seconds while the meter warms up. Once the meter is warmed up a flashing test strip appears and the meter begins the 180 second countdown. Blood must be applied to the test strip within 180seconds.
5. Using proper procedures perform a fingerstick on the side of the patients' finger and gently squeeze from the base of the finger to develop a hanging drop of blood. **Capillary Tube**: Touch the capillary tube to the first drop of blood and allow it to fill halfway by capillary action. Put your finger over the hole in the bulb, hold the capillary tube directly over the target area on the top of the test strip and gently squeeze the bulb to dispense one hanging drop of blood. The meter will beep and the flashing drop symbol disappears. **Direct Application:** With the drop of blood on the fingertip either bring the patients finger to the test strip or take the meter to the fingertip and hold the drop of blood to the test strip until you hear a beep. The flashing drop symbol disappears. **\*\*\*\*Do not wipe away the first drop of blood. Blood must be applied within 15 seconds of sticking the fingertip. Do not add more blood to the test strip. Do not touch the test strip or move the meter.**
6. The meter automatically performs a two level on board quality control. “QC” appears on the display. If the QC is successful a checkmark appears after “QC”
7. The patients INR result appears in about 1 minute.
8. Record the patient result in Standing Stone.
9. Dispose of sharps and capillary tube in red bio hazard container. Strips may be discarded in the waste container.
10. The meter powers off automatically after three minutes of no activity.

**\*\*\*Note:** If the test has to be repeated for any reason a new fingerstick must be performed on a different finger.

**RESULT REPORTING:**

The patient results are recorded in Standing Stone - Patient Progress Notes and discussed with the patient at the time of the visit. A Laboratory Report is generated in the patients EMR.

**Expected Values:**

 Normal, healthy, Coumadin-free individuals demonstrate a Prothrombin time ranging from 9.0-12.5 seconds. This range may vary slightly based on reagent lot #.

 Therapeutic Range for patients on Coumadin:

 Less Intense Therapeutic Range INR: 2.0 – 3.0

 More Intense Therapeutic Range INR: 2.5 – 3.5

The CoaguChek XS will provide test results for an INR value of 0.8 to 8.0.

**\*\*\*Critical Values**: All INR values greater than 6.0 will be verified by venipuncture

**FOLLOW UP RECOMMENDATIONS:**

The results are discussed with the patient at the time of the visit by the RN who will determine their dosing regimen and when the next appointment is needed.

**CALIBRATION:**

A Test Strip Code Chip containing specific information that calibrates the CoaguChek XS with that particular lot # of strips is included with each vial of test strips. The Test Strip Code Chip must be inserted into the meter each time a new box of test strips is opened.

Make sure the meter is powered off and with the code number facing up; insert the code chip into the code chip slot until it snaps in place. This number must be checked with each test performed.

**METER MAINTENANCE**

The outside of the meter is cleaned after each day of use or whenever visibly soiled using a soft lint free cloth dampened with a 1:10 bleach solution or the prepackaged Roche disinfectant towlettes.

**Interior Cleaning** is performed each time a new test kit is opened or when dirty

* Turn the monitor off
* Wipe the entire exterior of the meter being careful not to allow fluid to enter any of the openings.
* Us your thumbnail to open the cover of the test strip guide by pressing it front edge upward to remove. Wipe it clean and set safely aside.
* Hold the meter upright with the test strip guide facing down and clean accessible area with a cotton swab damped (not wet) with the cleaning agent.
* With the cover off, allow the test strip to air dry for at least 10 minutes.
* Reattach the clean test strip guide cover making sure it snaps into place.

 **PERFORMANCE/PROFICIENCY EVALUATION**

Split patient samples will be performed quarterly. The RN’s performing the testing on the meter will perform the test on two different patients as usual and then have the patient drawn for a protime to be run at the hospital. The results must agree within +/- 0.5 INR

**Electronic Authorizations:**

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