VA Salt Lake City Health Care System, MC 113
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Document Title: CoaguChek XS Plus Procedure

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.

Procedure:

Supplies:

1. CoaguChek XS Plus meter
2. CoaguChek XS PT Test Strips and matching code chip

   Test strips must be stored between 2-30°C and are valid until the expiration date on the test strip container.
3. Single-use lancing device. Lancets are not to be reused ever and must be discarded.
4. Cotton ball/gauze and alcohol wipe
5. CoaguChek XS Pro PT Controls, diluent droppers and quality control chip provided

Maintenance:

Clean CoaguChek XS Plus meter daily or when visibly contaminated with disinfecting wipe of 70% ethanol or isopropyl alcohol. Ensure the wipe is only damp and not wet. Ensure that not liquid enters the meter. Clean the test strip guide daily or when visibly contaminated with 70% ethanol or isopropyl alcohol.

<u>Cleaning meter:</u>

Turn off meter and apply cleaning agent for >1 minute. Do not over wet meter. Wipe away residual moisture with lint free tissue/gauze. Ensure meter is completely dry before turning back on to perform patient testing.

<u>Cleaning Test strip guide</u>:

Turn meter off and then open cover of the test strip guide by pressing its front edge upward. Rinse the cover with water or wipe it clean. Hold meter upright with the test strip guide facing down. Clean the easily accessible areas with a cotton swab. Apply cleaning agent for contact time >1 minute and then wipe away residual moisture. Let the inside of the test strip guide dry for at least 10 minutes and then close the test strip guide cover and make sure it snaps into place.

Quality Control:

The CoaguChek XS Plus has a two-level, on-board quality control test that is performed within the test chamber as part of every blood test. The meter also has:

-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 carried out by the code chip.

Two levels of liquid quality controls will also be completed monthly.

To complete liquid quality controls:

1. Remove controls from refrigerator and remove rubber stopper.
2. Remove diluent dropper from control box and cut off the end of the cap with scissors.

   NOTE: To avoid loss of diluent, hold the dropper by the stem; do not squeeze the bulb of the dropper while cutting the tip.
3. Empty entire contents of dropper into the control vial. DO NOT DISCARD DROPPER.
4. Swirl the control and then let bottle sit for one minute. The control is now ready to be tested. The control vial is only stable for 30 minutes after reconstitution.
5. Turn on the meter. From the Main Menu select the "Control test" option.
6. Remove a test strip and slide the test strip into the meter with the lettering facing up until it beeps.
7. Select the code stored for your current control solution or touch "New Code" to use a new control solution.
8. Select the level of control, either Level 1 or Level 2
9. An hourglass icon appears to indicate that instrument is warming up. Once it beeps you may apply the sample with the Dropper.
10. Apply one drop within 180 seconds.
11. The test result will appear. If the value is too high or low an arrow (↑or↓) appears.
12. Remove strip and continue with the second level.

Specimen:

Capillary samples are to be used with the CoaguChek Plus. Before testing, identify patient with full name and full social security number. You may have the patient was his hands with warm water to increase blood flow. To obtain sample, clean finger with alcohol only and let air dry before puncturing the side of the fingertip. Once the CoaguChek Plus meter is ready for the sample, squeeze finger and puncture with lancet. Apply one drop onto the test strip. Being careful to avoid "milking" the finger, this can cause interference via tissue fluids diluting the sample.

NOTE: Hand hygiene should be observed before and after interacting with each patient. Gloves are to be worn when handling specimens and while completing all testing. Gloves should be changed between patients.

Performing the test:

1. Identify patient and wipe the finger with alcohol. Allow the patient's finger to dry completely before performing the fingerstick.

2. Power on the meter
3. Ensure the correct Test strip code chip is installed.
4. Select "Patient Test" from the Main Menu
5. Enter in Operator ID
6. Enter in the Patient ID, full Social Security Number and hit the green check mark.
7. Take a test strip out of the container. CLOSE THE CONTAINER TIGHTLY.
8. Insert the test strip as far as you can. The meter will beep
9. Confirm that the number displayed matches the number on the test strip container, then press **M**. If the numbers are different, make sure you are using the code chip that came with the test strips you are using.
10. An hourglass flashes as the meter warms the test strip, which takes up to 30 seconds.
11. When the test strip is warmed, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 180 seconds to apply blood to the test strip.
12. Use the lancet to perform a fingerstick.
13. Apply 1 drop to the top of side of the target semicircle area. **You must apply blood to the test strip within 15 seconds of lancing the finger.**
14. Do not add more blood. Do not touch or remove the test strip when a test is in progress. The flashing blood drop symbol changes to an hourglass symbol when the meter detects sufficient sample. The meter will beep as well.
15. The result appears in about 1 minute.
16. Dock the meter to document result into the patient chart.
17. Dispose of lancet and used test strip.
18. Power off meter if all testing is complete.

Expected Results:

The CoaguChek XS PT Test was performed on 121 normal, healthy, warfarin-free individuals using venous and capillary samples, 97% of the INRs ranged from 0.9 to 1.1, which is the normal range. The reportable range is 0.8- >4.0. If the INR is ≥4.0, the person performing the test is required to draw a blood sample in a blue top (Sodium Citrate) tube for laboratory confirmation testing. A standard PT/INR order will be placed for the sample by a provider.

Note: Proper blood volume must be obtained in the coagulation (sodium citrate) tube. The minimum fill line is etched on the tube. Samples submitted that do not meet the volume requirements will be rejected by the laboratory.

- The laboratory critical value for INR is >5.0. If the blue top tube INR is >5.0 then the laboratory will call and document the notification of the physician.

NOTE CBOC SAMPLES: If a CBOC patient has a result of ≥4 for the INR the test must be repeated. If the result is still ≥4 the patient needs to be sent to the local Emergency Department to have a venous sample tested.

Any patient with a INR result ≥4 on the CoaguChek needs to have 2 venous samples that are within therapeutic range before point of care INR testing can resume.

Troubleshooting:

If the meter displays an unusual test result (other than an error message), check the following items:

1. Is the correct code chip in the meter? The 3-number code on the test strip container must match the 3-number code on the code chip.

2. Is the meter set up with the correct date and time.

If the result as a < or > symbol next to it a venous sample must be drawn and sent to the main laboratory. If a "c" is displayed along with the result the hematocrit may be too high or too low or due to erroneous blood collection. If a "c" is displayed, repeat the test with a new finger stick sample, if the "c" persists a venous sample must be drawn to check for hematocrit. If the hematocrit is too high a modified blood tube will have to be prepared by the main laboratory and a venous PT/INR will need to be collected and tested.

If the results do not correlate with the patient's symptoms or clinical picture, send a STAT PT/INR to the main laboratory. If the meter is unable to be used for any reason send a venous blood draw PT/INR to the main laboratory for testing.

Procedural Notes:

1. Close the strip container immediately after removing a test strip

2. Operate the meter at an ambient temperature between 15 ° C and 32 °C.

3. Place the meter on a level, stable surface (table) when testing

Limitations of the Procedure:

1. The CoaguChek XS System should not be used for patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivalirudin and Argatroban.
2. The CoaguCheck XS PT Test uses only fresh capillary blood or nonanticoagulated venous whole blood. Plasma or serum cannot be used.
3. Use only plastic syringes without anticoagulants or additives. Glass tubes or syringe must not be used.
4. The blood drop must be a minimum of 8 µL in volume. Low sample volume will cause an error message.
5. Never add more blood to a test strip after test has begun or perform another test using the same fingerstick.
6. When a patient is on intravenous infusion therapy, do not collect sample from arm receiving the infusion line.

7. Hematocrit ranges between 25-55% do not significantly affect test results.
8. Testing performed with the following *invitro* spike 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

   -Heparin concentrations up to 0.8 U/mL

   -Low molecular weight heparins (LMWH) up to 2 IU anti-facor Xa activity/mL

   -Clopidogrel up to 20 mg/dL

   -Fondaparinux up to 5 mg/L

9. 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.

10. Is the meter displaying "ERROR 6"? Sporadically occurring ERROR 6 are generally due to an activation of the system fail safe mechanisms that are designed to prevent the release of wrong measurement results. However, in rare cases, "ERROR 6" may be received with patients who are under treatment with warfarin (vitamin K antagonists) in combination with antibiotics and/or chemotherapeutics leading to extremely high coagulation times (>10 INR, 5% Quick). In this case, and if "ERROR 6" is displayed repeatedly, the results must be checked using another method.

11. 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, the result must be checked using another method.

References:

CoaguChek® XS PT Test Package Insert 2013

CoaguChek® XS Operator's Manual 2013

Revision History

Section	Change	Date	Requester	Approver
Header	Update header	01/17/2017	Hung Ho	E. Hart MD
Font, Size	New Time Roman, 12	01/17/2017	Hung Ho	E. Hart MD
Note CBOC Sample	Change from >4.0 to ≥4.0	06/02/2017	Ola, Peters Ayoade	E. Hart MD
Expected Results	Added needed action to draw blood; from >4.0 to ≥4.0	06/02/2017	Ola, Peters Ayoade	E. Hart MD