283.282 coaguchek

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Comments for version 2.0
Added pictures of meter, supplies.

Minor: corrected grammar and formatting

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	2/20/2024	2.0	yahyaelshimali JohnYahya Elshimali	
Approval	Lab Director	1/23/2023	1.0	yahyaelshimali JohnYahya Elshimali	

Prior History
in proquis

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.0	Approved and Current	Major revision	2/12/2024	2/20/2024	Indefinite
1.0	Retired	Initial version	1/20/2023	1/23/2023	2/20/2024

West Texas V A Health Care System Laboratory

Roche Coaguchek XS PLus

This testing is CLIA Waived

Purpose

To outline the policy and procedures used by West Texas VA Health Care System (WTVAHCS) staff certified to perform ancillary whole blood Prothrombin Time (PT/INR) testing using the Roche CoaguChek XS Plus System for outpatients. The PT/INR is used to monitor oral anticoagulation therapy.

Scope

All WTVAHCS ancillary testing sites will undergo inspections and accreditations by the external laboratory accrediting bodies. The use of the CoaguChek XS Plus PT/INR meter is strictly limited to certified operators. Nurses and Pharmacists performing ancillary tests must be trained by the designated trained personnel. Trained personnel undergo initial competency certification, six month post initial training and then annual competency checks. Trainees will be trained by a competent operator. The Laboratory will monitor compliance with accreditation requirements, oversee the quality control program of the meters. Point of Care testing subscribes to College of American Pathologists Proficiency Testing Program. Proficiency samples will be tested by operators on a rotating basis, and results submitted by testing site personnel, after submission to CAP and evaluation is concluded, the results will be reviewed by the Lab Ancillary testing Coordinator (ATC) or the Lab Supervisor. The Director of Pathology and Laboratory Medicine will review CAP results according to the Proficiency Testing Policy.

The policies and procedures for whole blood PT/INR testing with the approved systems in use are to be reviewed by the Director of Pathology and Laboratory Medicine every other year. Any changes in the test as they apply to methodology, instrumentation, or testing policy are to be approved be the Laboratory Director before being placed in use.

Principle

The CoaguChek XS Plus PT/INR Test, will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. Patients receiving warfarin therapy are monitored through the Pharmacy's anticoagulation clinic either in person or via telemedicine. The purpose of performing whole blood PT/INR testing is to offer health care providers quick, accurate, and reliable results that may be used to adjust dosages or make therapeutic decisions regarding warfarin therapy.

Location of testing:

1. Within the outpatient setting of a clinic performing anti-coagulation therapy.
2. Curbside at the clinics for vulnerable populations at the discretion of the provider. This is particularly important during epidemics, flu season, or patients that have disabilities that make it difficult to get in and out of vehicles.
3. At the direction of the telemedicine director for telemedicine visits.

Specimen Collection and Handling

The CoaguChek test strip uses only fresh capillary whole blood.

A. Patient preparation:

1. No specific patient preparation required. Patient must have clean, dry finger. (See

"Procedure" section below for detailed information)

2. If patient is new to fingerstick testing, explain to the patient the purpose and steps of the procedure.

B. Acceptable Specimen handling:

1. Meter must be level during entire testing cycle.
2. Required type of specimen: fresh capillary whole blood obtained by fingerstick, applied *immediately* to test strip.
3. The blood must be applied to the test strip within 10 minutes of removing the test strip form its container.
4. The meter must display the flashing test strip and blood drop symbols prior to the fingerstick.
5. The sample must be applied to the strip within 15 seconds of the fingerstick. Additional blood CANNOT be added to the test strip once testing has begun which is after the beep.
6. Minimum sample size is 8 µL of blood.
7. Apply specimen directly from the finger to test strip. Top dosing or side dosing are acceptable. The finger must stay in place next to the strip until the beep sounds.
8. If the test needs to be repeated for any reason, perform a second fingerstick from different cleaned finger on the opposite hand if possible.
9. See the **"Limitations"** section for additional information on specimen requirements or handling.

C. Criteria for Unacceptable Specimens / Specimen Rejection:

1. Plasma, serum, clotted whole blood, or anti-coagulated whole blood cannot be used as a testing sample.
2. Sample size cannot be less than 8 µL.
3. DO NOT add additional blood to the test strip once testing has begun.
4. The sample must be used immediately after collection.
5. DO NOT move the meter (keep level) or touch the test strip during the testing cycle. Otherwise, erroneous results or error codes may appear.
6. See the **"Limitations"** sections or call the Lab ATC for more information.

Equipment, Reagents and Supplies

A. Equipment:

Roche CoaguChek XS Plus meter.

B. Reagents

1. CoaguChek XS Plus test strip: and matching code chip. Strips contain reagent (human recombinant thromboplastin 1.5U), stabilizers, preservatives, and additives. Intended for in vitro use only.
2. CoaguChek XS Plus Quality Control – Level 1 and 2 with the diluent pipettes and matching code chip when Quality Control (QC) testing is needed.

C. Supplies

1. Gloves
2. Lancets, auto-disabling single use.
3. Alcohol wipes
4. Bleach wipes
5. Gauze / bandages

6. Biohazard Container
7. Bleach wipes

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Login screen after meter turns on.

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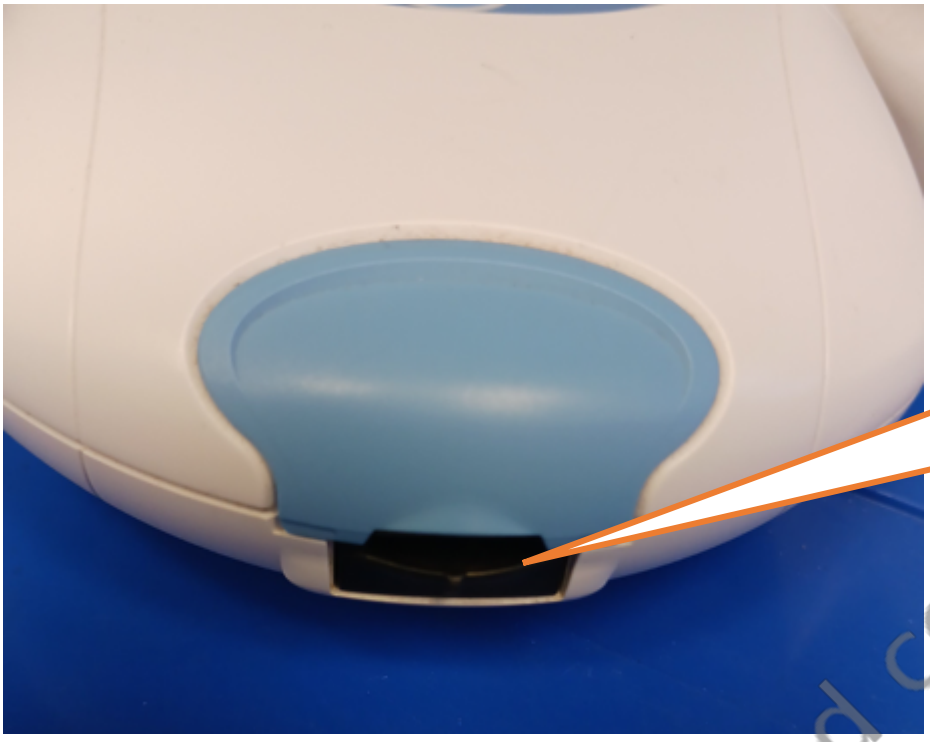
Main menu after logging into meter



Storage and Handling

A. Equipment: CoaguChek XS Plus Meter

1. The Meter must be placed on a flat, clean, dry surface free of vibrations while testing.
2. Keep the meter at room temperature. (65°-90°F / 18°-32°C). If the meter gets too cold or too hot, testing will not be allowed, giving the operator a temperature icon warning when the strip is inserted. Allow the meter to warm up or cool down for 30 minutes in the appropriate temperature range before testing.
3. Never store the meter at extreme temperatures or damp/humid conditions.
4. Never store the meter near a strong magnetic field, such as a microwave oven.

B. Reagents: CoaguChek XS Plus test strips

1. Store the test strips in their original container with the cap tightly closed. Strips may deteriorate in high humidity. Close the container tightly.
2. Store test strips at room temperature or in the refrigerator (36°-86°F / 2°-30°C).
3. When stored properly, the test strips can be used until the expiration date printed on the test strip container.
4. When you are ready to test, open the test strip container and remove one strip from the container, only touching the pad area. Immediately close container, and make sure cap is sealed tightly.
5. Use this test strip within 10 minutes after removing it from the container.
6. Do not open a vial of test strips or touch a test strip with wet hands or gloves as this may damage the test strip. Do not lay a strip down on a wet or dirty surface.
7. If any test strip is suspected of being damaged, or left out more than 10 minutes, discard / do not use.

8. Discard test strips if they are past their "Use By" date.

C. Reagents: CoaguChek XS Plus Controls

1. Use Standard Precautions when handling Quality Control solutions and diluents.
2. Keep controls and diluent pipettes refrigerated. (36-46F or 2-8FC)
3. Once diluted, controls are good for only 30 minutes.
4. When stored properly, the controls can be used until the expiration date printed on the box / bottle.
5. Do not use past 30 minutes after dilution. Do not use past expiration date.
6. Discard expired controls.
7. Discard Quality Control bottles in a biohazard sharps container.

Coding the Meter with the Test Strip Code Chip

A. Each box of test strips comes with a specific matching code chip and must be matched to the test strip lot. The test strip code chip provides the meter with important information that it needs to perform the coagulation test. (Test method, lot#, expiration date, etc.)

1. The test strip code chip is required when a new strip container is opened to store the lot information about the test strips in the meter.
2. The CoaguChek XS Plus meter stores the data from up to 60 code chips.
3. Use the test strip code chip that was supplied with each new test strip container before you perform the first test.
4. Leave the code chip in the meter to protect the electrical contacts in the meter from becoming dirty.
5. Protect the code chip from moisture and equipment that produces magnetic fields.

B. 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. 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 into the slot in the meter,
4. If the code chip is missing or incorrectly inserted, error messages appear in the display.

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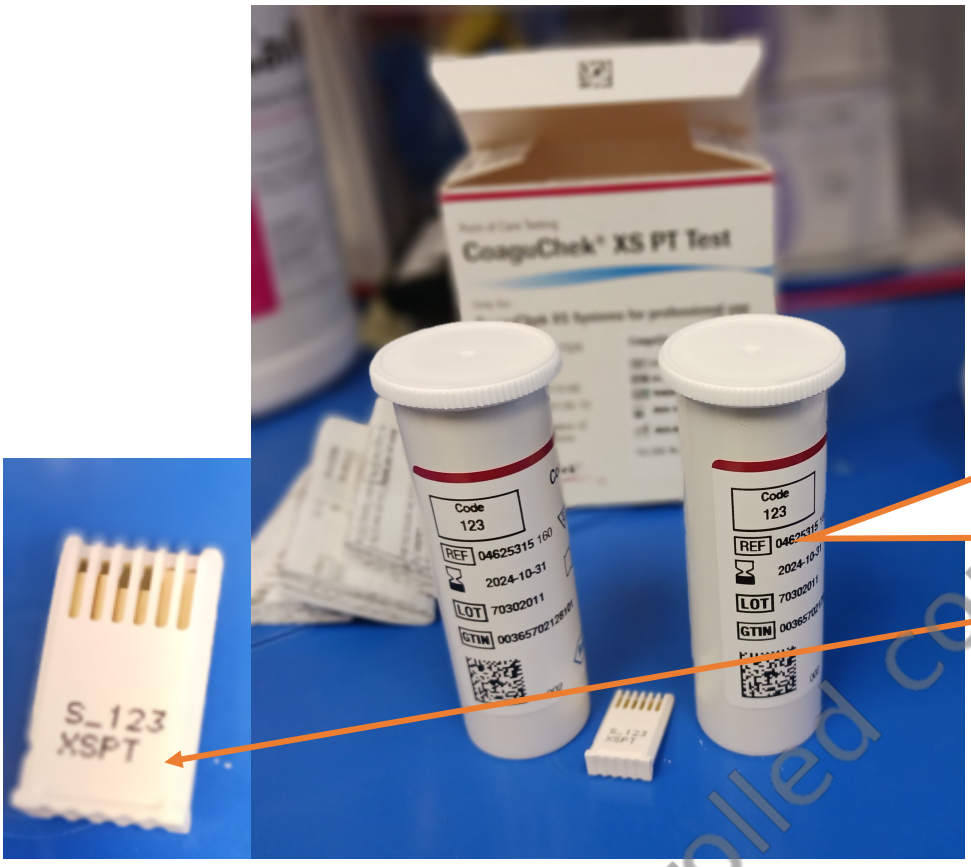
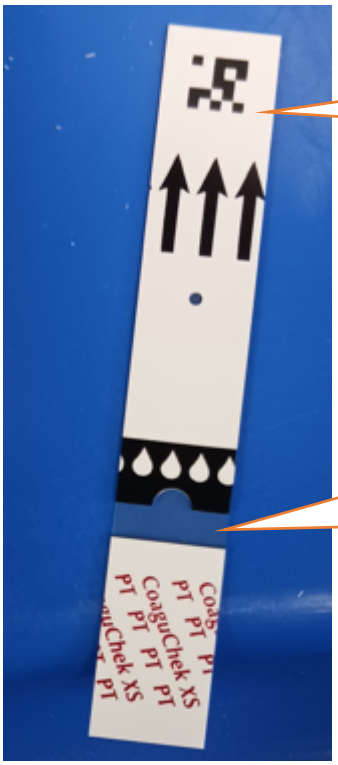


Code matches code chip. S indicates Strip



End that goes into meter

Where sample or control is applied.

C. PROCEDURE: Inserting the Test Strip Code Chip

1. Be certain the meter is OFF.
2. Remove old code chip if there is one inserted in the meter. Store the code ship with the appropriate strip lot.
3. Insert the matching code chip into the code chip slot in the meter with the printed side facing UP until it snaps into place.
4. Turn on the meter to confirm the chip is accepted and matches the new strip lot.

Calibrations

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

1. 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 characteristic information so it is calibrated for use with its corresponding specific lot of test strips and controls.
2. The manufacturer established the performance characteristics based on extensive testing. Each code chip is verified to show it will produce expected results. In addition, every time the meter is turned on, it goes through a series of self- diagnostic checks.

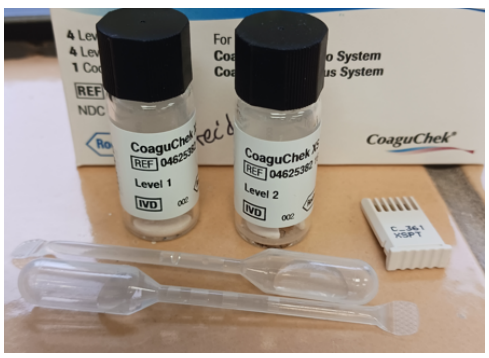
Quality Control

A. Equivalent Quality Control

1. The CoaguChek XS Plus System has 2 levels of quality control functions integrated into the meter and test strips. The system automatically runs its own 2 – level quality control test as part of every blood test. These internal checks monitor all portions of the test systems analytical components each time a test is performed.
2. Internal QC is performed before patient results are displayed. Successful internal QC is demonstrated by the meter display of QCV.
3. The Lab follows CLIA guidelines on internal Equivalent QC (EQC). 2 levels of QC have been run for 10 or more consecutive working days thus accepting and validating EQC.
4. If any part of the internal systems fails, the patient test will not be completed and the operator will be notified by error code(s).

B. External Liquid Quality Control

2 Levels of External QC will be run once each calendar month. (See notations above about QC storage and handling).



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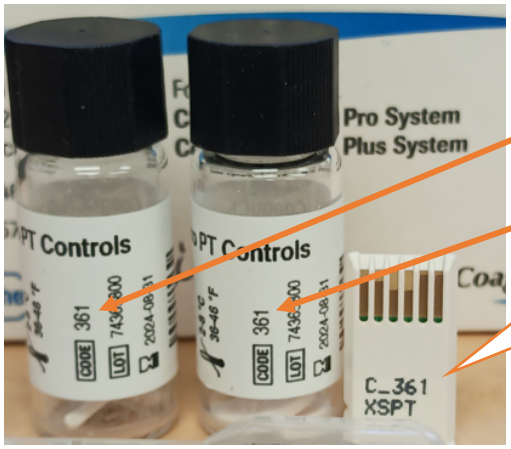

Both levels of control should match the code chip. C indicates control.

PROCEDURE FOR RUNNING External Liquid QC:

Gather QC supplies: 2 levels of QC, 2 diluents pipettes, and scissors.

1. Wash / dry hands (or alcohol rub); put on gloves, follow Standard Precautions.
2. On the Main Menu, touch Quality Control.
3. Choose the QC lot. If a new lot of QC is being used, insert the new QC code chip into the meter (found in each box of QC material)
4. Follow these directions or the directions on the package insert for making up 2 levels of the QC.
   a. Take QC vials 1 and 2, plus 2 diluent pipettes from refrigerator.
   b. Open the vials (unscrew lid, remove rubber stopper)
   c. Flick diluent away from the end of the pipette.
   d. Cut off the very end of the tip with scissors.
   e. Invert diluent pipette into the open QC vial. Do not touch the pipette tip to the dried reagent button.
   f. Squeeze the pipette bulb so all of the diluent enters the QC vial.
   g. Keep the pipette on a clean dry surface for later use.
   h. Replace the rubber stopper and gently swirl the vial a few times so the contents are mixed. Ensure the fluid does NOT touch the rubber stopper.
   i. Let the vial stand for at least 1 minute. This QC is good for 30 minutes. Swirl it one more time to mix it before testing.
   j. Repeat the process for Level 2 QC.
5. **Prepare the meter**. Place the meter on a level vibration free surface; turn the meter on; Press Control Test on the main menu; insert a test strip when indicated. Confirm control lot number (insert new code chip if need).
6. Choose the QC level you will be testing on the meter screen.
7. When the insert strip ion appears insert a test strip.
8. When the drop icon appears, swirl the QC vial, open it, and using the diluting pipette place 1 drop of QC on the test area of the strip. The meter will beep when enough sample has been applied.
9. The meter displays the control ranges when the QC is run.
10. If both levels of QC are acceptable (within manufacturers range), you may proceed with patient testing.

11 . If either level of QC is not within the acceptable range this will be indicated by an arrow (↓ -for results too low and ↑ for results too high). Repeat the QC level that is out of range. If it is still out of range, make up a new QC vial and repeat testing. Also confirm the strips are acceptable (i.e. not damaged or expired, etc.). Open a new vial of strips if necessary. If problems still occur, call the Laboratory Ancillary Testing Coordinator or the Laboratory Supervisor for help.

12. QC must be run within 30 minutes of reconstitution.
13. Discard QC vials in a biohazard sharps container.
14. Clean the meter with bleach wipes, Cavi-wipes, or SaniCloth.
15. Always use 2 wipes. The first wipe will remove any debris or contamination and the second wipe for disinfection.

Testing Procedure

A. Meter Preparation

1. Gather all supplies needed.
2. Wash / dry hands (or alcohol rub); put on gloves (new pair for every patient). Follow Standard precautions.
3. Have patient wash / dry hands if possible or clean the finger with alcohol.
4. Prepare single-use lancet device according to the manufacturer's instructions.
5. Place the meter on a flat surface, free of moisture, dirt, and vibrations.
6. Turn the meter ON by pressing the blue circle on the meter (meter takes approx 5 seconds to turn on and go thru self checks. Meter will beep when it is ready)
7. Confirm that the rechargeable battery is at a sufficient level for testing. (At least 1 bar). **ALWAYS Confirm that the date and time on the meter are correct.**
8. MAIN MENU will appear. Press PATIENT TEST.
9. Enter (after confirming) patients FULL 9 digit Social Security Number. Press the (√).
10. An hour glass will appear while meter is readying itself for testing.
11 . Confirm test strips are not expired.
12. Remove 1 test strip from the vial. Close the container tightly.
13. Hold the test strip at the lettered end. Hold the test strip so the lettering "CoaguChek XS PT" is facing upward. Do not touch the gold shiny areas of the test strip. This is on the back of the strip.
14. Slide the test strip into the testing area (arrowed end into meter), as far as it will go.
15. An hour glass will appear, warming up the strip (approx 30 seconds). Confirm the Code # on display is the same as the code # on the strip vial.
16. An icon of a strip with a flashing drop will appear. You have 3 minutes to obtain the patients sample and apply it to the strip.

B. Patient

Capillary

1. Patient is identified by confirming their social security numbers and full name (or other methods stated in facility HCSM).
2. Warm the finger. Massage the finger from its base before lancing.
3. Patient's finger is cleaned with alcohol or soap and water. Patient's finger must be dried thoroughly before testing. Warming the fingers will promote blood flow.

4. DO NOT puncture the patient's finger until the flashing test strip and blood drop symbol appears on the meter screen.
5. With the patient's hand hanging down, and the meter ready with flashing drop icon, stick the side of finger with the lancet.
6. **DO NOT WIPE AWAY THE FIRST DROP OF BLOOD.**
7. Immediately after lancing the finger, it's acceptable to gently massage the finger near the first joint/knuckle to help with blood flow if needed.

C. Testing Procedure

1. Confirm the meter is in a horizontal position, free of vibrations.
2. While the flashing test strip and blood drop symbol appear on the display, apply the first drop of blood to the top semi circle transparent testing area or side of said target area on the test strip.
3. Apply the blood sample within 15 seconds of lancing the finger.
4. It is important to HOLD the finger/drop to the strip UNTIL the meter beeps. DO NOT apply a second drop. Avoid air bubbles in sample.
5. Do not touch the test strip or move the meter during testing.
6. Once there is enough blood the meter will beep and the blood drop symbol will disappear, an hourglass symbol will appear indicating testing has started.
7. The meter automatically performs 2 levels of internal quality control (QC) on the strip before it runs the patient's test and displays the results.
8. "QC" and a check mark, **(QCv)** indicates a successful test.
9. Results will take approximately 1 minute or longer for longer PT results.
10. Once the test is complete, remove the strip and discard it in an appropriate waste container. Turn the meter off (Press and hold on/off button) or move on to the next patient.
11. Dispose of all biohazardous materials in the appropriate containers.'
12. If a repeat test is necessary, **you MUST repeat the fingerstick** and procedure above using a finger from the patients opposite hand if possible.
13. Clean the Meter after every test patient or QC. Clean the meter with bleach wipes, Cavi-wipes or Sanicloth.
14. Always use 2 wipes. The first wipe will remove any debris or contamination and the second wipe for disinfection.
15. All results should have a comment or comments attached up to 3.
    a. Time verify
    b. Cleaned meter
    c. Temperature in range—note meter will not operate if temperature is out of range.

Results

If the meter displays an error message follow any directions given with the error message. The meter may need to be turned off and then back on to clear the error message. The test will need to be repeated.

The meter can only report results of 0.8 - 8.0 INR. 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. The test will need to be repeated by an alternate method.

If the result does not match the clinical symptoms, repeat the patient test using a fresh fingerstick to rule out a procedural error.

In rare cases Error Message 7 can occur in patients with long coagulation times. Repeat the test on the Coaguchek or order a venous blood draw to be tested in the Laboratory. Only repeat a test one time on the Coaguchek meter.

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

1. 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.
2. 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.
3. Debris on the test strip guide can cause problems with results. Check to see if strip guide is dirty. Follow cleaning instructions if needed.

   The CoaguChek XS Plus meter displays test results in International Normalized Ratio (INR).

If Results are **>5.5**, A venous blood draw should be ordered and the patient sent to a lab to assure this result is accurate. Critical is greater than 4.5 INR. The provider may repeat or request a venous draw starting at 4.5.

A. General Expected Results from a fingerstick INR :

1. For normal anticoagulation INR 2.0 - 3.0
2. For mechanical valve anticoagulation INR 2.5 – 3.5

B. ACTION HIGH Results: INR >5.5

If results are >5.5, testing staff should:

Repeat the fingerstick INR using a finger from the patients opposite hand if possible. If the second fingerstick is also >5.5, then the laboratory recommends ordering a PT/INR test that will be tested in a Laboratory.

Results greater than 4.5 INR are critical and the provider may repeat or request a venous draw at their discretion starting at 4.5.

C. Decisions / Action Plan :

1. Decisions on treatment / action: when critical results are obtained, the testing staff will immediately notify the Coumadin Clinic Provider.
2. The Laboratory recommends making any significant medication changes based on the more accurate Laboratory generated result.

Memory: The meter will hold up to 500 results. From the Main Menu, tap Results Review. Then choose from patient or QC results you wish to review. The most recent results are on top of list.

Result Documentation / Reporting Results

A. All Point of Care testing results must be documented in CPRS under the Lab tab. Documentation must include a minimum of: the result, the normal ranges, the time and date of testing, who performed the test, the serial number of the meter. This data collection

and transfer is managed by the Abbott RALS Web program. After testing on the Coaguchek it is docked in its recharging / downloading base. The results are transferred through the RALS system into Vista/CPRS and all the required information appears under that patients CPRS Lab tab. Any other information that is needed for Regulatory tracking is stored in the RALS Web system.

Error Codes and Troubleshooting

A. Depending on the circumstances, an error message may appear on the display of the meter. Error messages can have up to three warning levels as indicated by the symbols, icons, and their messages.

1. **i. is a Warning message** such as the strip is unusable, the meter is too cold, the battery level is too low, the test strip guide is open, there is a code chip error, the strip is expired, a time limit has been exceeded, etc.

2. **O ! General message:** There should be an explanation of the error displayed on the meter.

3. **Δ ! Serious error message such as:** There was a Blood application error, QC error, internal memory error, and:

    a. 4: Test strip unusable

    b. 6 / 7 : Measurement

    c. 8 : Diagnostic testing error

B. Follow any instructions displayed on the meter with the error code. Troubleshooting in most cases means repeating the test with a fresh test strip and a fresh fingerstick from the opposite hand if possible.

C. Additional Corrective actions to try:

1. Turn the meter off, then
2. Remove the old test strip.
3. Confirm that all codes match.
4. Confirm the test strip guide is clean of dirt and/or blood, clean it if necessary.
5. Then repeat the patients test.
6. If the error occurs again, a venous blood draw and Laboratory testing on the patient is recommended. You may need to contact the lab ATC (ext. 7232) if errors persist. All meter problems should be documented in the problem / corrective action area of the Maintenance log.

Limitations

A. General: **Always** refer to the latest test strip package insert for the latest limitations.

1. Any results that are not expected or unusual in any way should be rechecked and /or tested on venous blood by a Laboratory.

2. The results are unaffected by heparin concentrations up to 0.8 U/ml.
3. The CoaguChek XS Plus ProTime test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mlL.
4. Hematocrit ranges between 25-55% do not significantly affect test results. A "c" next to the patients test result may indicate a hematocrit that is out of range.
5. No significant effect on test results occurred with: Bilirubin <30 mg/dl; triglycerides <500 mg/dl; Hemolysis ,1000 mg/dl;
6. Lupus antibodies can potentially lead to prolonged clotting times.
7. Testing can only be performed with fresh capillary blood which includes the **first** drop.
8. The Coaguchek Plus system should not be used for patients being treated with any direct thrombin inhibitors – including Hirudin, lepirudin, Bivalirudin, and Argatroban.
9. Never add more blood to the test strip after testing has begun or perform another test using the same fingerstick.

B. Medications:

1. Certain drugs may affect a result by interfering with the warfarin pharmacology. The potential effect of drug interaction with warfarin or the effect of underlying disease (i.e. liver, congestive heart failure) must be considered when interpreting results. No significant effect on test results occurred with: Clopidogrel <20 mg/dl; Fondaparinux <5 mg/dl.

C. Diet:

Changes in a patient's diet are thoroughly reviewed by the Coumadin Clinic provider at the patient's appointment. All necessary recommendations are managed by the Provider.

Certifications and Competency

A. **The meters are only operated by fully trained staff**:

1. Training and/or certification/re-certification is performed the Laboratory ATC (or designee), or any previously trained Super-users. Initial training is online at Medtraining.org. Competency following training will be done with with the ATC via Teams or in Room 233A.
2. Six months after initial training a second competency will be done in an approved manner.
3. Initial training is performed before staff is able to use the instrument. All staff are re-certified annually using an approved method.
4. Training and re-certifications must include at least two of the items to follow: attending skills fairs; passing test >90%; successful Quality Control testing; or successful proficiency testing.
5. These records will be maintained by the laboratory ATC.

Maintenance and Cleaning the Meter

A. Daily Maintenance (on each day of testing only)

1. Every time the meter is used it must be cleaned, this **MUST** be recorded in the meter.

2. Clean meter after every test (QC, patient, etc.).

B. Instructions for cleaning the exterior of meter:

1. The meter should be cleaned after every test, and when the meter is visibly dirty.
2. Wear disposable gloves when cleaning.
3. Use only 10% Sodium hypochlorite solution without any other additives (in the form of bleach wipes). **Do NOT use sprays.**
4. Turn the meter off. Ensure the strip guide remains tightly closed while cleaning.
5. Wipe the outside of meter clean with a wipe. Do not let the solution get into the strip area, AC plug area, or accumulate in any opening.
6. Dry the meter with gauze or lint –free soft cloth if necessary.
7. Allow meter to air dry at least 10 minutes before performing a test

C. Cleaning the test strip guide.

1. If the test strip guide area is dirty or soiled with blood, the area must be cleaned.
2. Remove the test strip cover (blue oval cover) by using your thumb and pressing upwards from the front edge. This cover may be cleaned with water, or a moistened swab or gauze. This part **MUST** be completely dry before replacing it on the meter.
3. Clean the white test area with lint free swab, dry or slightly moistened with small amount of 70% alcohol or 10% bleach. **DO NOT use any other disinfectants or cleaning solutions. The use of any other cleaning /disinfecting solutions could result in damage to the meter.**

   Make sure that NO liquid enters the meter. Do not insert any object into test strip area. Either may damage electrical contacts behind the test strip area.
4. Hold the meter upright with the test strip guide facing down.
5. Clean the easily accessible areas with a damp cotton swab.
6. Allow strip area to air dry for at least 1 minute. Wipe away any residual moisture and fluids with a dry swab or gauze.
7. All areas must dry completely for at least 10 minutes, before replacing the test strip cover.
8. Reattach the test strip cover. Make sure the cover is inserted then snapped down into place.

Safety

All Coaguchek operators will follow all WTVAHCS patient and employee safety policies as well as Standard precautions and blood borne pathogen policies. These policies are on the WTVAHCS web page and include items such as:

A. Patient safety includes but is not limited to: proper patient ID with at least two complete identifiers, proper specimen collection which is also included in this policy; unexpected results documentation and action; timely error correction, use of a clean meter.

B. Employee safety includes but is not limited to: following Standard precautions (gloves, PPE) when handling reagents, QC, and patient samples; use of auto disabling single use lancets; proper discarding of biohazardous waste and sharps; cleaning blood spills and instrument per this policy.

C. General safety includes: SDS available on the WTVAHCS webpage.

Contact Names and Numbers

Laboratory ATC: ext.7232.
Laboratory Supervisor ext. 7230
Laboratory AO: ext. 7231

Personnel

Initial training is done by the Instrument Manufacturer's team on initial instillation, the Laboratory ATC (or designee), or any previously trained Super-users. All training and certification records will be kept in the employees 6-part folders and in the ATC electronic files on the Lab Share folder.

Six month competency is performed and documented as close to the six month mark as possible. Annual competency is assessed- by written test, observation of adherence to written procedures (either directly or through records reviews), and/or successful performance of proficiency testing, patient testing, and/or QC testing. All testing personnel must follow manufacturers written instructions for test performance and troubleshooting. This policy/procedure includes manufacturer's instructions. If personnel problems are identified, staff may be retrained and corrective action noted.

Responsibilities

The Chief of Pathology and Laboratory Medicine Service and the Ancillary Testing Coordinator or designee oversees all aspects of testing, reporting, and maintaining of the Coagucheks.

Individual Coaguchek operators are responsible for: proper patient ID, sample collection, result information hand off and documentation, any other documentation , any troubleshooting possible with documentation by notification to ATC for action log, as well as compliance with CAP Proficiency Testing. After which if a problem is not solved they are to notify Laboratory Personnel at one of the above mentioned extensions. The meter will take limited custom comments to document issues.

References

A. CoaguChek XS Plus Policies and Procedures Manual.
B. CoaguChek XS Plus Operator's Manual.
C. CoaguChek Package inserts for test strips and Quality Control.

Coaguchek
West Texas V A Health Care System Laboratory