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Clinical Laboratory: Point of Care Testing

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COAGUCHEK XS PLUS
INR

PURPOSE

The CoaguChek XS Plus is a **CLIA Waived** test system. The CoaguChek XS Plus is intended for use by professional healthcare providers for quantitative prothrombin time (INR) testing for the monitoring of Coumadin or Warfarin therapy. The system uses fresh capillary (fingerstick) blood.

INR (International Normalized Ratio) is a standardized measurement of the rate at which blood clots. A low INR can indicate an increased risk of blood clots, while an elevated INR can indicate increase risk of bleeding. It is indicated for use by Healthcare Professionals only. The system is ideally suited to monitor coagulation values for patients who are taking warfarin anticoagulation medications.

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.

TESTING PERSONNEL

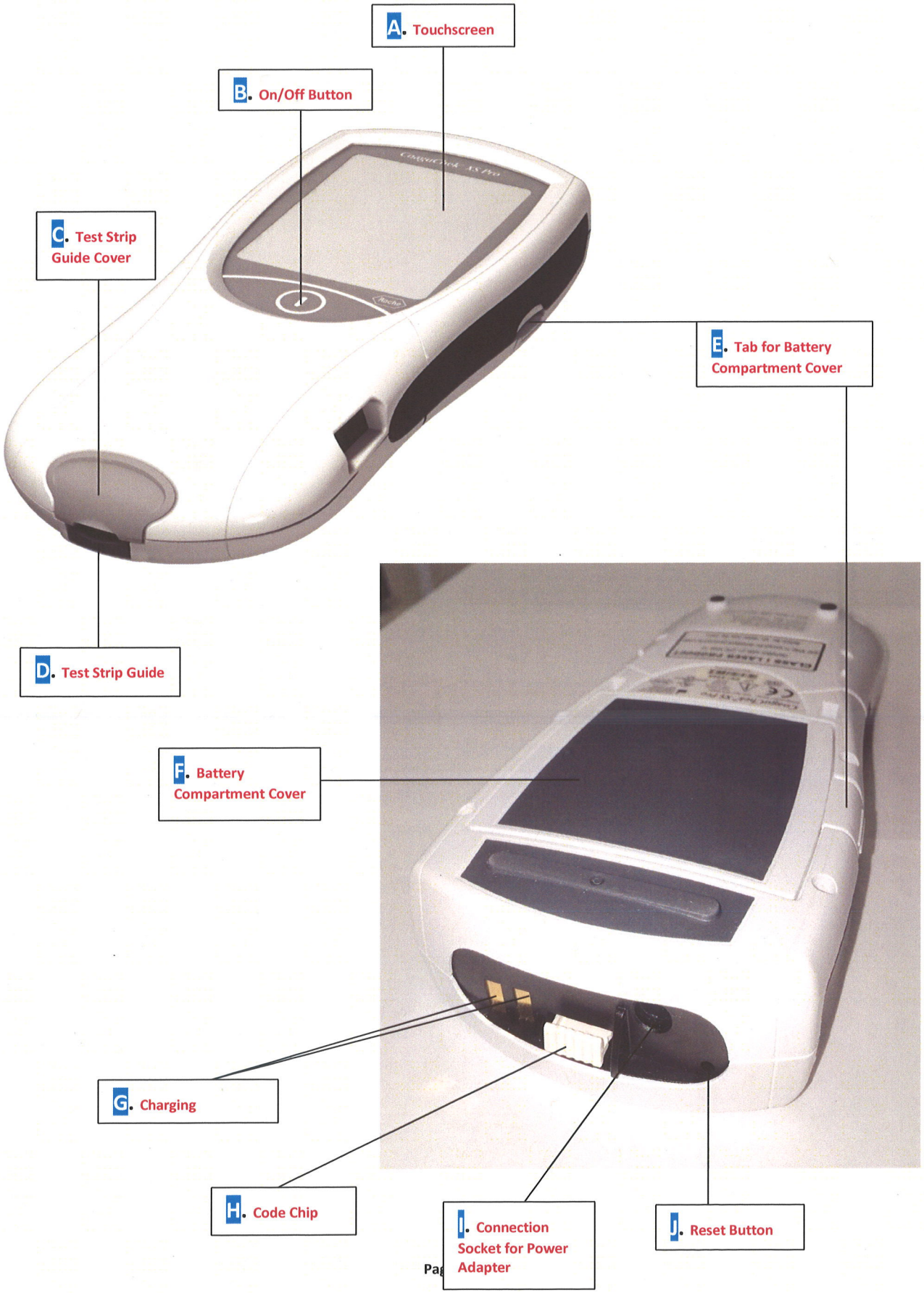
A. Only trained **Licensed Pharmacists** or **other approved healthcare professionals** may operate the CoaguChek XS Plus system at ZSFG. Operators must have received comprehensive instruction in the operation, quality control, and care of the CoaguChek XS Plus system and be approved by the POCT Committee.
B. Testing personnel are required to take the **Initial Orientation and Training and Competency Testing** which includes successful demonstration of skills and knowledge. This Competency Testing is required upon initial training, twice during the first year, and annually thereafter.
C. If an operator's ID is active (is working), it signifies the operator has completed all prerequisites for patient testing and is currently approved to perform this POCT.
D. If an operator's ID is not active (not working), it signifies the lack of approval for performing this POCT and the need to renew their Competency test.
E. There must be a test order for the INR test and sign by Pharmacists or Health Care Provider.
F. Students are not trained, nor approved, to perform this POCT at ZSFG. Their educational experience may be gained only when an employee with an active ID is with them at the patient's testing encounter supervising and taking full responsibility for the experience, results, documentation, and follow-up actions.

EQUIPMENT

A. CoaguChek XS Plus Meter
B. CoaguChek Handheld Base Unit
C. CoaguChek XS PT Test Strip
D. CoaguChek XS PT Test Strip Code Chip
E. CoaguChek XS Plus PT Controls
F. CoaguChek XS Plus PT Quality Control Code Chip
G. Handheld battery pack (4 standard AA alkali-manganese batteries or the rechargeable battery pack)
H. Single-use, single patient lancets
I. Disposable Gloves
J. Alcohol Wipes
K. Gauze
L. Approved cleaning solutions as listed in the user manual

M. CoaguChek XS Plus System User Manual

THE COAGUCHEK XS PLUS METER



GENERAL SAFETY INSTRUCTIONS

A. Follow standard universal precautions.

OVERVIEW OF THE COAGUCHEK XS PLUS METER:

A. **Touchscreen** – shows test results, information, icons, and results recalled from memory. To select an option, simply touch the button lightly.
B. **On/Off Button** – press and hold this button to power the meter on or off.
C. **Test strip guide cover** – remove this cover to clean the test strip guide (if it has become soiled, e.g., with blood).
D. **Test strip guide** – insert the test strip here.
E. **Tab for battery compartment cover** – depress to access battery compartment.
F. **Battery compartment cover** – covers the battery compartment (rechargeable battery pack).
G. **Charging terminals** – used for power supply and/or charging the battery pack, when the meter is docked in the Handheld Base Unit.
H. **Code chip slot** – insert the code chip here.
I. **Connection socket for power adapter** – plug in the power adapter here.
J. **Reset button** – use this button to reset the meter in case of software or power-up errors.
K. **Infrared interface** – (covered by the semi-transparent panel) supports data communication.

NOTE: *For buttons and icons overview refer to CoaguChek XS Plus Operator's Manual pages 22-24.*

REAGENTS / SUPPLIES STORAGE AND HANDLING

A. **CoaguChek XS PT Test Strips**
   1. 1 Vial = 48 Test Strips and 1 PT Test Code Chip.
   2. Test strips are intended for in vitro diagnostic use only.
   3. **Storage:**
      a. Store the test strips in their container with the cap closed.
      b. Store at **Room Temperature (15-25°C)** until the expiration date printed on the test strip container (if stored properly).
   4. **Handling:**
      a. Immediately close the container and seal tightly after opening the test strip container.
      b. Use the test strip within **10 minutes** after removing it from the container.
      c. Do not open a vial of test strips or touch a test strip with wet hands or wet gloves. This may damage the test strips.
      d. Discard any outdated test strips.

B. **CoaguChek XS PT Test Strip Code Chip**
   1. **CoaguChek XS PT Test Strip Code Chip** – calibrates the system for each new box and new lot of test strips.
   2. The Test Strip Code Chip contains information about the test method, the lot number, and the expiration date.
   3. The Test strip code chip is required when a new test strip container is opened and new test strip lot is used, to store the lot information about that particular lot of test strips in the meter.
   4. The CoaguChek XS Plus meter stores the data from up to 60 code chips.
   5. Use the test strip code chip that is supplied with each new test strip container before you perform the first test from that container.

6. Each code chip belongs to a particular lot of test strips. Change the code chip with every new container of test strips.
7. Leave the code chip in the meter to protect the electrical contacts in the meter from becoming dirty.
8. Protect the code chip from moisture and equipment that produces magnetic fields.

C. **CoaguChek XS Plus PT Liquid Controls**
1. 1 Box = 4 bottles of Level 1 and Level 2 Quality Control lyophilized plasma, 8 diluent-filled droppers and 1 Quality Control Code Chip.
2. **CoaguChek XS Plus PT Quality Control Code Chip** – tells the meter the acceptable ranges and expiration dates for each box of controls.
3. PT controls are intended for in vitro diagnostic use only.
4. **Storage and Handling**:
    a. Store at **Refrigerator Temperature (2-8°C)** until the expiration date. **DO NOT FREEZE**.
    b. Controls are stable for 30 minutes after adding the diluent.
    c. Discard any outdated controls.

QUALITY CONTROL

A. The CoaguChek XS Plus System has 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. The system performs:
1. A check of the electronic components and functions every time the meter is turned on,
2. A check of the expiration date and lot information on the test strip,
3. A quality control function incorporated into the test strip.
4. **Automatic Internal Quality Control**
    a. The CoaguChek XS Plus meter performs an **Automatic Quality Control** test on the test strip before it displays the test result. "**QC**" appears in the display.
    b. A two-level, on-board quality control test is performed within the test chamber as part of every blood test.
    c. Following a successful outcome of the internal quality control test, a checkmark appears after "QC".
    d. If the test strip fails the Internal Quality Control check, the test strip is unusable. Remove the test strip. Repeat the test using a new test strip and a new fingerstick from a different finger. If internal QC still fails, open a new box of test strip and retest. If test strip fails internal QC more than 3x, contact Point of Care Testing (POCT) Clinical Laboratory Scientist (CLS).

B. **Liquid Quality Control Testing must be performed:**
1. With every New lot or New Shipment of Test Strips,
2. With every New or New Shipment lot of Quality Control,
3. When temperature is out of range, and
4. After troubleshooting or preventive maintenance is performed on the meter.

C. **Preparing a Liquid Quality Control Solution**
1. Universal Precautions should be observed through all phases of the testing Procedure.
2. Each control bottle contains nonhuman plasma with varied levels of coagulation factors, stabilizers, and preservatives. Each diluent filled dropper contains a calcium chloride solution with preservatives.
3. Gather Supplies:
    a. CoaguChek XS Plus Meter
    b. CoaguChek XS PT Test strip(s) with matching test strip code chip

c. CoaguChek XS Plus PT Controls: Level 1 and Level 2 with matching quality control code chip
d. Diluent dropper(s): one for each control to be run
e. Scissors

4. Insert the quality control code chip into the meter. This tells the meter the acceptable ranges and expiration dates for each box of controls.

   NOTE: *When using test strips from a new unopened container, change the Test Strip Code Chip. The meter recognizes only those test strips that match the Test Strip Code Chip.*

5. Remove the screwcap and rubber stopper from the quality control bottle. Label the bottle with the date and time that you reconstitute it.
6. Using scissors cut off the tip of the dropper at the end of the stem. Hold the dropper a safe distance from your face to prevent accidental exposure, or wear a face shield.

   CAUTION: *To avoid loss of diluent, hold the dropper by the stem; do not squeeze the bulb of the dropper while cutting the tip.*

7. Invert the dropper and place the tip into the bottle. Be careful to avoid losing any diluent.
8. 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.*

9. Remove the dropper from the bottle. DO NOT discard the dropper. Replace the cap first and gently swirl the bottle to dissolve the dried material**. Do not shake or invert the bottle**.
10. Let the bottle sit undisturbed for at least **ONE MINUTE** to ensure that the dried material dissolves completely.
11. Use the reconstituted quality control solution **within 30 minutes** from the time the diluent is added.

D. **Performing a Liquid Quality Control Test**

1. Place the meter on a flat surface, (like a table or countertop) or hold it roughly horizontal so that it will not vibrate or move during testing. Vibrations or other movement can result in an error message.
2. Power the meter ON by pressing the ON/OFF button for approximately 1 second.
3. Or slide the test strip in as far as it will go. This turns the meter ON. A beep tone indicates that the meter has detected the test strip
4. Check the battery level.

   IMPORTANT: *If the battery icon turns red (one bar left), there may not be enough power left for another test. If there are no bars left in the battery icon, you cannot perform any more tests. Power the meter off using the ON/OFF button. In both cases, restore power by inserting new batteries, recharging the battery, or using the power adapter.*

5. Check that the date and time are correct.
6. Press **Control Test** on the meter display.
7. The test strip icon prompts you to insert a test strip. Remove one test strip from the container and immediately close the container. Make sure it seals tightly.

   IMPORTANT: *Do not open a container of test strips or touch a test strip with wet hands or wet gloves. This may damage the test strips. Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, always*

close the container immediately after removing a test strip.

8. Use the test strip **within 10 minutes** of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test
9. Hold the test strip so the lettering is facing upward.
10. Slide the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go into the meter. A beep tone indicates that the meter has detected a test strip.
11. The meter automatically checks to see if you have the right test strip code chip. **The three digit code on the test strip container must match the number on the test strip code chip before the test can be run**.
12. If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now. Otherwise you cannot perform a quality control test.

    IMPORTANT: *As with the test strips, a quality control code chip is also provided with the control solutions. This chip informs the meter about the acceptable ranges of results for that lot of controls. The information on the code chip is retained in the memory so you can use the same control solutions at any time.*

13. Select the code already stored for your current control solution, or touch **NEW CODE** to use a new control solution.

    IMPORTANT: *The first time you run a control, the meter skips this Quality Test Screen option because there are no code chip parameters in memory yet. The next time you use the control, this screen will display, offering you a pick of the code(s) already stored as well as the option:* ***NEW CODE****.*

    If you are using a ***new control solution****, remove the strip code chip from the meter and insert the code chip that came with the control solution instead.*

    If the code chips get mixed up, check the letter on the code chips to tell them apart. A ***capital S*** *in front of the number indicates that this* ***code chip is for test strips****. A* ***capital C*** *in front of the number indicates that it is a* ***control solution code chip****.*

14. Select level for this control test measurement (Level 1 or Level 2).
15. The hourglass symbol shows that the test strip is warming up. When the warming-up process is complete, a second beep indicates that you can now apply the control solution.
16. The dropper symbol 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. Otherwise, you will receive an error message.
17. 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**.
18. Draw control solution into the dropper and put one drop of the liquid on the **TOP** of the target area (clear area of the test strip). DO NOT add more control.
19. DO NOT touch or remove the test strip while the test is in progress. The flashing dropper symbol changes to an hourglass symbol when the meter detects a sufficient sample. You will hear a beep tone when you have applied enough control solution.

    NOTE: *If any control solution 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, in case the control test needs to be repeated.*

20. The result appears in approximately one minute.
21. The result of the quality control is displayed. It is automatically saved to memory.
22. The acceptable range of results for the liquid control is displayed below the current result (**NUMERIC**) along with **PASS or FAIL**.

    NOTE: *If the quality control test fails, an up arrow (too high) or down arrow (too low) flashes on the display.*

23. If you want to add a comment, touch 💬 icon.
24. Select the desired predefined comment(s) from the pick list. Once you have selected the desired comment, press (**√**) to return to the results screen.
25. Remove the test strip from the meter. If you are performing a 2-level control, you will now be asked to proceed with the second level.
26. Record the result. After you verify the validity of the control result, discard the test strip, dropper and the reconstituted bottle of quality control.
27. Remove the quality control code chip and store it with the opened box of controls. Reinsert the test strip code chip if necessary.
28. Turn the meter OFF and clean the meter (see Maintenance & Care, section C, page 13) or proceed to patient testing.
29. Clean the meter.

E. **Quality Control Expected Results**
1. The meter displays the acceptable control range and the result. The reading is automatically saved in the memory of the meter.
2. The system is working properly and all handling has been done correctly when the test results obtained are within the acceptable control range.

F. **Documenting Liquid Quality Control Testing Results**
1. All Quality Control results (along with any CORRECTIVE ACTION entered to restore that result to the acceptable range) must be recorded on a Quality Control Log. This log includes the following:
    a. Test strip lot number and expiration date
    b. Control solution lot number and expiration date
    c. Meter Serial Number
    d. Control Ranges
    e. Operator Identification
    f. Date the test was performed

2. Retain the records for **at least 3 years** per laboratory regulation.

G. **Unacceptable Liquid Control Results**
1. An out of range result is indicated by an arrow. An arrow pointing up means the result is too high. An arrow pointing down means the result is too low. To resolve out of range results or error messages, check for the following:
    a. Controls may be expired or stored improperly.
    b. The control may not have been used within 30 minutes of reconstitution.
    c. Make sure you run the test within **10 minutes** of removing the test strip from its container.
    d. You may not be doing the test correctly. Repeat the control test, using a new test strip.

e. If QC still fails, discard the reconstituted control solution. Open a new bottle of control solution and reconstitute. Repeat QC with the newly reconstituted control and new vial of test strips.

2. If you follow all these guidelines and your result is still unacceptable, call POCT CLS.

CALIBRATION

A. 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 characteristics information to the meter so it is calibrated for use with its corresponding specific lot of test strips and controls.
B. The manufacturer establishes the performance characteristics based on testing of specimens from donors on warfarin therapy. Each code chip is verified to show that it will produce expected results. In addition, every time the meter is turned on, it goes through a series of self-diagnostic checks.
C. The CoaguChek XS Plus System cannot be adjusted externally to fit a certain linearity curve.

SPECIMEN / SAMPLE COLLECTION AND HANDLING

A. Universal Precautions should be observed through all phases of the testing procedure.
B. The CoaguChek XS Plus System test may be performed with fresh capillary whole blood from a fingerstick.
C. The results are unaffected by heparin concentrations up to 0.8 U/mL.
D. The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL.
E. The blood sample must be applied to the test strip within **10 minutes** of removing the test strip from its container.
F. The meter should display the flashing test strip and blood drop symbols prior to sample collection.
G. Capillary sample must be applied to the strip within **15 seconds** of the fingerstick.
H. Minimum sample size is **8 µL** of blood.

I. **Criteria for Unacceptable Specimen:**
   1. Plasma or serum CANNOT be used as a testing sample.
   2. Sample size CANNOT be less than 8 µL.
   3. Additional blood sample CANNOT be added to the test strip once testing has begun.
   4. When a patient is on intravenous infusion therapy, sample CANNOT be collected from arm receiving the infusion line.

PATIENT TESTING PROCEDURE

A. **Getting Ready to Test**
   1. Universal Precautions should be observed through all phases of the testing procedure.
   2. Gather Supplies:
      a. CoaguChek XS Plus Meter
      b. CoaguChek XS PT Test strip(s)
      c. Test Strip Code Chip
      d. Lancet device
      e. Alcohol wipe, gauze or cotton ball, bandages
      f. Gloves

Important: *If you are using test strips from a new, unopened container, you must*

change the Test Strip Code Chip. The three-number code on the test strip container must match the three-number code on the code chip.

3. Place the meter on a flat surface (like a table or countertop) or hold it roughly horizontal so that it will not vibrate or move during testing. Vibrations or other movement can result in an error message.

B. **Getting a Good Drop of Blood**

1. Increasing the blood flow in the finger will help you get a good drop of blood. Before you lance the finger, try the following techniques until you see that the fingertip has increased color.
    a. Warm the hand by having the patient hold it under his or her arm, use a hand warmer, and/or wash the hand with warm water.
    b. Have the patient hold his or her arm down to the side, so hand is below waist.
    c. Massage the finger from its base. DO NOT MILK THE FINGER.

C. **Performing the Test**

1. Using two patient identifiers, verify patient identification, and explain procedure to patient and/or family.
2. Wash the patient's hands with warm, soapy water or wipe the finger with alcohol. Allow to air dry completely.
3. Wear gloves. Make sure your hands and gloves are dry before proceeding.
4. Take a test strip out of the container. Close the container tightly.
5. Hold the test strip so the lettering "CoaguChek XS PT" is facing upward.
6. Slide the test strip into the test strip guide in the direction indicated by the arrows.
7. Slide the test strip in as far as it will go. This turns the meter ON. A beep tone indicates that the meter has detected the test strip.
8. Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests.
9. Check that the date and time are correct.

    NOTE: *If a lockout (**QC/Quality Control Lockout**) is displayed instead of PATIENT TEST, you must run a quality control before you can perform a test. **Refer to Quality Control Instructions.** When the meter is in lockout status, a test cannot be performed.*

10. Enter "Operator Identification" manually. Touch √ [OK] to log on and move to the main menu.
11. Press **Patient Test** on the meter display.
12. The next screen allows for the **PATIENT ID**. **Enter Patient's Medical Record Number (MRN),** and then press (**√**) to move to the next screen. An hour glass symbol indicates the test is warming up.
13. Confirm that the code number displayed on the meter matches the number on the test strip container.

    NOTE: *The meter automatically checks to see if you have the right test strip code chip. The 3 digit code on the test strip vial must match the number on the test strip code chip before a test can be run.*

14. The blood drop symbol 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.

    IMPORTANT: ***DO NOT*** *"perform finger stick" until the flashing drop of blood appears on the display. Strip must be used within **10 minutes** of removing it from the container.*

15. Collect the finger stick blood sample. **DO NOT** wipe away the first drop of blood. Apply the first drop of blood to the top or side of the target area 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.

    NOTE: ***DO NOT*** *add more samples.* ***DO NOT*** *touch the test strip or move the meter until the result is displayed.*

16. After the sample is applied, the meter automatically performs a two-level, on board Quality Control test on the test strip before it displays the test result. "**QC**" appears in the display.
17. Following a successful outcome of the quality control test, a **check mark** appears after "**QC**."
18. The patient result appears in approximately one minute.
30. Read and Record the patient's result. It is automatically saved to memory.

    NOTE: *Results that are above or below the measuring range are indicated by the symbols > (above) or < (below).*

    IMPORTANT*: "C" may be displayed along with the result if the hematocrit value is very low or may be due to erroneous blood collection (e.g. wet hands),* ***Repeat*** *the measurement and make sure that the patient's hands are dry.*

    When interpreting results refer to the detailed information on limitations and interferences.

19. If you want to add a comment, touch 💬 icon. Select the predefined comment(s) from the display and touch **√** to return to the results screen.
20. After the test result is displayed, a strip and arrow symbols appear on the screen, prompting you to remove the strip.
21. Remove the test strip from the measurement chamber.
22. Turn the meter OFF.
23. Dispose of all biohazard materials in the appropriate designated biohazard or sharps container.
24. Clean the meter (see Maintenance & Care, Section C, page 13).

    NOTE: *Use a new fingerstick and a new test strip if you must retest. DO NOT add more blood to the first test strip.*

REPORTING / DOCUMENTATION OF RESULTS

A. **Reviewing Test Results**
   1. Press Review Results.
   2. Select the type of results you want to view.
      a. Display **Patient Result** memory
         i. This memory area contains all test results for your patients.
         ii. Touch the entry / MRN you want to open.
         iii. The results for the selected patients are displayed.

      b. Display **QC Result** memory
         i. This memory area contains all liquid quality control tests that were run.
         ii. Touch the entry you want to open.
         iii. The results for the selected quality control are displayed.

B. **Expected Results**
   1. The CoaguChek XS Plus meter displays test results in units equivalent to laboratory plasma measurements.

2. Results display in INR (International Normalized Ratio). INR units are calculated from a mathematical formula that is designed to compensate for differences in reagents, thereby standardizing PT results from different systems. The CoaguChek XS Plus meter performs INR calculations automatically. The formula is as follows:

   INR = (PT result/Mean Normal PT)^{ISI}
   ISI = International Sensitivity Index (=1.0). This is a numerical value assigned to the reagent used in the test strip.

C. **Interpreting Test Results**

1. Any unexpected results should always be followed up with an immediate call to the attending physician.
2. If the meter displays a message other than a result, refer to the Error Messages in this policy or refer to Operator's Manual.

   NOTE: *In rare cases, an **Error Message** can occur in patients with long coagulation times. If this error message appears again when the test is repeated, a fresh sample should be sent to the Clinical Laboratory (in Building 5, 2M) for testing.*

3. If the meter displays an **unexpected test result** (other than an error message), check the following items:
   a. 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.
   b. 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 are programmed correctly on the meter.
   c. Certain drugs may affect results by interfering with warfarin pharmacology. The potential effect of a drug interaction with warfarin or the effect of underlying diseases (e.g., liver disease, congestive heart failure) must be considered when interpreting a result.
   d. Changes in patient's diet can cause unusually low or high results.
   e. Any unexpected result can be followed up with inquiries to define the cause of the result. If the result does not match the clinical symptoms, repeat the patient test to rule out a procedural error.
4. Debris on the test strip guide can cause problems with results. Clean the meter. Refer to Maintenance and Care instructions, Section C, page 13.
   a. Do not use spray to clean the guide or any part of the meter.
   b. Do not let liquid enter the meter.
   c. Do not drench meter.

5. **Limitations and Interferences**
   a. The CoaguChek XS Plus System should not be used for patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivlirudin and Argatroban.
   b. The CoaguChek XS PT Test uses only fresh capillary finger stick blood. Plasma or serum cannot be used.
   c. The blood drop must be a minimum of 8 µL in volume. Low sample volume will cause an error message.
   d. Never add more blood to test strip after test has begun or perform another test using different fingerstick.

e. When a patient is on intravenous infusion therapy, do not collect sample from arm receiving the infusion line.
f. Hematocrit ranges between 25-55% do not significantly affect test results.
g. Testing performed with the following in vitro spiked samples or native blood samples (Triglycerides) indicated no significant effect on test results:
    i. Biluribin up to 30mg/dL
    ii. Lipemic samples containing up to 500 mg/dL of triglycerides
    iii. Hemolysis up to 1000 mg/dL
    iv. Heparin concentrations up to 0.8 U/mL
    v. The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL
    vi. Clopidogrel up to 20 mg/dL
    vii. Fondaparinux up to 5 mg/L

h. The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values.

D. **Documenting Test Result**
1. Document INR results on the patient's medical chart (eCW).

E. **Reference Range**

ISI	PT (sec)	INR
1.0	12.0	1.0

F. **Reportable Range**
1. The CoaguChek XS Plus reportable range is:

INR	1.0 – 3.5

2. If INR is >3.5, value may not accurately reflect INR; Order a STAT PT/INR via standard venipuncture technique and send it to the Clinical Lab for immediate confirmation.

G. **RECORD KEEPING**
1. The Pharmacy Manager or designee will document the following:
    a. Quality Control (QC) log on QC log
    b. Daily Temperature on Temperature log

2. All records will be kept on file in the Clinical Laboratory for at least three years. Patient results are permanently documented in their medical record.

MAINTENANCE AND CARE

A. Document room air and refrigerator temperature daily on a Temperature Log Sheet provided by POCT Services. POC team will review the QC log **monthly**. Retain the records for at least 3 years.

B. **Storage**
1. Store the meter and test strips in the same environment in which they are used.
2. Do not store the meter in direct sunlight.

C. **Cleaning and Disinfecting the Meter**
1. Wear disposable gloves when cleaning and performing preventive maintenance.
2. It is important to keep the meter clean. Clean the meter before and after every patient test.

3. Follow the procedures outlined below to clean and disinfect the meter. Failure to follow these procedures may cause malfunction of the meter:
    a. Make sure the meter is powered off.
    b. Do not spray anything onto the meter and do not immerse or drench it in liquid.
    c. Ensure that cloth or swab/bud is only damp, not wet, to protect against moisture entering the meter.
4. **Recommended cleaning/disinfecting solutions:**
    a. 70% ethanol or isopropyl alcohol
    b. 10% sodium hypochlorite solution

    CAUTION: *Do not use any other disinfectants/cleaning solutions on the meter (housing or test strip guide). Use of other disinfectants/cleaning solutions could result in damage to the meter.*

5. **Procedure: Cleaning/disinfecting the meter housing (the exterior of the meter)**
    a. Ensure that the blue test strip guide cover remains tightly closed while cleaning the meter housing.
    b. With the meter powered off, wipe the meter's exterior clean.
    c. Apply the cleaning solutions for a contact time of more than 1 minute.
    d. Do not let liquid accumulate near any opening. Ensure that no liquid enters the meter.
    e. With a fresh dry cloth or lint-free tissue, wipe away residual moisture and fluids after cleaning the housing.
    f. Ensure the meter is completely dry before performing a test.

6. **Procedure: Cleaning/disinfecting the meter test strip guide**
    a. With the meter powered off, use your thumbnail to open the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter. Then rinse the cover with warm water or wipe it clean.
    b. To clean the test strip guide, hold the meter upright with the test strip guide facing down. Clean the easily accessible white areas with a moistened cotton swab/bud.
    c. Ensure the swab/bud is only damp, not wet.
    d. Apply the cleaning solutions for a contact time of more than 1 minute.
    e. Wipe away residual moisture and fluids.
    f. Let the test strip guide cover **dry for at least 10 minutes** before re-attaching it.
    g. Close the test strip guide cover and make sure it snaps into place.

    CAUTION: *Do not insert any objects in the test strip guide. Doing so may damage the electrical contacts behind the test strip guide.*

7. **Cleaning the Scanner Window**
    a. The scanner window should be cleaned periodically. Use a clean, dry cloth to wipe the scanner window.

TROUBLESHOOTING

A. The CoaguChek XS Plus meter continually checks its systems for unexpected and unwanted conditions. These may arise for technical reasons (e.g., defective components or consumables, environmental factors, or due to handling and procedure errors.

B. A message may appear on the display of the meter and are marked with an icon, either for a status message or for an error message. All messages displayed by the system are accompanied by a description of the error and a possible solution.

C. **Errors and unusual behavior without error messages.**

- Some conditions may arise that have no associated error or status message, such as:

Message	Description
Meter display does not power on	▪ Wait 10 seconds and try powering on the meter again. ▪ Check that the meter has power. • Place the meter in the Handheld Base Unit.
Meter displays an unexpected result	▪ Refer to Interpreting Test Results
Automatic Shutdown	• The meter powers off after 5 minutes without activity (e.g., pressing a key, touching the screen) to conserve energy. Reactivate the meter/screen as described in the following: • Press ON/OFF button of the meter.

D. Take the action suggested on screen to resolve the problem. If the error disappears, you may continue using the meter as desired. If the problem persists, contact Point of Care Services.

ORDERING INFORMATION

ZSFG PMM Item No.	Item Description	Manufacturer (ROCHE) Catalog Number
1047587	CoaguChek XS Pro PT Controls	04625382160
1047588	CoaguChek XS PT Test	04625315160
	Handheld Battery Pack	04805640001

REFERENCES

A. Roche Diagnostics. (2013). CoaguChek XS Plus PT Controls Package Insert. Reference Number: 04625382160. Roche Diagnostics, 9115 Hague Road Indianapolis, IN 46256. www.coauchek-usa.com.
B. Roche Diagnostics. (2013). CoaguChek XS PT Test Package Insert. Reference Number: 04625315160. Roche Diagnostics, 9115 Hague Road Indianapolis, IN 46256. www.coauchek-usa.com.
C. Roche Diagnostics. (2013). CoaguChek XS Plus Operator's Manual. Roche Diagnostics, 9115 Hague Road Indianapolis, IN 46256. www.coauchek-usa.com.
D. Roche Diagnostics. (2013). CoaguChek XS Plus System – Policies and Procedures Manual. Roche Diagnostics, 9115 Hague Road Indianapolis, IN 46256. www.coauchek-usa.com.
E. Joint Commission Standards, WT.01.01.01, WT.02.01.01, WT.03.01.01, WT.04.01.01, WT.05.01.01

DISTRIBUTION

A. Point of Care Testing Master Manual
B. Approved Point of Care Testing locations via POCT Website www.SFGH-POCT.org

REVISION HISTORY

Revision Date	Description:	Supervisor Signoff By:	Signoff Date: