Wake Forest Baptist Medical Center	**Prothrombin Time and INR Testing at the Point-of-Care Using the Roche Coaguchek XS Device** **OP-306-22**	**Document Control Number:**	**N/A**
		Effective Date:	**7/2013**
		Revised Date:	**9/2018**
		Contact:	**Laboratory Compliance, QA, Safety and Point-of-Care Testing**
CLIA Laboratory Medical Director Signature:		**Date Approved:**	
Name and Title: **Gregory Pomper, MD, Medical Director, Clinical Laboratories**			

1) **General Procedure Statement:**
It is the policy of Wake Forest Baptist Medical Center to perform Point-of-Care (POC) PT/INR testing according to established protocols and per manufacturer instructions. Each specific user site must have approval from the WFBMC Point of Care Committee to perform this testing. The Coaguchek XS results obtained will be used definitively in the care of established patients on warfarin therapy.

Only staff members who have been trained and completed required competency assessment for the Coaguchek XS system may perform this testing.

All testing personnel must read the procedure manual and demonstrate successful performance of POC PT/INR testing using the Roche Coaguchek XS device under the direction and supervision of an authorized staff member. Once successful demonstration of testing has been performed, it will be documented on the site-specific employee training checklist.

Staff members are responsible for performing point of care PT/INR testing with a physician or mid-level provider order or documented protocol. Staff should not perform testing on themselves, co-workers, or visitors.

a) **Scope:** All staff members who are educated and qualified to perform waived testing by their job descriptions and have demonstrated competency in the routine operation and quality control of the Coaguchek XS are responsible for following this procedure**.**

b) **Responsible Department/Party/Parties:**
   i. **Procedure Owner:** Laboratory Compliance, QA, Safety and Point-of-Care Testing Manager
   ii. **Procedure:** Coaguchek XS testing personnel shall adhere to processes outlined in this document.
   iii. **Supervision:** The Medical Director and/or laboratory director, as indicated on covering CLIA certificate for Point-of-Care Testing, shall supervise the person(s) performing activities outlined in this document.
   iv. **Implementation:** Each applicable POCT laboratory director and/or site manager is responsible for ensuring compliance with processes stated in this document.

2) **Definitions:** For purposes of this procedure, the following terms and definitions apply:

a) **Point-of-Care Testing (POCT):** Tests designed to be used at or near the site where the patient is located, do not require permanent dedicated space, and are performed outside the physical facilities of the clinical laboratory.
b) **Waived Tests:** Tests of low complexity as designated by the FDA; tests that are simple and have low risk for erroneous results.
c) **Clinical Laboratory Improvement Amendments (CLIA):** United States federal regulatory standards that apply to all laboratory testing performed on humans.
d) **Quality Control (QC):** A process to ensure the test system is performing as expected.
    i. **External QC** – External liquid material or substance with known value(s) for the test(s) being performed.
    ii. **Internal QC** – An internal check within the test system to validate the test system is working properly.
e) **Quality Assurance (QA):** A system for ensuring a desired level of quality. The POCT program incorporates activities to monitor the quality of processes and the test system.
f) **Technical Limits/Reportable Range:** The range at which the analyzer has been verified to obtain accurate results. Each analyte has a specific reportable range.
g) **Normal (Reference) Range:** The range of values for the average patient population.

3) Principle:

The CoaguCheck XS® test strip, when used as directed with CoaguChek XS® monitor, will provide accurate blood INR values.

When a drop of fresh blood is placed on the test strip, the blood is drawn into a reaction chamber and mixed with reagents that start the coagulation process. Tiny iron particles are also mixed with the test strip sample, and alternating magnetic fields cause the iron particles to move. The endpoint of the test is reached when the blood clot stops the iron particles from moving. The monitor then displays the INR result.

4) Procedure:

a) Reagent Storage/Information

i. Each CoaguChek XS® System test strip contains reagent (human recombinant thromboplastin), stabilizers, preservatives, and additives. Strips are intended for in vitro diagnostic use only.
ii. Store CoaguChek XS® System test strips in their original container with the cap closed.
iii. Test strips may be stored at room temperature or in the refrigerator (36ºF to 86ºF or 2ºC to 30ºC) until ready to use.
iv. When stored properly, test strips can be used until the expiration date printed on the test strip container.
v. When ready to test, open the test strip container and remove one strip. Immediately close the container and make sure it seals tightly.
vi. **Use the test strip within 10 minutes after removing it from the container.**
vii. Test strips past their "Use By" date will be discarded.
viii. Do not open a vial of test strips or touch a test strip with wet hands or gloves. This may damage the test strip.
ix. Close the strip container tightly.

b) Quality Control

i. External controls are not required or available for the CoaguChek XS® system.

ii. Each Day of Testing:
- With each patient test, observe the on-board, internal QC result and record it on the CoaguChek XS Daily Patient Result Log. If acceptable, patient test results can be reported.

iii. The system performs independent/automatic Quality Control Tests, which
- Check the electronic components and functions every time the meter is turned on
- Check the expiration date and lot information on the test strip
- Is incorporated into the test strip
- Is a two-level, on-board quality control test and patient result determination within every single test.
- Patient results will not be reported if the internal quality control fails. A QC error message appears.

iv. **In the event of failed QC,**
- Power the meter off and remove the test strip. Repeat the test using a new test strip and blood taken from a new finger stick from a different finger.
- Log event on the Coaguchek XS Maintenance and Problem/Corrective Action Log

c) Troubleshooting Persistent Out of Control QC Results

i. To resolve QC error messages, carefully follow the instructions in the user manual.
ii. Check that the test was performed exactly as directed and that the test was run within 10 minutes of removing the test strip from its container.
iii. If troubleshooting is unsuccessful, and control results are still unacceptable, call Roche Diagnostics Technical Service Center at 1-800-428-4674.
iv. Document all problems and corrective actions on the Coaguchek XS Maintenance and Problem/Corrective Action Log.

d) Equipment Required for Testing

i. CoaguChek XS® Test Strips and lot specific Code Chip
ii. CoaguChek XS® Meter (uses 4 non-rechargeable AAA batteries)
iii. Single use self-retracting disposable lancets
iv. Alcohol Prep Pads
v. 2 X 2 gauze
vi. WFMBC-approved exam gloves
vii. Adhesive bandage (paper tape should also be available)
viii. PLASTIC capillary collection tube and bulb, if this delivery technique is desired
ix. WFMBC-approved biohazard sharps container

e) Safety

i. All blood samples and analyzers should be treated as biohazardous and handled with care.
ii. Standard precautions should be taken to avoid accidental exposure. Refer to the WFBH Blood and Body Fluid Exposure Control Plan
iii. Testing staff members should wash their hands before and after testing.
iv. Lancets and capillary collection tubes should be discarded in a biohazardous sharps container.
v. Used test strips may be discarded in a biohazardous container.
vi. Disposable gloves should be worn during sample collection and analysis.
vii. Any device that is contaminated with body fluids should be handled using standard precautions. Refer to Blood and Body Fluid Exposure Control Plan

viii. The device should be cleaned with 10% bleach. Do NOT use strong cleaning solutions. They may deform the instrument's plastic components.

f) Sample Collection and Handling (gloves must be worn)

i. **Sample Type**

ii. Fresh capillary whole blood from the first drop of finger stick is applied directly to the test strip.

iii. A drop of fresh venous whole blood drawn in an anticoagulant-free plastic capillary tube may also be directly placed on the strip.

g) Sample Size

i. Minimum sample size is 8 µL of blood.

ii. The analyzer will indicate an error if insufficient blood was placed on the strip.

h) When to Test

i. The blood sample must be applied to the test strip within 10 minutes of removing the test strip from its container.

ii. The meter should display the flashing test strip and blood drop symbols, prior to sample collection.

iii. Capillary sample must be applied to the strip within 15 seconds of finger stick.

IMPORTANT Sample Notes:

iv. Refer to section on Limitations/Interferences/Method Notes for important information.

v. Additional blood sample cannot be added to the test strip once testing has begun

vi. If an inadequate sample is obtained from a finger stick, a different finger must be used for collection of a fresh sample(on the opposite hand if possible)

vii. When a patient is on IV infusion therapy, a blood sample cannot be collected from arm receiving the infusion

i) Test Procedure and Sample Analysis

i. **Note:** Laboratory policy mandates that staff will wash their hands before patient contact and wear exam gloves when collecting and handling all blood samples.

ii. Confirm correct patient identity, using at least 2 identifiers: Name and birth date. Medical record number may also be used as a 3rd identifier.

iii. Introduce yourself to the patient and briefly explain what you are going to do

iv. Gather materials

v. Prepare lancet device and set aside

vi. If plastic capillary tube is used, insert the capillary tube into the capillary bulb and set aside until needed

vii. Place meter on a flat surface that is free of vibrations. Do NOT place near a centrifuge or other device that may cause vibration.

viii. The monitor must be stationary once the blood has been applied to the strip.

ix. Take a test strip out of the container. Close the container tightly. **Use strip within 10 minutes.** Holding the test strip so the lettering is facing upward, 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 to turn the meter on. A beep tone indicates that the meter has detected the test strip (provided the beeper is turned on in the settings).

x. Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests. Change the batteries.

xi. Check that the date and time are correct. Correct any wrong entries.

xii. **Confirm that the code number displayed on the meter matches the number on the test strip container.**

xiii. If the numbers are different, make sure you are using the code chip that came with the test strips you are using. If the numbers match, press the M button to continue. If not, follow instructions in "Calibration" section.
xiv. **Incorrect results can occur if there is a mismatch between test strip calibration code and code chip in analyzer.**
xv. When the blood drop symbol flashes to indicate that the meter is ready to perform the test and is waiting for blood to be applied, a 180-second countdown begins.
xvi. *Do NOT collect the sample until the flashing test strip and blood drop symbols appear.*
xvii. Clean finger with alcohol prep pad and allow site to completely dry.
xviii. Note: alcohol can interfere with the testing.
xix. Collect the finger stick or venous blood sample as outlined below.
- **Finger stick sample**
  (i) Place the tip of the lancet against the top or bottom side of the finger and push down to trigger.
  (ii) Gently massage along the side of the finger to obtain a good blood drop without pressing or squeezing too hard.
  (iii) DO NOT wipe away the first drop of blood.
  (iv) Apply the first drop of blood to the top or side of the target area of the test strip within 15 seconds of puncture. Hold the blood drop to the test strip until you hear a beep (provided the beeper is set to ON).
- **Using the Capillary Tube** – Touch the CoaguChek Capillary tube to the blood drop. Keep tube level and allow it to fill halfway by capillary action. Put finger over hole in the capillary bulb. Hold capillary tube directly over sample target area and expel sample within 15 seconds. Avoid air bubbles
- **Venous Sample** – Expel the first four drops of blood from the syringe. Then, immediately place one drop of blood (at least 8 μL) directly onto the target area of the test strip, being sure not to introduce air bubbles into the sample.

xx. Target Area: Semicircular, transparent sample application area of the test strip. You will hear a beep tone when you have applied enough blood (provided the beeper is turned on). The blood drop symbol disappears and the test starts.
xxi. Note: DO NOT add more sample. DO NOT touch the test strip or move the meter until the result is displayed.
xxii. The meter automatically performs a two-level, on-board quality control test on the test strip before it displays the test result. "QC" appears on the display.
xxiii. A check mark appears after "QC" following successful outcome of the quality control test.
xxiv. The INR result appears in about 1 minute.
xxv. Press the Set button on the left side of the analyzer to display the PT (seconds) result.
xxvi. Record the PT and INR results on the patient result log and in the electronic health record.
xxvii. Remove the test strip when a strip and arrow symbol appear on the screen and discard in biohazard container.
xxviii. Using 2X2 gauze, apply gentle pressure to the patient's puncture site until bleeding stops. If necessary, apply adhesive bandage over the puncture site.
xxix. Dispose of all biohazardous material in the appropriate biohazard or sharps container.
xxx. Turn off monitor
xxxi. *Note: Use a new finger stick from the opposite hand and a new test strip if retesting is needed. DO NOT try to add more blood to the initial test strip.*

j) Interpretation of Results

The CoaguChek XS meter displays test results in units equivalent to laboratory plasma

measurements. If the meter displays a message other than a result, refer to the Error Messages section of the CoaguChek XS System User Manual.

k) Reporting of Results

i. Prothrombin Times are reported in seconds.
ii. The INR is a mathematical formula that compensates for variations in thromboplastin reagents, automatically standardizing PT results. The CoaguChek XS® reports the INR automatically.
iii. **Process for reporting results in electronic health record**
   - Results are entered against order in the electronic health record.
   - ALWAYS verify patient identity (name and DOB) when entering patient results into the electronic health record
   - Enter "Prothrombin Time (PT)" and the INR values
   - Any INR reported by the Coaguchek XS® that is <0.8 or > 4.5 should be verified by a venous sample tested in a Clinical Laboratory.
iv. **Critical Values** represent an emergency condition and should be reported immediately to the patient's attending physician, nurse, or mid-level provider. Documentation of notification should be noted in the patient record. Documentation should include: Notifying individual's name, the result, date, time of result, time of notification, and the name of the person that is notified of the critical value.
v. **INR critical value: >/= 5.0**
vi. **Clerical Errors**
   - If any errors are discovered in identifying a patient sample or in reporting the results, the patient's electronic health record will be corrected and the provider notified. Documentation in the patient's electronic health record should be clear as to the changes that were made.

l) Reference Range (Normal Range)

Reference range:
PT (seconds): 8.9-12.1
INR: Therapeutic Range established by provider

m) Reportable Range (Technical Limits)

Coaguchek XS reportable range:
INR 0.8-8.0
PT (seconds) 9.6-96

n) Limitations/Interferences/Method Notes:

Results may be affected by:

i. ***Wrong code chip in meter***
ii. Incorrect date and time on meter.
   - The expiration date of the strips is programmed into the code chip and it is compared to the date on the meter.
   - Therefore, it is important that the date and time be programmed correctly on the meter.
iii. Expired strips
iv. Strip not used within ten minutes of removal from container
v. Proper monitor maintenance and cleaning procedures were not followed
vi. Incorrect sample volume: The drop of blood must be a minimum of 8 µL
   - **Sample Rejection Criteria--Reject the following samples:**
     (i) Plasma or serum

(ii) Sample size less than 8 µL
(iii) Venous sample collected in a syringe containing anticoagulant
(iv) Sample collected and there is a delay in testing
(v) Sample collected in a glass tube or glass syringe (plastic is acceptable)

Method limitations (refer to the test strip package insert for more information)

vii. The results obtained cannot be used for the determination or the assessment of a therapy with factor II and factor X antagonists.
viii. Do not use the CoaguChek XS System for testing patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivalurudin, Argatroban, and Dibigatran etexilate.
ix. When a patient is on IV infusion therapy, do not collect sample from arm receiving the infusion line.
x. The presence of antiphospholipid antibodies may prolong clotting times and results may not be accurate.
xi. Test results were NOT significantly affected by the following:
- Hematocrit ranges between 25-55%
- Lipemic samples with up to 500 mg/dL of triglycerides
- Bilirubin up to 30 mg/dL
- Hemolysis up to 1000 mg/dL
- Heparin concentrations up to 0.8 U/mL
- Low Molecular Weight Heparins (LMWH) up to 2 IU anti-factor Xa activity/mL
- Clopidogrel up to 20mg/dL
- Fondaparinux up to 5mg/L

5) Maintenance:

a) Disposable gloves should be worn when cleaning and performing preventive maintenance. Follow Disinfection of Non-Critical Medical Devices & Equipment.

b) Follow the procedures below to clean and disinfect the meter. Failure to follow these procedures may cause malfunction of the meter.

c) Do not use sprays of any sort.

d) Ensure that swab or cloth is only damp, not wet.

e) Clean the exterior of the meter after each patient use and when contaminated with blood.

i. Use only 10% Sodium hypochlorite solution (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours) for cleaning/disinfecting the CoaguChek XS analyzer housing for a contact time of >1 minute.
- NOTE: Do not use any other disinfectants/cleaning solutions on the meter housing.

ii. Ensure that the blue test strip guide cover remains tightly closed while cleaning the housing.
iii. With the meter powered off, wipe the meter's exterior clean.
iv. Do not let liquid accumulate near any opening. Make sure that no liquid enters the meter.
v. After 1 minute contact time, with a lint-free tissue, wipe away residual moisture and fluids.
vi. Allow wiped areas to dry for at least 10 minutes before performing a test.

f) Cleaning/disinfecting the meter test strip guide

i. Clean test strip guide monthly and when visibly soiled.
ii. Use only 10% bleach solution to clean the CoaguChek XS test strip guide.
- NOTE: Do not use any other cleaning/disinfecting solutions on the test strip guide. Use of other cleaning/disinfecting solutions could result in damage to the meter.

iii. 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 water or wipe it clean.

iv. Hold the meter upright with the test strip guide facing down
v. Clean the easily accessible areas with a cotton swab.
vi. Ensure the swab is only damp, not wet.
vii. Apply cleaning agent for a contact time of >1 minute (refer to the corresponding product labeling).
viii. Wipe away residual moisture and fluids.
ix. Caution: Do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide.
x. Let the inside of the test strip guide dry for at least 10 minutes.
xi. Close the test strip guide cover and make sure it snaps into place.
xii. Document on the Coaguchek XS Maintenance and Problem/Corrective Action Log

6) Calibration:

a) The code chip supplied with each box of test strips automatically calibrates the meter for that particular lot of strips. The CoaguChek XS System calibration is traceable to the WHO International Reference Preparations. 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. In addition, every time the meter is turned on, it goes through a series of self-diagnostic checks. The CoaguChek XS System cannot be adjusted externally to fit a certain linearity curve.

b) Use the test strip code chip that was supplied with each new test strip container before performing the first test:

i. Turn meter off.
ii. Remove the old code chip if there is one inserted in the meter.
iii. Insert the code chip that was supplied with each new test strip container into the code chip slot with the printed side facing up until it snaps into place.
iv. Compare the code number on the display with the number printed on the test strip container. If the two code numbers do not match, insert the correct code chip in the slot in the meter.
v. An error message is displayed if the code chip is missing or incorrectly inserted. Refer to the CoaguChek XS User Manual Errors section for more information about error messages.
vi. Leave the correct code chip in the meter to protect the electrical contacts in the meter from becoming dirty.
vii. Document the strip lot number, calibration code, date in use, and name of staff member entering code in analyzer on the Coaguchek XS New Test Strip In-Use Log.

7) Operational Notes/Troubleshooting:

a) If the patient's PT/INR value seems unusually low or high and the testing procedure was performed correctly, verify results via an alternate methodology.

b) If the monitor displays a message other than the results, refer to the Error Messages section of the CoaguChek XS® System User's Manual.

i. Document all error messages on the Coaguchek XS Maintenance and Problem/Corrective Action Log.

c) **<u>ERROR 6</u>**

i. Sporadically occurring "ERROR 6" is generally due to an activation of the system fail safe mechanisms that are designed to prevent the release of wrong measurement results.
ii. However, in rare cases, "ERROR 6" may occur in certain clinical conditions which exhibit extremely high coagulation times (> 10 INR), e.g. treatment with warfarin

(vitamin K antagonists) in combination with antibiotics and/or chemotherapeutics.

iii. If "ERROR 6" is displayed repeatedly, the result must be checked immediately using another method.

d) ERROR 7

i. In rare cases, patients with long clotting times (INR>8) may receive an "ERROR 7" message on the Coaguchek XS analyzer display.

ii. If this error appears, the result must be checked using another method.

8) Staff Education and Competence:

a) Staff members who have been trained and demonstrate competency may perform Coaguchek XS testing.

b) All testing staff members must read the procedure manual and demonstrate successful Coaguchek XS testing under the direction and supervision of an authorized staff member.

c) Once successful demonstration of testing has been performed, it will be documented on the employee's site-specific training checklist.

d) An authorized staff member will assess competency annually.

e) May be completed by Ambulatory Care Coordinator (clinic manager), Clinical Nursing staff member, the Department Supervisory Staff, and/or Laboratory Compliance, QA & Safety staff.

i. Annual competency assessments (written and observed), will be kept in the clinic/test site.

f) Competency will be assessed using at least two of the following methods:

i. Testing staff member performs a test on a blind sample.

ii. Supervisor observes testing staff member's performance of routine work.

iii. Testing staff member's quality control performance is monitored.

iv. Testing staff member completes written exam specific to the method.

g) If a testing staff member fails to achieve these passing requirements, then re-education and re-assessment must be completed and documented, prior to performing additional patient testing.

9) Product Information:

1-800-428-4674 may be called for technical assistance

10) Review/Revision/Implementation:

a) Review Cycle: Each 2 years

b) All new policies/procedures/guidelines and those that have major revisions must be reviewed/signed by the CLIA Laboratory Medical Director.

c) Review/sign-off can be completed by the designated section Medical Director or section manager in the following circumstances:

i. Biennial review

ii. Minor document revisions

d) Office of Record: Laboratory Compliance, QA, Safety and Point-of-Care Testing

11) Related Policies:

a) Blood and Body Fluid Exposure Control Plan

b) Disinfection of Non-Critical Medical Devices & Equipment

12) References:

a) The Joint Commission Standards Manual E-dition, 2016 Resources

b) Roche Diagnostics Corporation. *CoaguChek XS® System User Manual,* Roche Diagnostics, 9115 Hague Road, Indianapolis, IN 46256. Copyright 2011-2016
c) Roche Diagnostics Corporation, *CoaguChek XS® PT Test package insert*, Roche Diagnostics, 9115 Hague Road, Indianapolis, IN 46256. 2016-01 V5.0
d) Roche Diagnostics Corporation. CoaguChek XS® *Policies and Procedures Manual,* Roche Diagnostics, 9115 Hague Road, Indianapolis, IN 46256. Copyright 2008-2012

13) Attachments: All related to Coaguchek XS

a) Attachment A: Training Checklist
b) Attachment B: Problem/Corrective Action Log
c) Attachment C: Competency Assessment Form
d) Attachment D: Written Exam
e) Attachment E: Reagent Receipt Log
f) Attachment F: Patient Log
g) Attachment G: Maintenance Log
h) Attachment H: Package Insert

14) Revision Dates:
Effective date 7/2013
Revised: 12/2015
1/2017
9/2018

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Attachment A – Training Checklist

Employee: _____
Test: _____ Date: _____

Skill	N/A	Preceptor	Initial	Date
System Overview				
Operators Manual / Package insert				
Daily / Monthly Maintenance if needed				
Self-test function				
Self-test frequency				
Sample Material and Storage				
Sample volume requirements				
Sample type and storage				
Proper finger stick procedure / Sample collection				
Sample processing / handling				
Quality Control				
Frequency of testing				
Storage and handling of control material				
Sample requirement / mixing				
Logging results				
Test Procedure				
Storage and handling of reagent/cartridge				
Sample requirement/mixing				
Running a test				
Removing/discarding used materials				
Reporting / Documenting Results				
Critical value documentation				
Expected Values				
Limitations				
Possible interferences				
Troubleshooting				
Technical Service contact information				
Operators Manual				
Other				

Preceptor Sign /Date	Employee Sign /Date

Attachment B – Problem/Corrective Action Form

Test: _____

Date	Problem/Error	Corrective Action

Attachment C – Competency Assessment Form

TEST NAME: _____
Employee Name: _____ USER SITE: _____
WFBH Employee ID: _____ Date: _____

Each user of point-of-care testing equipment/supplies must have initial education and competency assessment documentation. Competency must also be completed on an annual basis. This form should be completed by a Clinical Laboratory authorized preceptor. Testing personnel should have their competency assessment documented by the preceptor on this form. After ALL items are completed on this form, please retain a copy in the user site.

Two (2) of the following procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing for each test that the individual is approved by the laboratory director to perform: COMPETENCY ELEMENTS INCLUDE TW0(2) OF THE FOLLOWING COMPONENTS:

1. Assessment of problem solving skills.
   - Written exam will include questions that address these skills. Passing score is at least 80% correct.

2. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
   - Compliance will be documented by performance of proficiency testing samples or by testing of liquid QC as a patient sample.
   - Results of liquid QC will be unknown to the testing personnel at the time of testing.

3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
   - These records are reviewed by a Clinical Laboratory authorized preceptor as part of on-going Quality Assurance (QA) activities.
   -

Written Exam Score: ELEMENT 1 _____

Date Test Procedures/Policies Read: Refer to written exam

	Date Liquid QC Tested	Result	Acceptable Range	Pass/Fail
Performance of Liquid Quality Control - ELEMENT 2 or 3 (User must test at least one level of QC for each competency cycle) Indicate QC Lot Number	_____	_____	_____	_____

Employee Signature: _____

Employee Initials: _____

Final Clinical Laboratory Review: _____ Date: _____

Attachment D – Written Exam

Employee Name: _____ Date: _____
Facility: _____ Score: _____

(*Staff must score >=80% on exam)

I have read the Coaguchek XS procedure for the current year.
Employee Signature: _____

1. When coding the CoaguChek XS meter, you must use the code chip with the same number as that printed on the label of the test strip vial you are using.
   TRUE or FALSE

2. After removing the test strip from the container, it is important to close the cap tightly.
   TRUE or FALSE

3. When performing a blood test, it is important to hold the finger to the test strip until the meter beeps.
   TRUE or FALSE

4. A venous sample must be collected in a plastic syringe free of anticoagulants.
   TRUE or FALSE

5. Sample must be applied to the test strip within ten minutes of removing the strip from the container.
   TRUE or FALSE

6. INR is a reporting format that stands for International Normalized Result.
   TRUE or FALSE

7. Every time a blood test is performed, the meter also performs a built-in quality control test.
   TRUE or FALSE

8. If the built-in quality control test fails, the meter will still give a test result.
   TRUE or FALSE

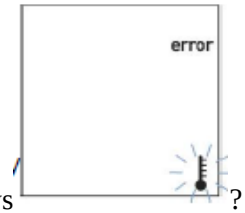
9. The most recent patient result appears first when reviewing memory.
   TRUE or FALSE

10. The CoaguChek XS meter stores up to 300 results with time and date.
    TRUE or FALSE

11. What is used to clean the exterior of the CoaguChek XS meter? _____

12. What could cause 

to appear on the display? _____

13. What does it mean when the display shows 

? _____

14. What could cause 

to appear on the display? _____

15. How long can strips be stored at room temperature? _____

Preceptor Signature: _____ Date: _____

Attachment E – Reagent Receipt Log

1	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

2	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

3	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

4	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

5	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

6	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

7	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

8	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

9	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

10	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

11	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

12	**Lot #:**	**Exp. Date:**	**Date in Service:**
	Employee Name:		**Cal Code:**

Monthly manager review: _____ Date: _____

Attachment F - Patient Log

Site Name: _____ DATE: _____

Monthly Manager Review: _____ Date: _____

TIME _____ TECH _____ **Test result: _____** **QC OK ____ Critical Report:**	**TIME _____ TECH_____** **Test result: _____** **QC OK_____ Critical Report:**	**TIME _____ TECH_____** **Test result: _____** **QC OK ___ Critical Report:**
TIME _____ TECH_____ **Test result: _____** **QC OK ____ Critical Report:**	**TIME _____ TECH_____** **Test result: _____** **QC OK _____ Critical Report:**	**TIME _____ TECH_____** **Test result: _____** **QC OK ___ Critical Report:**
TIME _____ TECH_____ **Test result: _____** **QC OK ____ Critical Report:**	**TIME _____ TECH_____** **Test result: _____** **QC OK ____ Critical Report:**	**TIME _____ TECH_____** **Test result: _____** **QC OK ___ Critical Report:**
TIME _____ TECH_____ **Test result: _____** **QC OK ____ Critical Report:**	**TIME _____ TECH_____** **Test result: _____** **QC OK ____ Critical Report:**	**TIME _____ TECH_____** **Test result: _____** **QC OK___ Critical Report:**

Attachment G: Maintenance Log

Site: _____ Instrument: _____

Maintenance Log

Date	Initials	Meter Test Strip Guide Cleaned	Comments

Manager Review: _____ Date: _____