CoaguChek® XS System

Policies & Procedures Manual

This Policies and Procedures Manual was prepared by Roche Diagnostics with the contribution of Sheila Dunn, D.A., MT(ASCP). It contains sample policies and procedures to help you provide the highest quality anticoagulation testing program. We hope this manual becomes a valuable tool for you and your staff. Before using the CoaguChek XS System*, customize this Policies & Procedures Manual to reflect the actual circumstances of your testing program by entering your specific protocol in the spaces indicated. Review and modify this program as desired to meet your own medical practice needs and to accommodate any future changes to CLIA or other applicable regulations. Because procedures are subject to occasional change, always refer to the reagent package insert for the most current information and modify this manual accordingly.*

For assistance with any aspect of your anticoagulation management program, contact Roche Diagnostics Technical Service Center at 1-800-428-4674, available 24 hours a day, 365 days a year.

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Policies & Procedures Manual for the CoaguChek XS System

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Getting Started with the CoaguChek XS System

	Where to Find Help
Before You Begin Testing Patients	
Step 1: Define the purpose, goals and structure of your systematic anticoagulation management (SAM) program.	Section 1
Step 2: If your facility does not currently hold a CLIA certificate, apply to the CLIA program for a certificate of waiver. If your facility already has a CLIA certificate, no action is necessary.	Appendix A
Step 3: If your facility is located in a state with more stringent regulations than the federal CLIA program such as Maryland or Pennsylvania, OR if your facility is accredited by either the College of American Pathologists (CAP) or the Joint Commission, determine any other necessary enrollment forms or quality requirements for CLIA-waived testing on the CoaguChek XS.	Appendix A
Step 3: (Optional) If required by state regulations or if the SAM program director requests it, perform a study to determine the instrument bias between the new CoaguChek XS System and your previous method for PT/INR testing. Place results on the **CoaguChek XS Method Comparison Log**.	Section 2
Step 4: Read this Manual and fill-in-the-blanks to indicate your exact procedures for testing. Strike through those procedures that are not performed in your facility (initial and date this change) or add verbiage to indicate additional procedures that pertain to your SAM program.	This Policies & Procedure Manual
▪ The SAM program director signs the **Policies & Procedures Approval Form** to accept these customized procedures.	Page ii
Step 5: Ensure that all operators have been trained to perform patient tests. File the completed **CoaguChek XS Operator Certification Checklist**.	Section 2
▪ Be sure all operators are aware of the key points specified in this Policies & Procedures Manual and have signed the **Policies & Procedures Approval Form**.	Section 1

Once Testing Has Begun

Each Day of Testing:

- Ensure that on-board QC results are acceptable during testing.
- Follow the policies and procedures in this Manual for collecting and handling samples, testing patient samples, and reporting test results.
- Log patient tests on the **CoaguChek XS Patient Test Log**.

Once a Month (optional):

- Complete the **Monthly QA Checklist**. This checklist ensures that the testing aspect of your entire anticoagulation management program is optimal.

Every 3- 6 Months (optional):

- Perform an external evaluation of accuracy, such as split sample testing or have two operators test the same patient and compare results.

As Needed:

- Train new operators using the **CoaguChek XS Operator Certification Checklist**.
- Evaluate whether the anticoagulation management program is achieving stated goals

CoaguChek XS System Policies & Procedures Approval Form

This **Policies & Procedures Manual** for our Systematic Anticoagulation Management Program was read by:

Date	Name/Title

Prepared/Customized By (Name/Title): _____

Approved By (SAM program director): _____

Date Adopted: _____ **Date Discontinued: _____**

Revisions:

Revision Date	Revised By	Approved By	Read By

SECTION 1: SYSTEMATIC ANTICOAGULATION MANAGEMENT (SAM) PROGRAM OVERVIEW

Purpose of the SAM Program

Anticoagulation is a high-risk treatment that can lead to adverse events due to the complexity of dosing anticoagulation medications, monitoring their effects, and ensuring patient compliance with outpatient therapy. The use of standardized practices that include rapid test results and patient involvement can reduce the risk of adverse events associated with the use of warfarin or Coumadin® (Warfarin Sodium Tablets, USP, Bristol-Meyers Squibb Company)[1]. Other purposes for the SAM program are:

_____

_____

_____

SAM Performance Goals (financial, clinical and operational)

Define the context in which CoaguChek XS System test results are used in patient care, treatment and services:

- To better manage patients receiving warfarin therapy by monitoring their INR values to be sure that patients are taking the correct dose and are complying with therapy.
- To have a rapid INR result in order to use it as one of the criteria to determine optimum patient therapy.
- To reduce the likelihood of adverse events associated with the use of anticoagulation therapy.
- To establish baseline INRs for patients being started on warfarin.
- To discuss patient test results during the visit, which enhances compliance with therapy and dietary restrictions.
- Other performance goals specific to this facility:

  _____

  _____

  _____

  _____

  _____

[1]Campell P, Radensky P, Denham C. Economic analysis of systematic anticoagulation management vs. routine medical care for patients on oral warfarin therapy. Disease Management and Clinical Outcomes, 2000;2.

CoaguChek XS Meters Used in the SAM Program

Location/Date Put in Use	CoaguChek XS Serial Number

SAM Program Director

_____ is responsible for the overall performance and administration of the anticoagulation monitoring program, including oversight and coordination of the development, testing, and implementation of the testing program. The program director ensures that only certified operators perform testing on the CoaguChek XS meters.

Individuals Involved in the SAM Program

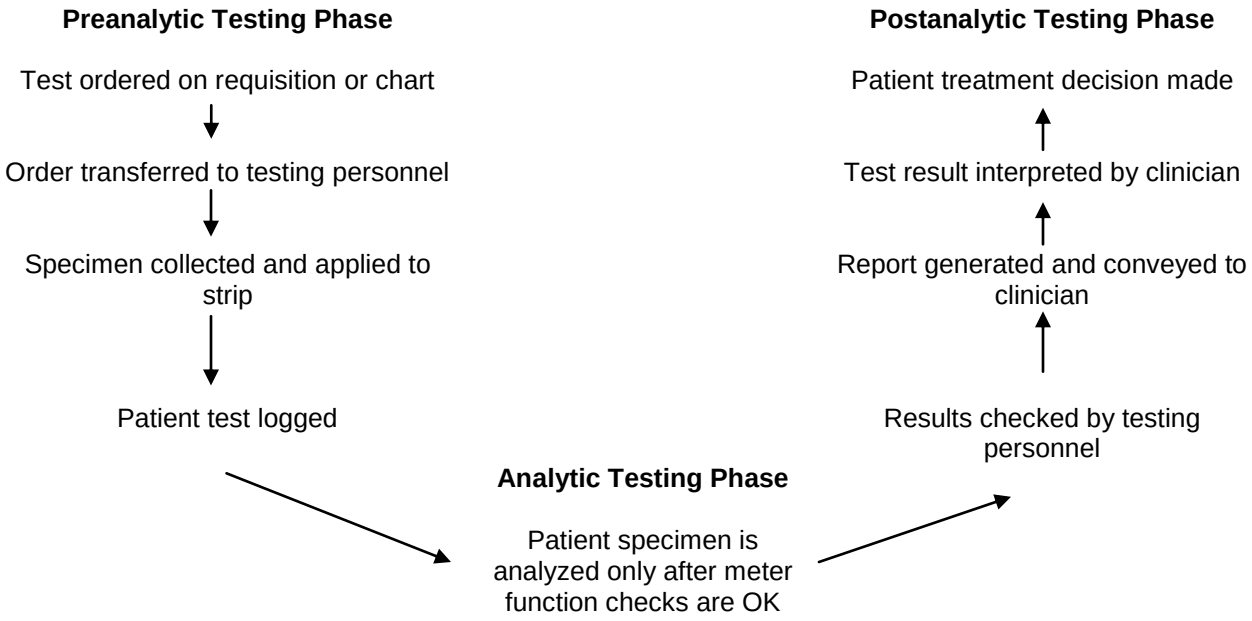
Indicate those responsible for management, testing, providing education to patients and their families, safety and regulatory compliance:

Name	Title	Role(s) on SAM Team

Policies and Procedures for the SAM Program

Our policies and procedures for the SAM program are located in this manual and are arranged according to CLIA regulation requirements for performing laboratory tests. Note that Sections 5, 6 and 7 are arranged according to the sequence of testing:

- Preanalytic – tasks performed before the test is performed
- Analytic – the test process
- Postanalytic – tasks performed after the test is completed



SECTION 2: PERSONNEL TRAINING POLICIES AND PROCEDURES

Personnel Policies

Persons who perform tests on the CoaguChek XS system have the proper training and experience to provide high quality PT/INR test results and thus achieve the anticoagulation management program goals.

Those who perform tests on the CoaguChek XS system are termed “testing analysts” or “operators.” As required by the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA), all CoaguChek XS operators receive extensive training prior to using the CoaguChek XS system for patient testing. In this facility, only those personnel “certified” to operate the CoaguChek XS system may perform tests.

Anticoagulation Program Director Responsibilities

The anticoagulation program director is available for on-site, telephone, and electronic consultation as needed. The anticoagulation management program director approves this Policies and Procedures Manual (page ii) and ensures that all testing personnel are competent to perform test procedures and to record and report test results accurately.

CoaguChek XS operators are to report any situation that could affect test performance or compromise employee or patient safety to the anticoagulation management program director.

The anticoagulation management program director ensures that:

- Test methodologies provide quality results and are adequate to determine accuracy, precision, and other performance characteristics.
- Test operators are qualified to perform their responsibilities and perform tests according to the manufacturer’s instructions to obtain accurate and reliable results.
- Test operators have documented evidence of training (**CoaguChek XS Operator Certification Checklist**) before testing patient samples.
- This Policies & Procedures Manual is available to CoaguChek XS operators.
- CoaguChek XS operators have signed the **Policies & Procedures Approval Form** on page ii.
- Any time there is a change in the test procedure or any other part of the anticoagulation management progr
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- am, personnel are notified and signify their understanding by signing the Policies & Procedures Approval Form on page ii.
- Test results are reported only when all performance specifications for a test are within acceptable limits.
- Remedial actions are taken and documented when required. When instrument problems are detected, all patient results obtained since the last acceptable quality control run are evaluated to determine if they have been adversely affected.
- Result reports include pertinent information required for interpretation.

Operator Qualifications
In this facility, all operators must be certified to perform CoaguChek XS tests. Operator certification is documented on the **CoaguChek XS Operator Certification Checklist** (FORMS Section).

CoaguChek XS Operator Responsibilities
Testing analysts are responsible for:

- Performs test methods as specified, following this facility's procedures for specimen handling and processing, test performance, and reporting and maintaining records of patient results.
- Notes and documents quality control results and performs instrument cleaning when needed.
- Follows established corrective actions whenever QC or patient test results are not within the established acceptable levels of performance.
- Can identify problems or factors that may adversely affect test performance or reporting of results and either corrects the problem or notifies the anticoagulation management program manager or director.
- Documents all corrective actions taken when problems occur.
- Reports concerns of safety and quality of patient testing to the Anticoagulation management program director.
- Reports device-related adverse events to FDA's MedWatch.

In this facility, the following personnel are authorized to perform CoaguChek XS testing:

Testing analyst (Operator)	**Supervision Required?** *(circle one)*	**Supervisor Review to Report Results?** *(circle one)*
_____	Yes No	Yes No
_____	Yes No	Yes No
_____	Yes No	Yes No

_____	Yes	No	Yes	No
_____	Yes	No	Yes	No
_____	Yes	No	Yes	No
_____	Yes	No	Yes	No
_____	Yes	No	Yes	No
_____	Yes	No	Yes	No
_____	Yes	No	Yes	No

Procedures for CoaguChek XS Operator Training and Evaluation

Operator Training/Certification

For our anticoagulation management program, CoaguChek XS operators have documented training for the tests that they are authorized to perform. Roche representatives may provide this training during installation of the CoaguChek XS System. After the training session, a **CoaguChek XS Operator Certification Checklist** (FORMS Section) is completed for each operator. Keep a copy of the **CoaguChek XS Operator Certification Checklist** for at least 2 years.

When additional operators must be trained after the initial CoaguChek XS System installation, the anticoagulation management program director, a current operator (under the anticoagulation management program director's supervision) or a Roche representative can provide this training.

Use the CoaguChek XS System Training DVD as the basis of the training session. This program runs approximately 15 minutes and provides step-by-step instructions for setting up the meter, preparing for and performing a blood test, and cleaning the meter.

Familiarize operators with the contents and structure of:

- The CoaguChek XS System User Manual.
- The CoaguChek XS System Getting Started Guide.
- Package inserts for test strips and instructions for lancets.

If you need additional copies of the training materials, you may download them at www.coaguchek-usa.com

Document personnel training on the **CoaguChek XS Operator Certification Checklist** (behind FORMS Section). Keep training records for at least 2 years or for the life of the instrument, whichever is longest.

After initial training, CoaguChek XS operators must carefully follow the instructions for test performance and troubleshooting (found in this Policies & Procedures Manual and also in the CoaguChek XS package insert and CoaguChek XS User Manual).

For institutional settings where several operators are trained on several shifts, a suggested in-service curriculum follows.

Suggested In-service Curriculum

The following framework is suggested to help you plan training time, determine class size and provide optimal conditions for the practice portion of the training. Plan to have sufficient space, time, and one-on-one coaching during the training session. Repeated exposure to a consistent message and hands-on practice are keys to successful training.

Select a space for training that is free of distractions and which has adequate space for operators to take notes, to practice with the meters, and to see the video screen. Plan on at least one and a half hours for the session, in order to allow plenty of time for operators to practice the testing procedure and to ask questions. Keep in-service classes small so that each operator can receive individual attention during the practice session if needed.

Before the in-service begins, program the CoaguChek XS meter with the time, date, and result format (INR, seconds, or %Quick).

Instructors
The instructor may be a Roche representative, a nursing supervisor or quality assurance nurse, or another designated individual who has been trained on the CoaguChek XS System. It may be helpful to have one or more assistants, especially during the practice session, to allow the instructor to maintain class momentum.

Training Materials
Have one of each available in the training space:

- **CoaguChek XS System Training DVD**. This program runs approximately 15 minutes, provides step-by-step instructions for setting up the meter, preparing for and performing a blood test, and cleaning the meter. This DVD is intended to be the basis of the training session.
- **CoaguChek XS System User Manual**. This is a reference guide for CoaguChek XS operators. During training, familiarize the operators with its content and structure.
- **CoaguChek XS System Getting Started Guide**. This is an easy resource for operators. During the in-service, familiarize the operators with its contents and structure.
- **Package Inserts for test strips and instructions for lancets**. These inserts contain information about proper storage and use. During the in-service, familiarize operators with their contents. Remind operators to refer to the latest package insert inside each container of test strips for the latest information about test performance and interpretation.
- **CoaguChek XS Operator Certification Checklist**, located in the FORMS Section of this Policies & Procedures Manual.
- **CoaguChek XS System Policies & Procedures Manual**

If you need additional copies of the training materials, you may download them at www.coaguchek-usa.com

Supplies
Have at least one complete set of CoaguChek XS System supplies for demonstration purposes:

- CoaguChek XS meter (with batteries inserted and set-up options selected)
- CoaguChek XS PT Test strips
- CoaguChek XS Code chip
- CoaguChek Capillary tubes and bulbs for capillary samples (only if used in your facility)
- Anticoagulant-free plastic syringes and needles for venous samples (only if used in your facility)
- CoaguChek Lancet or other single use lancet device
- Approved cleaning solutions as listed in the user manual
- Biohazard waste and sharps containers
- Alcohol wipes
- Cotton balls or tissue
- Disposable gloves

Organize teaching supplies and test electronic equipment before the in-service. You need:

- CoaguChek XS System Training DVD
- DVD player

Suggested Class Outline
This outline will help operators know what to expect and help you pace the class. You may wish to distribute it as part of your introduction.

Topic	Time to present (minutes)
1. Introduction and overview	5
2. CoaguChek XS System Training DVD	15
3. Test kit, meter and components	10
4. Operating guidelines	5
5. Performing the test ▪ Setting up the system ▪ Collecting and applying a sample ▪ Reading, responding to, and recording patient test results ▪ Practicing and confirming	30
6. Cleaning the system	5
7. Troubleshooting	5
8. CoaguChek XS Operator Certification Checklist, Operator Certification Test (see FORMS Section)	10
9. Q&A, conclusion	5
Approximate total time:	1 hour, 30 minutes

1. Introduction and Overview (about 5 minutes)
- Begin the class by introducing yourself and your assistant. Ask operators to introduce themselves.
- Review the class outline and tell participants what will be expected of them, and how they will be evaluated.
- Review the criteria for completing the course:
  - CoaguChek XS Operator Certification Checklist
  - Operator Certification Test
- Ask for questions.

2. CoaguChek XS System Training DVD (about 15 minutes)
- The CoaguChek XS System Training DVD provides an overview of the system, setting up the meter, testing procedure, and maintenance. These topics will be covered in depth during the remainder of the training session.
- Show the CoaguChek XS System Training DVD.
- When the DVD is over, ask for questions. Address any concerns that will not be explicitly covered in class. If operators ask questions about material that will be covered, respond briefly, and assure them that they will get a detailed answer later.

3. Test Kit, Meter and Components (about 10 minutes)
- Review these components with participants.

Component	Description
CoaguChek XS meter	A portable coagulation meter for PT/INR testing.
4 AAA batteries	The meter's power source.
CoaguChek Lancets with instructions	Devices used to obtain fingerstick blood sample for testing.
CoaguChek XS System User Manual	A detailed resource manual for CoaguChek XS System operators.
CoaguChek XS System Getting Started Guide	A resource of key information for CoaguChek XS System operators.
CoaguChek XS System Policies & Procedures Manual	A detailed Policies and Procedures Manual for evaluation and use of the CoaguChek XS System.

CoaguChek XS Meter Elements

Show participants each of the following elements on a CoaguChek XS meter:

Side	Description
Code chip slot	Insert code chip here
Set button	Used to change settings on meter
Front	**Description**
Display	Shows results, information, symbols and results recalled from memory.
ON/OFF button	Press and hold until the meter turns on or off.
Test strip guide	Insert test strip here.
Test strip guide cover	Remove to clean the test strip guide.
Back	**Description**
Battery cover and tab	Covers the battery compartment. Press tab to slide cover off.
Roche Diagnostics Technical Service Center	Call 1-800-428-4674 for technical service 24 hours a day, 7 days a week.

CoaguChek XS PT Test Strip

Show each of the following components:

Component	Description
CoaguChek XS PT Test strip	Provides a platform for the blood and reagents to react.
Target area of the Test strip	Apply blood sample here.
CoaguChek XS PT Test strip code chip	Calibrates the system for each new box of test strips.
CoaguChek XS PT Test Strip Insert	Provides important reference material on how to use and store the test strips.

4. Operating Guidelines (about 5 minutes)

Stress the importance of this information to participants, ensuring that they understand that test results may not be accurate if they do not strictly adhere to these conditions.

Carry the meter in a well-protected case.

- Explain the proper conditions for operating the meter:
  - At temperatures between 59°F and 90° F (15°C and 32°C) in areas without condensation.
  - In artificial light or indirect sunlight. (Avoid bright sunlight.)
  - On a level, vibration-free surface or hold it so it's roughly horizontal.
  - At altitudes no higher than 14,000 feet (4,300 meters).
  - Away from strong magnetic fields, such as microwave ovens, which may interfere with proper operation of the meter.
- Explain how to store and handle test strips:
  - In their container with the cap tightly closed.
  - At room temperature or in the refrigerator (2°C to 30°C or 36°F to 86°F). Do not freeze test strips.
  - When stored properly, the test strips can be used until the expiration date printed on the test strip container. Dispose of test strips that are past their "Use By" date.

5. Performing the Test (about 30 minutes)

- Turn the meter on.
  - Explain that CoaguChek XS meter can operate only with four alkaline-manganese AAA batteries.
  - Show participants the battery symbol on the meter display. The battery symbol is divided into four segments. With new, fresh batteries in the meter, the battery symbol shows all four segments. When only one segment appears, replace the batteries. When only one segment appears you can still access results stored in the meter's memory. If you insert new batteries within 1 minute of removing the old batteries, the date and time settings will remain in memory. But if you do need to reset the date and time, refer to the Meter Setup section in the CoaguChek XS System User Manual.
  - To save power, the CoaguChek XS meter automatically turns itself off after three minutes, unless a button is pressed or test strip is inserted.

- Allow an operator to practice changing the batteries:
  - With the meter OFF, press the battery compartment cover release tab and slide cover off.
  - Insert four (4), AAA batteries as indicated by the diagram inside the battery compartment.
  - Slide the battery compartment cover back onto the meter and close it.

Using the Test Strip Code Chip

- Explain that each box of test strips comes with its own code chip. The code chip provides the meter with information such as the lot number and expiration date of the test strips.
- Have operators follow these steps to match the code chip to the test strip:
  - Before each test, make sure 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.***
  - Show operators how to install the code chip.
  - Explain that if the code chip is missing or incorrectly inserted, error messages appear in the display. (Refer to Error Messages in the CoaguChek XS System User Manual.)

Set-up Options
Explain the display options for the CoaguChek XS meters used in your facility (INR,Seconds, and %Quick)

Collecting the Sample
- Gather supplies listed previously and show participants how to perform a capillary fingerstick (using either the direct drop method or using the capillary bulb) and how to place the sample on the test strip.
- If your facility will be performing venous draws, address venipuncture technique in this section too.

Testing a Patient Sample
- Place the meter on a flat surface, free of vibrations (or hold it in your hand so the meter is roughly horizontal). Take a test strip out of the container. Wearing disposable gloves and washing hands before and after testing, demonstrate how to perform a patient test.

Reading Results
- Results appear on the meter's display immediately after the test.
- Results are also stored in the meter's memory:
  - The CoaguChek XS meter stores the most recent 300 test results along with the time and date. When reviewing memory, the most recent result is displayed first. If the memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved.
  - Review the following steps to recall patient test results that are stored in memory:
    1. Press the **M** button. The meter turns on, if it is not already on, and goes to the Memory mode.
    2. The most recent test result appears. The letters **mem** indicate you are viewing a result in memory. If there are no results in memory, a **0** appears in the top right corner.
    3. Use the **M** button to scroll through the meter's memory.
    4. Turn the meter OFF.
- When viewing results in memory, results can be changed between INR and Seconds by pressing the "Set" button on the side of the meter. This will allow the user to toggle back and forth between seconds and INR.

Responding to Results
- Discuss expected values and that providers determine the best PT level for a patient depending on the reason for anticoagulant treatment and how each individual responds to treatment (based on prothrombin time).
- Discuss the < 0.8 INR or > 8.0 INR message, which indicates that the test result is outside the measuring range for that lot of test strips.
  - Explain that if the < 0.8 INR or > 8.0 INR message appears and test was performed within the Limitations of Procedure as outlined in the CoaguChek XS PT Test Insert, repeat the test. If the result is still out of range, follow your facility policy for unexpected results (call to provider).
- Review error messages, their causes, and the appropriate action with operators.

Recording Results

- Instruct operators to record the PT result on the appropriate documentation log for your facility.

Practicing and Confirming

- Allow operators ample time to practice the entire testing process: running patient samples, reading and recalling results, responding to results and recording results.

6. Cleaning the System (about 5 minutes)

- Explain that it is important to keep the meter clean. Advise participants to clean the meter whenever it looks dirty, or whenever stipulated by your facility (if your facility has a regular cleaning schedule).
- Show participants how to check the test strip guide regularly for signs of soiling.
- Show participants how to decontaminate the test strip guide (which is potentially infectious) if it has become soiled with blood or any other material according to the instructions in the User Manual.
- Caution participants never to spray any cleaning solution on the CoaguChek XS meter, as this may enter the meter and damage it.
- Advise participants to decontaminate the CoaguChek XS meter before shipping or disposal.

7. Troubleshooting (about 5 minutes)

- Explain that the occasional testing problem can be solved through referencing the User Manual, while more extensive problems may require the help of Roche Diagnostics Technical Service at 1-800-428-4674.
- Explain that for most problems, the meter will display an error message.
- Show participants the Error Messages chapter of the CoaguChek XS System User Manual that details potential causes for each message and appropriate action.

8. CoaguChek XS Operator Certification Checklist, Operator Certification Test (about 10 minutes)

- Distribute the **Operator Certification Test** (FORMS Section) and ask participants to complete it. This will determine whether they have understood key concepts and uncover potential areas of confusion.
- Collect tests and use the answer key to score the tests.
  - Individual instructors determine the criteria for a passing score.
  - Require those who do not perform adequately on the **Operator Certification Test** to attend a second class.
- Complete the **CoaguChek XS Operator Certification Checklist** for each participant. Review any areas of confusion with the class.
- File each operator's **CoaguChek XS Operator Certification Checklist**. State where these are located: _____.

9. Q & A Session, Conclusion (about 5 minutes)

- Question attendees to be certain that everyone is clear on every aspect of testing and is confident that they can obtain acceptable results.

Operator Competency Evaluation (Optional)

Operator competency evaluation is required by some accreditation agencies (Appendix A).

In this facility, the anticoagulation management program director may request operator competency evaluation at any time, and will oversee employee retraining if required.

Personnel competence is always assessed when problems are observed or identified during specimen collection, handling, testing or reporting test results.

Assess operator competency by visual observation to ensure that written procedures are followed. Another way to assess personnel competency is by requiring an operator to perform a test on a patient sample, followed by another (problem-free) operator performing a test on that same patient. Test results should be almost identical.

Use the **CoaguChek XS Operator Evaluation Checklist** (FORMS Section) to document operator competency. If retraining is required, document it on the **CoaguChek XS Operator Certification Checklist** and re-evaluate the operator. Document this on the **CoaguChek XS Operator Evaluation Checklist**.

Document personnel concerns and corrective action pertaining to personnel on the **Monthly QA Checklist** (behind FORMS Section). If problems with personnel competency persist, these personnel procedures may be changed to require more frequent personnel training or ongoing periodic re-evaluation.

SECTION 3: METHOD COMPARISON (OPTIONAL)

Although not required for CLIA-waived tests such as the CoaguChek XS system, some anticoagulation management program directors may request an evaluation to ensure that the CoaguChek XS System performs as well in their setting as the manufacturer claims before instituting the method. Another reason for comparing a new method to the previous method is to assist physicians in interpreting test results from the new system.

Some state regulations require method comparison before using any new method for patient testing. For more information about state requirements, see Appendix A. If you are unsure whether method comparison is a requirement in your state for a CLIA-waived test such as the CoaguChek XS system, contact your state CMS office.

Note that method comparison is an inexact science and no two methods will provide exact results even when testing the same patient sample. Differences in reagents, instruments, and pre-analytical variables will affect prothrombin time results, so consider these factors when comparing different prothrombin time test methods.

For best method comparison results, locate a referral laboratory that can test the patient sample within a few hours of collection and that uses one of the following laboratory reagents: Dade Innovin, Ortho Recomboplastin, and Dade Thromboplastin C+. Other clinical laboratory reagents may not consistently correlate with the CoaguChek XS System.

Each lot of test strips is calibrated to a reference lot that is traceable to the WHO International Reference Preparations. For the purpose of providing universal INR results, the Mean Normal Prothrombin Time (MNPT) for the CoaguChek XS meter has been established at 12 seconds and the ISI for the system has been established at 1.0.

If the anticoagulation management program director of the anticoagulation management program wishes to do this comparison, a sample Method Comparison/Split Sample Analysis procedure follows.

Suggested Procedure for Method Comparison

1. Select at least 20 patients to compare. About ¾ of the samples should be from patients on warfarin therapy, evenly distributed and selected so that INRs throughout the therapeutic range are represented. About ¼ of the total method comparison samples should be from nonsmoking healthy patients who are not on warfarin, aspirin or any other medication that affects clotting. Do not include patients who are on heparin therapy in this study.
2. From each patient, collect a venous blood specimen:
    - Use a butterfly collection set with a 3.2% citrate blue top vacuum tube installed (make sure you have the correct adapter on the end of the butterfly tubing.) Fill to the appropriate fill line. Under filling or overfilling can affect test results, so if the tube is not filled correctly, discard and redraw.
    - After filling the vacuum tube, remove the tube from the adapter, gently mix the contents and set aside. Send to a referral lab that is able to test it within 4 hours.
    - If using venous blood for testing on the CoaguChek XS meter, remove the adapter, attach a 3 cc plastic syringe, and collect about 1 cc of blood into the syringe. Pinch off the tubing or close the luer lock and remove the syringe.

- Expel **the first four drops** of blood from the syringe. Then place one drop of blood (at least 8 µL) from the syringe directly on the strip sample target area.
- Record the result from the CoaguChek XS meter on the **Method Comparison Log** (FORMS Section*).* For the purpose of this study, repeat any CoaguChek XS PT Test result greater than 4.0 INR with a fingerstick sample from the opposite hand. Place the second result in parentheses after the first result in the **Method Comparison Log**.

3. If the referral lab cannot test the venous samples within **four hours,** spin the samples according Clinical and Laboratory Standards Institute (CLSI) guidelines. Pipette off the plasma without disturbing the cell layer into an appropriately labeled tube. The referral lab may also require the original blue top to accompany the plasma.
    - When results are returned from the referral lab, record on the **Method Comparison Log**. Note that a bias factor is calculated on this log, which is the average amount that results will differ when performed on the CoaguChek XS meter and the comparison instrument. The CoaguChek XS results may be consistently lower or consistently higher than the comparison instrument. In evaluating results, as long as the bias factor remains consistent, the split-sample verification of results may be considered successful.

    If statistical data is requested by the anticoagulation management program director, you may fax the **Method Comparison Log** to the attention of Roche Diagnostics Point of Care Technical Support at 1-800-858-8075. The results will be calculated and returned within three business days. Expected statistical results for accuracy are located on the CoaguChek XS PT Test Strips package insert.
4. When the study is complete, provide results to the anticoagulation management program director. The director will determine whether or not a clinically significant difference exists between the two methods and whether or not providers need to be informed of the bias between results from the method they used previously and the new CoaguChek XS System.

Sources of Error in Method Comparison Studies

Some inherent sources of error in method comparison studies include:

Specimen collection:

- Incorrect volume, type, or concentration of anticoagulant in the collection tube. The anticoagulant used should be 106 to 109 mmol/L, 3.13% to 3.2% of the dihydrate form of trisodium citrate, buffered or nonbuffered. Other anticoagulants are unacceptable.
- Overfilling or under filling collection tubes. Improper filling may interfere with the correct ratio of blood to the sodium citrate dehydrate anticoagulant.
- Failure to correct the citrate volume for persons with high (>.55) hematocrit.

Transport, processing, and sample storage:

- Specimen storage at incorrect temperature. Keep specimens at 15°C to 24°C.
- Excessive time (more than 4 hours) between collection and testing.
- Report results from both the CoaguChek XS System and the referral lab method in International Normalized Ratio (INR). The Mean Normal PT (MNPT) for the CoaguChek XS System has been predetermined through the calibration process for all strip lots. The meter automatically gives results in INR based on that calibration. The referral laboratory will need to establish MNPT for their system before method comparison may begin. The MNPT should NOT be taken directly from the package insert for the referral lab system.

SECTION 4: SAFETY IN THE TESTING AREA

Safety Policies

It is our intent to provide a safe testing environment for patients and staff. This facility meets the manufacturer's recommendations for maintaining a testing environment to ensure instrument reliability. This laboratory also meets all federal, state, and local requirements for safe operation.

To minimize problems during specimen handling, test performance and reporting test results, the area where testing is performed contains the proper space, ventilation, utilities, and supplies necessary for conducting PT/INR tests on the CoaguChek XS System. The testing area also contains adequate lighting for visual interpretation of test results.

CoaguChek XS operators are offered the Hepatitis B vaccine (free of charge). Employees who choose not to receive the Hepatitis B vaccination must sign a declination form. Hepatitis B vaccination records are kept: _____.

CoaguChek XS operators follow the safety procedures below to prevent potentially dangerous accidents.

Safety Procedures

Safety Precautions for the Testing Area

- Do not eat, drink, smoke, apply cosmetics or insert contact lenses where specimen collection or testing is performed.
- Do not store food in refrigerators where test reagents or specimens are kept.
- Clean countertops where testing is performed daily and whenever visibly soiled. Clean spills immediately. Effective disinfectants include a 10% bleach solution and EPA-approved hospital-level disinfectants, such as quaternary ammonium compounds. Wear rubber utility gloves when cleaning.
- If the exterior of the CoaguChek XS meter is visibly soiled with blood, clean with approved solutions as listed in the user manual.

Safety Precautions for Working with Potentially Infectious Material

Consider all patient specimens to be potentially infectious. Wear gloves to prevent skin and mucous membrane contamination when collecting specimens and handling blood samples for testing.

Blood specimens are potentially capable of transmitting bloodborne pathogens such as the human immunodeficiency virus, hepatitis C virus or hepatitis B virus in three ways:

1. A splash or spray to non-intact skin
2. A splash or spray to a mucous membrane
3. A puncture wound from an item contaminated with blood.

Wearing gloves and washing hands are the two most important infection control measures to prevent bloodborne pathogen transmission.

Wear gloves whenever you:

- Collect specimens (fingerstick or venipuncture) or touch patients' mucous membranes or open wounds.
- Touch items or surfaces soiled with blood or body fluids.
- Are in the testing area and have cuts, scratches, or breaks in your skin.

Wash hands:

- After removing gloves.
- Before touching your eyes or mouth.
- Immediately, if a specimen or reagent has been spilled on your bare hands.
- Before eating, drinking or smoking.

Hazardous Waste Disposal

OSHA's bloodborne pathogens standard (1910.1030) defines biohazardous waste as:

> *"Liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials."*

Examples of Biohazardous Waste	Examples of Regular Waste
▪ Gauze bandage saturated with blood	▪ One drop of blood on a bandage
▪ Exam gloves coated with blood	▪ Exam gloves not visibly contaminated
▪ Sharps container: phlebotomy supplies (needles/syringes, lancets)	▪ Used CoaguChek PT Test strips

Placed used needles, lancets and other contaminated sharp objects into a sharps container that is spill-proof, tamperproof, and puncture-proof. Do NOT recap, bend, break or remove needles from a syringe before discarding them.

In Case of Accident

Notify the anticoagulation management program director or your immediate supervisor as soon as possible after an accident. If an accident involves exposure to potentially infectious materials (e.g., a splash or spray of blood onto non-intact skin or mucous membrane or a needle stick), follow OSHA's bloodborne pathogens standard requirements.

Procedure for Reporting Device-Related Adverse Events

When information reasonably suggests that a laboratory product has or may have caused or contributed to a patient death or serious patient injury, the FDA requires you to report the event. If the event is death, make the report to both the FDA and the device manufacturer. If the event is serious patient injury, the report may be made to the manufacturer only. Submit FDA Form 3500A (http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html) no later than 10 working days from the time personnel become aware of the event.

SECTION 5: PREANALYTIC POLICIES AND PROCEDURES

Policies for the Preanalytic Phase of Testing

Our anticoagulation management program abides by “good laboratory practices” that include actions such as using two unique patient identifiers, recording the time and date of testing and having written (instead of verbal) test orders from the ordering physician. Proper specimen collection and handling is also an essential component of our preanalytic policies.

It is the policy of our anticoagulation testing program to adhere to the following procedures, which govern all activities from the time tests are ordered through the time that specimens are received and processed at the testing site.

Procedures for:

Test Ordering

An order for a PT/INR test may be placed on the patient chart, the superbill or on a test requisition form. Test requisitions must include the patient’s full name, age or date of birth, gender, source of specimen and time of collection. If a verbal test order is given to a CoaguChek XS operator, the patient chart or a written test requisition will be generated by the end of the day. Check one:

- ❑ This facility uses patient charts as test requisitions.
- ❑ This facility uses superbills as test requisitions.
- ❑ A sample test requisition is attached and is located_____.

Handling Incomplete Requisitions

When patient is brought to the testing area accompanied by an incomplete requisition, the ordering physician or his/her nurse is questioned to provide the missing information. This information is recorded on the Monthly QA Checklist so we can keep track of problems with this aspect of our testing program. If needed, procedures will be changed to decrease the occurrence of incomplete requisitions.

Standing Orders

Indicate below how standing orders are documented. Include how requisitions for standing orders are stored:

_____

_____.

Specimen Collection and Handling

Proper specimen collection and handling is essential for reliable CoaguChek XS PT/INR test results. Personnel who collect blood samples for testing are trained in specimen collection technique during initial CoaguChek XS system training to avoid inadequate samples. The specimen collection procedure below is followed for each patient.

Fingerstick Blood Collection Procedure

1. **Select and organize the appropriate supplies in the testing area**
   - CoaguChek XS meter
   - CoaguChek XS PT Test Strips and matching code chip
   - CoaguChek Lancet
   - CoaguChek Capillary tube/bulb (if needed)
   - Cotton ball or gauze, alcohol wipe and bandage

2. **Identify the patient**
   - Identify patients by having them (or a guardian) state their full name and another identifier, such as date of birth. If more than one patient is present with the same first and last name, look for possible gender differences, social security number, patient identification number, birth date, different middle name, and relevance of the test to the patient's history. In this facility, the second patient identifier is: _____.
   - Explain to the patient the purpose and steps of the procedure.

3. **Remove a test strip** from its container and immediately re-cap the container shortly before performing the fingerstick. The blood sample must be applied to the test strip within **10 minutes** of removing the test strip from its container.

4. **Collect the blood sample**
   - If possible, ask the patient to wash his hands prior to testing.
   - Warm the patient's hand by having the patient wash his hand under warm water.
   - Ask the patient to let his arm hang down for several moments before lancing his finger.
   - Wash hands and don gloves.
   - Massage the patient's finger from its base until the fingertip has increased color.
   - Clean the selected finger to be lanced with an alcohol wipe. Allow to air dry.
   - Prepare the lancet device according to the manufacturer's instructions.
   - When the meter displays the flashing test strip and blood drop symbols, with the hand still down, stick the side of finger with a lancet. Immediately after lancing, massage gently along the side of the finger to obtain a good blood drop without pressing or squeezing too hard. The minimum sample size is 8 µL of whole blood.
   - For PT/INR testing on the CoaguChek XS system, do NOT wipe away the first drop of blood.
   - Proceed to step 5 if you plan to apply the blood directly to the strip OR to step 6 below if using a CoaguChek capillary tube.

5. **Hold the blood drop directly onto the test strip** within 15 seconds of the fingerstick until the meter beeps (if beeper is set to ON). Do not apply a second drop of blood or disturb the strip while testing.

   Or

6. **Touch a CoaguChek Capillary tube to the blood drop**.
   - Keep capillary tube level and allow it to fill half way by capillary action. Avoid getting air bubbles into the capillary tube. Do not touch the bulb during sample collection. If blood gets into the capillary bulb during sample collection, discard the bulb.
   - Put finger over hole in the capillary bulb and hold capillary tube directly over sample target area. While the test strip and blood drop symbols are flashing on the display, place one drop onto the test strip within 15 seconds of the puncture.

Note: *Since the CoaguChek XS PT Test is performed immediately after specimen collection, labeling the patient's blood sample is not feasible. Therefore, it is critical to positively identify all patients to be tested with the CoaguChek XS System!*

Venipuncture Procedure

1. **Identify the patient**
   - Identify patients by having them (or a guardian) state their full name and another identifier, such as date of birth. If more than one patient is present with the same first and last name, look for possible gender differences, social security number, patient identification number, birth date, different middle name, and relevance of the test to the patient's history. In this facility, the second patient identifier is: _____.
   - Move the patient to a location where his arm can rest comfortably while remaining straight.
   - Explain to the patient the purpose and steps of the procedure.

2. **Select the appropriate collection supplies**
   - Use a plastic syringe with no additives or anticoagulants for collection of venous samples for testing on the CoaguChek XS system. Use at least a 23-gauge needle or larger in size.
   - Remove a CoaguChek XS PT Test strip from its container and immediately re-cap the container shortly before performing the venipuncture.

3. **Prepare the patient**
   Wash hands and don gloves. Reassure the patient that although the venipuncture may be slightly painful, it won't last long. Position the patient with the elbow extended and the arm supported. Have the patient make a fist, but avoid vigorous hand exercise ("pumping"). Apply the tourniquet about 3-4 inches above the venipuncture site. Do not stop the blood flow for more than one minute before the blood is drawn. If necessary, release and reapply the tourniquet.

4. **Select and clean the venipuncture site**
   The median antecubital and cephalic veins are most commonly used. Avoid the following areas:

   1. Scarred areas, such as healed burns.
   2. Avoid areas with tattoos.
   3. Thrombosed veins. These veins feel thick and cord-like and tend to roll.
   4. Bruised areas. If you cannot avoid collecting from a bruise site, then draw the specimen from the site farthest away from the bruised area.
   5. The arm on the side of a prior mastectomy. Because this surgery results in lymphostasis, specimen collection may be difficult.
   6. In a dialysis patient, do not collect from the arm that has the A-V shunt.
   7. A recent IV site, or the same side of the body as the IV site.

   Clean the venipuncture site making one smooth, circular pass with an alcohol pad. Allow the skin to dry to prevent the patient from having a burning sensation when the needle is inserted. Do not touch the vein site after cleaning it.

5. Perform the venipuncture

Note: Venipuncture should be performed after the meter begins to display the flashing test strip and blood drop symbols, and the 180-second dosing countdown. Collecting blood and/or dosing the meter prior to the appropriate time will result in error messages.

a. Gently grasp the patient's arm near the venipuncture site, using the thumb to draw the skin tight.
b. With the needle bevel facing up, line up the needle with the vein. Penetrate the skin and enter the vein at an angle of approximately 15-30 degrees. Holding the barrel of the syringe steady and immobile with one hand, begin slowly pulling back on the syringe plunger with the other hand.
c. As the blood begins to flow into the syringe, release the tourniquet and open the patient's fist. Collect approximately 1 to 2 ccs of blood (you need 8 microliters of blood for testing on the CoaguChek XS meter, plus 4 drops of "discard" sample).
d. If a blood sample cannot be obtained, change the position of the needle. If the needle has penetrated too far into the vein, pull it back a bit. If it has not penetrated far enough, move it further into the vein, but do not probe with the needle.
e. Gently remove the needle from the venipuncture site. Discard the first four drops of blood, then immediately place one drop of blood (at least 8 µL) on the target area of a test strip, which has been inserted into the meter. Ensure that the sample drop is applied within fifteen seconds of the collection of the sample. Discard both the needle and the plastic syringe in the sharps container.
f. Apply sterile gauze to the puncture site, while keeping the arm extended. Keep pressure on the site for at least 2 minutes. Ensure that bleeding has stopped, and apply a bandage over the site. Instruct the patient to wear the bandage for at least 15 minutes.

Specimen Handling

Apply sample to the test strip within 15 seconds of collection.

Specimen Accessioning

Log patient specimens to be tested on the **CoaguChek XS Testing Log,** (behind FORMS Section), or, if another method is in use, indicate below what record is kept to record that patient specimens were collected and tested.

_____

Specimen Rejection Criteria

- Do not accept glass capillary collection tubes or tubes containing heparin or other anticoagulants for testing on the CoaguChek XS meter.
- Do not accept plasma or serum specimens for testing on the CoaguChek XS meter.
- Do not accept samples less than 8 µL.
- Do not accept venous samples collected in a syringe containing anticoagulant.
- Do not test samples that have sat for more than 15 seconds after finger puncture.
- Do not accept samples collected in glass tubes or glass syringes. Use only plastic.
- Do not accept samples collected from the arm receiving the infusion line from patients who are on intravenous infusion therapy.
- Do not use the CoaguChek XS meter for testing patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivalurudin, Argatroban, and Dibigatran etexilate.
- Do not add additional blood sample to the test strip once the testing has begun.

- Do not perform a test on any specimen that is unsuitable for analysis. Either notify the ordering provider or re-collect the specimen from the patient.

SECTION 6: ANALYTIC POLICIES AND PROCEDURES

Analytic Testing Policies

In order to ensure accurate and reliable test results, testing must be performed properly, with special attention to quality control and instrument maintenance. It is the policy of this facility to follow the manufacturer's written instructions regarding the operation and maintenance of the CoaguChek XS System, found in this Policies & Procedures Manual and also in the CoaguChek XS PT Test Strip package insert and the CoaguChek XS User Manual.

Always refer to the latest Test Strip package insert, since changes may occur over time. Moreover, this Policies & Procedures Manual does not reiterate all that is contained within these documents. Rather, the analytic procedures below condense and organize the materials provided by the manufacturer, so that they can be used on a daily basis.
In this facility, only operators who are qualified under CLIA and who have documented evidence of training perform testing on the CoaguChek XS System.

Meter Settings

Indicate the selections established when initially setting up the CoaguChek XS meter:

Result Units ☐ INR ☐ SEC ☐ %Q
Date (format): _____ Time (format): _____

Options:
Beeper Tone: ☐ Off ☐ On
Therapeutic Range: ☐ Off ☐ On
Set Range: Lower Range_____ Upper Range_____

Procedures for:

Setting Time and Date

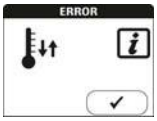
If the date and time are not set (after turning the meter on for the first time or because the batteries were removed from the meter for more than 1 minute), the CoaguChek XS System will not perform a test. Rather, turning on the meter takes you immediately to the SETUP mode, where you must set the date and time.

Once the date and time are set, the meter automatically moves to the main menu, where you can start a test or enter more settings. The next time you turn the meter on, the date and time will remain and you will automatically go to the main menu.

Storing the Meter and Test Strips

The CoaguChek XS System contains built-in self-checks to ensure that the meter and test strips were stored properly; the CoaguChek XS System will not allow patient test results to display when temperature ranges have been exceeded.

If the storage of the meter exceeded the proper temperature limits, the thermometer symbol below will appear on the meter:



In this case, turn the meter off and let sit at room temperature for 30 minutes. Check room temperature and adjust if necessary. Contact Roche Diagnostics' technical service (1-800-428-4674) for guidance if needed.

To minimize wasted tests, operate the CoaguChek XS System at a room temperature between 15-32°C (or 59-90°F) and 10-85% humidity. Store CoaguChek XS PT Test strips at room temperature OR in the refrigerator (2 to 30°C or 36 to 86°F).

- Store test strips in their container with the cap closed.
- Remove one strip at a time from the test strip container, and keep the container closed between tests.
- Do not remove a test strip with wet hands or gloves; this may damage the test strip.
- Use the strip within 10 minutes after removing it from the container.
- When stored and used properly, CoaguChek XS PT Test strips are stable until the "Use By" expiration date.
- Discard the strips if they are past the "Use By" date. Do not use expired strips.
- Always use the code chip from the current box of test strips – do not mix code chips and strips from different boxes.

Code Chip Storage and Stability

Protect code chips from moisture and equipment that produces magnetic fields.

Ordering Test Supplies

CoaguChek XS PT Test strips are purchased from:

Company Name	Telephone

Instrument Maintenance

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

- Do not use sprays of any sort.
- Ensure that swab or cloth is only damp, not wet.

Cleaning/disinfecting the meter housing (the exterior of the meter)

- Use only the following items for cleaning/disinfecting the CoaguChek XS or CoaguChek XS Plus meter housing for a contact time of >1 minute:
    - 70% isopropyl alcohol
    - 10% Sodium hypochlorite solution (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours)
    - **NOTE: Do not use any other disinfectants/cleaning solutions on the meter housing.**
- Ensure that the blue test strip guide cover remains tightly closed while cleaning the housing.

1. With the meter powered off, wipe the meter's exterior clean.
    - Do not let liquid accumulate near any opening. Make sure that no liquid enters the meter.
2. With a lint-free tissue, dry the meter.
    - Wipe away residual moisture and fluids after cleaning the housing.
    - Allow wiped areas to dry for at least 10 minutes before performing a test.

Cleaning/disinfecting the meter test strip guide

- Use only 70% isopropyl alcohol or 10% bleach solution to clean the CoaguChek XS test strip guide.
- **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.**

1. 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.
2. To clean the test strip guide:
    - Hold the meter upright with the test strip guide facing down
    - Clean the easily accessible areas with a cotton swab.
        - Ensure the swab is only damp, not wet.
        - Apply cleaning agent for a contact time of >1 minute (refer to the corresponding product labeling).
        - Wipe away residual moisture and fluids.

Caution: *Do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide.*

3. Let the inside of the test strip guide dry for at least 10 minutes.
4. Close the test strip guide cover and make sure it snaps into place.

Onboard Quality Controls

Quality Control (QC) checks the accuracy and precision of the analytical process and helps detect immediate errors, performance over time, and variance in operator performance. The CoaguChek XS System has a number of built-in quality-control functions that control the entire analytical process:

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

Refer to the CoaguChek XS System User Manual for more information about quality control functions and the internal monitoring system. Because of these advanced features, Roche Diagnostics does not recommend nor provide liquid quality control material with this test system.

QC Procedures

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

Troubleshooting Out of Control QC Results

To resolve QC error messages, carefully follow the instructions in the User Manual. 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.

If troubleshooting is unsuccessful, and control results are still unacceptable, call Roche Diagnostics Technical Service Center at 1-800-428-4674. Document this on the **Monthly QA Checklist** (FORMS Section).

QC Record Retention

Keep all QC records for at least 2 years. Indicate where these records are stored:

QC Record	Where Stored
CoaguChek XS Patient Test Log	_____
Monthly QA Checklist	_____

Calibration: Coding the Meter with the Code Chip

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.

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

1. Turn meter off.
2. Remove the old code chip if there is one inserted in the meter.
3. 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.
4. 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.
5. 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.
6. Leave the correct code chip in the meter to protect the electrical contacts in the meter from becoming dirty.

Procedure for Performing Patient Tests

With each new box of CoaguChek XS PT Test strips, read the manufacturer's instructions included on the package insert to check for changes in procedures. Retain the current package insert for reference.

Testing Patient Samples

Collect and run patient samples according to the directions below, first checking the product insert if a new box of test strips is opened to be sure no changes have occurred since the previous box. Keep it available for CoaguChek XS operators, if they do not use the following procedure on a daily basis. If changes occur on a package insert, make changes in the procedure below and remove old package inserts. Indicate how Operators will be notified of any changes to the testing procedure: _____.

1. In order to create an audit trail to link the patient test with the appropriate CoaguChek XS meter, complete the **CoaguChek XS Testing Log** (FORMS Section) for each patient tested.
2. Prepare the lancet device or venipuncture supplies according to the manufacturer's instructions.
3. Place meter on a flat surface, free of vibrations, or hold it in your hand so the meter is roughly horizontal. Do not move the meter during testing.
4. Take a test strip out of the container. Close the container tightly. 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).
5. Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests. Change the batteries.
6. Check that the date and time are correct. Correct any wrong entries as described on page 6-2.
7. Confirm that the code number displayed on the meter matches the number on the test strip container. 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.

8. 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.
9. Collect the fingerstick or venous blood sample as outlined below.
    - *Fingerstick 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 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.
    - *Venous Sample* – **Expel the first four drops** of blood from the syringe or syringe needle. 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.
10. Apply the blood directly to the 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.

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

11. 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. Following a successful outcome of the quality control test, a check mark appears after "QC."
12. Wait for results—this takes about one minute.
13. The result is displayed in the unit of measure you chose when setting up the meter. It is automatically saved to memory.
14. Read and record results on the **CoaguChek XS Testing Log**.
15. Remove the test strip from the measurement chamber.
16. Turn meter OFF.
17. Dispose of all biohazardous material in the biohazard or sharps container.

Note: *Use a new fingerstick from the opposite hand and a new test strip if you must retest. DO NOT add more blood to the first test strip!*

Turnaround Time

The typical time from the test being ordered to the time that the results are given to the provider is: _____.

Procedure Notes

- Operating the meter outside the temperature range of 15 to 32^{o}C (59 to 90^{o}F) will cause an error message to be displayed on the meter.
- Make sure the correct test code chip is in the meter. Don't remove or insert a test code chip while performing a test.
- Follow the information on correct handling of test strips in the package insert.
- Keep the vial of test strips securely capped when not in use, and don't handle test strips with wet hands or gloves. Improper handling or storage of test strips may cause an error message to be displayed on the meter.
- Begin collecting sample when the meter displays the flashing test strip and blood drop symbols.
- Use the test strip within 10 minutes of removing from its container.

- Apply a capillary sample to the test strip within 15 seconds of the fingerstick.

Limitations of the Procedure

- 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.
- The blood sample must be at least 8 µL. Low sample volume will cause an error message to appear on the meter.
- The CoaguChek XS System uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used.
- Use only plastic syringes without anticoagulants or additives. Do not use glass tubes or syringes.
- Never add more blood to test strip after test has begun or perform another test using the same fingerstick.
- When a patient is on intravenous infusion therapy, do not collect sample from arm receiving the infusion line.
- No significant effect on test results was seen with:
  - Bilirubin up to 30 mg/dL
  - Lipemic samples containing up to 500 mg/dL of triglycerides
  - Hemolysis up to 1000 mg/dL
  - Hematocrit ranges between 25-55%
  - Heparin concentrations up to 0.8 U/mL.
  - Clopidogrel up to 20 mg/dL
  - Fondaparinux up to 5 mg/L
  - Low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL.
- The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values. A comparison to an APA-insensitive laboratory method is recommended if the presence of APAs is known or suspected.
- In rare cases, patients with long clotting times (>8 INR) may receive an “ERROR 7” message on the meter display. If this error message appears again when the test is repeated, check the result using another method.

SECTION 7: POSTANALYTIC POLICIES AND PROCEDURES

Policies for Interpreting, Reporting and Recording Test Results

The documentation system used in this facility ensures that CoaguChek XS operators examine results before reporting to the ordering physician. Results from one patient are not mixed up with another; laboratory test reports reach the ordering physician within the time frames specified, and all results are retrievable. In order to consistently deliver accurate results reflecting patients' true status, the following procedures for mitigating possible sources of error have been instituted.

Procedures for:

Normal (Reference) Ranges

The health provider determines the optimum INR level for each patient depending on the reason for anticoagulation treatment and how the patient responds to treatment as measured by the prothrombin time.

There are two recommended therapeutic ranges: a less intense range of 2.0-3.0 INR and a more intense range of 2.5-3.5 INR for patients with mechanical heart valves (Ref: Hirsh J MD FCCP Chairman, et al, "Oral Anticoagulants Mechanism of Action, Clinical Effectiveness, and Optimal Therapeutic Range." *Chest.*1995; 108(4): 231S-246S). The physician determines the appropriate therapeutic range for his or her patient population or individual patients. Notes regarding normal ranges in this facility: _____

_____

_____.

Reportable Ranges (Operating Ranges)

The operating ranges listed below are the ranges over which the CoaguChek XS System displays and transmits results. If a result of < 0.8 INR or > 8.0 INR is displayed, the test result could not be measured or the result may be outside the measuring (reportable) range for the particular lot of test strips. Repeat the test with a new strip and a new fingerstick.

In rare cases, Error Message 7 can occur in patients with long coagulation times (> 8 INR). If this error message appears again when the test is repeated, check the result using another method. (e.g, consult with provider, then collect a venous specimen and refer to an outside laboratory, if requested).

Parameter	Operating (Reportable) Range	Units
PT	9.6 - 96	Seconds
PT	0.8 – 8.0	INR

Interpreting 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.

Recognizing Unusual or Clinically Inconsistent Results

Once a result is obtained, consider:

- Is the result within the established reference range (if known for this patient)?
- Are results comparable to results from previous office visits?

Physicians and operators should question any patient test result that appears inconsistent with clinically relevant criteria or previous patient test results. For example:

- Certain drugs may affect results by interfering with warfarin pharmacology. Consider the potential effect of a drug interaction with warfarin or the effect of underlying diseases (e.g. liver disease, congestive heart failure) when interpreting a result.
- Changes in the patient's diet can cause unusually low or high results.
- Any unusual result can be followed up with inquiries to the patient and physician to define the cause of the unusual result. If the result does not match the clinical symptoms, repeat the patient test to rule out procedural error.

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

- 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.
- 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.
- Debris on the test strip guide can cause problems with results. Clean the meter as recommended in the CoaguChek XS System User Manual.
  - Do not use a spray to clean the guide or any part of the meter.
  - Do not let liquid enter the meter
- Refer to Limitations of the Procedure on page 6-6.

Critical/Alert/Action Value Procedures

Insert the patient PT/INR test values that require immediate notification of the provider:

Result	Critical/Alert/Action Values
PT (seconds)	
INR	

Indicate exactly what action your laboratory takes when critical values are obtained:

_____

_____.

Recording and Reporting Results

Record results for each patient on the **CoaguChek XS Testing Log** (behind FORMS Section) as you read the results. If test results are also written onto the patient chart, include the name of the test, the test result and unit of measure, the date the test was performed, and the initials of the testing personnel as well as the test result. Include the calendar year in the date. Also, if the same test is performed on a patient multiple times in one day, include the time of each test.

Note: *Never place patient test results on post-it notes or pieces of scrap paper that can be misplaced!*

The documentation system for PT/INR test results should contain the date(s) the specimen was collected, tested and reported a well as the initials of the testing analyst and the name and address of the laboratory where the specimen was tested. Indicate where the following are located:

CoaguChek XS Testing Log:_____

Patient test requisitions: _____

Final test results: _____

Keep these items for a minimum of 2 years.

Describe the process for reporting PT/INR results to the ordering physician. Include how abnormal results are treated differently than normal results, if applicable:

_____

_____

_____

_____.

Correcting Erroneous Test Results and Issuing Corrected Reports

Immediately after recognizing an erroneous result has been reported:

1. Contact the individual who received the original report and notify him/her of the error. If the patient is available for testing, tell the caregiver whether or not a corrected result will be forthcoming. If the patient is not available, ask the caregiver if the patient should be re-drawn and re-tested.
2. Document on the original report that the result was in error. Have the ordering physician re-sign the report indicating awareness of the error.
3. When possible, retest to obtain the correct result.
4. Report the corrected result, noting on the report the original result and that this is a corrected result.
5. Document the incident on the **Monthly QA Checklist.** Include all the actions associated with the erroneous result, including:
    - All patient information.
    - Dates.
    - Times.
    - Individuals involved.
    - Original and corrected results.
    - Why the erroneous result occurred.
6. Maintain original and corrected reports for two years.

Ensuring the Security of Patient Test Results

Do not allow visitors and unauthorized personnel access to the testing area where patient information may be easily viewed. During the testing process, keep patient test requisitions and results in an area where they cannot be viewed by visitors and unauthorized personnel.

Procedures for Using Alternative Methods

At the ordering physician's request or when there is a concern that the results obtained from the CoaguChek XS System may be questionable, or if the CoaguChek XS System is otherwise unavailable for use, specimens may be referred out to a CLIA-certified laboratory. Note on the test report that the specimen was sent out for testing.

List the name of the laboratory(s) used if not solely dependent on the patient's insurance:

_____.

Follow directions from the referral laboratory for handling and transporting specimens, but make arrangements for the test to be performed within 4 hours of specimen collection. If this is not possible, the patient may need to be sent to that laboratory for testing.

Communications and Laboratory Complaints

Record any complaints about the anticoagulation management program on the **Monthly QA Checklist**. Include the nature of the complaint, investigative steps taken to identify the problem, and how the problem was resolved.

Incident Management

An incident is an event that could result in serious injury for patients or staff. These incidents stem from systemic non-compliance with written policies and procedures. When an incident occurs in this testing program, collect and verify the facts and review and discuss them with the anticoagulation management program director promptly. Determine if the incident was medically significant by evaluating its impact on clinical diagnosis and treatment of patients.

The following are some incidents that might lead to the wrong diagnosis, wrong treatment, delay in treatment, serious injury or death (but are not limited to):

- Misidentification of the patient
- Injury to the patient due to phlebotomy
- Misinterpretation of results due to improperly trained or unqualified personnel
- Accidents causing injury to operators
- Results not reported, reported incorrectly, placed on wrong chart or critical or panic values not reported properly

Address the problem immediately, identifying who will be responsible for managing the incident. Determine whether testing should be stopped. Develop a corrective action plan and implement the corrections. Verify an effective resolution before resuming patient testing. Record these actions on the **Monthly QA Checklist**.

If the incident did affect patient test results, the anticoagulation management program director will handle each incident on a case-by-case basis and determine whether to recall, retest, re-evaluate or re-release patient test results. The anticoagulation management program director will also determine how to notify patients, staff, and referring physicians.

If the incident is believed to have resulted from an instrument malfunction, the incident may need to be reported to the FDA. If the event is death, make the report both to the FDA and the device manufacturer. If the event is serious patient injury, the report may be made to the manufacturer only. Submit FDA Form 3500A (http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html) no later than 10 working days from the time personnel become aware of the event.

Procedure for a Power Failure

The CoaguChek XS meter can operate only with four AAA batteries. The batteries should last for up to 2 years or 300 tests, depending on the type of battery used. Therefore, a power failure will not affect the CoaugChek XS meter.

To save power, the CoaguChek XS meter automatically turns itself off after three minutes, unless a button is pressed or test strip is inserted.

Replacing the Batteries

When replacing the batteries, insert the new batteries within 1 minute of removing the old ones, to keep the date and time settings. If you take longer than this, you may need to re-enter the date and time.

SECTION 8: QUALITY ASSESSMENT

QA Policies

This Quality Assessment (QA) Program comprises the steps taken to assure the overall reliability of our anticoagulation management program, starting with proper specimen collection and ending with interpreting patient test results and taking the appropriate patient management decisions based on test results.

Unlike quality control, which monitors the test system only, QA involves the entire testing process including safety, personnel, specimen collection and handling, performing the test, recording results and finally reporting patient test results to providers.

The **Monthly QA Checklist** is a means of ongoing assessment, which helps to evaluate how well our systematic anticoagulation management program is working.

The anticoagulation management program director oversees the implementation of the QA plan and helps identify and correct problems as they occur. The QA process involves investigation, identification and resolution of any problems with subsequent development of policies that will prevent recurrence. These new policies will be periodically reviewed to ensure the actions taken corrected the initial problem over time.

QA Procedures

Once a month, complete the **Monthly QA Checklist**, including the chart review portion. If an item is marked “no”, then take action and document that action on the **Monthly QA Checklist**. Action to take involves determining why a quality measure was not taken.

When necessary, revise the policies and procedures in this Policies & Procedures Manual based on problems identified on the **Monthly QA Checklist**. Communicate any revisions to concerned staff by having them read the change in this manual and documenting this on the **Policies and Procedures Approval Form** (page ii).

Our specific policies and procedures for ensuring quality are written throughout this **Policies & Procedures Manual** and are readily available to the testing staff at all times. These measures will ensure total quality throughout the preanalytic, analytic and postanalytic phases of our testing program.

Note: Proficiency testing is not required by the federal CLIA regulation for the CLIA-waived CoaguChek XS System. However, some states, such as Maryland and Pennsylvania that do not recognize the federal CLIA waived test category, require an external measure to assess external quality of testing. Since proficiency testing is not available for the CoaguChek XS System, split sampling is another equally acceptable means to externally assess the accuracy of the test system.

Split Sample Procedure

The SAM program director will requests a periodic external evaluation of accuracy, depending on:

- How the test is used
- Reagent stability

- Manufacturer's recommendations
- The facility's experience with the test
- Currently accepted guidelines

Also, Maryland state regulations require 5 meter to lab comparisons three times per year. Pennsylvania state regulations require split samples at least twice per year using specimens from both normal and therapeutic ranges. (Be sure to check your state's regulations for the most current information and policies).

In this facility, split sampling (*check one*)

❑ Is performed Frequency: _____

❑ Is not performed

A procedure for split sampling follows:

1. Select one or more operators to perform split sampling. Attempt to rotate these duties so that all operators can periodically perform this exercise.
2. If you performed method comparison, use the same referral laboratory for split sampling. This is because the bias between that method and the CoaguChek XS System has already been established. Be sure this laboratory can test split samples within 4 hours of collection.

Note: *The Mean Normal PT (MNPT) for the CoaguChek XS System has been predetermined through the calibration process for all strip lots. The meter automatically gives results in INR based on that calibration. The referral laboratory will need to establish MNPT for their system before method comparison may begin. Do not take the MNPT directly from the package insert for the referral lab system.*

3. Select 5 patients to compare. Include patients on warfarin therapy and nonsmoking healthy patients who are not on warfarin, aspirin or any other medication that affects clotting. Do not include patients who are on heparin therapy.
4. From each patient, collect a venous blood specimen:
    - Use a butterfly collection set with a 3.2% citrate blue top vacuum tube installed (make sure you have the correct adapter on the end of the butterfly tubing.) Fill to the appropriate fill line. Under filling or overfilling can affect test results, so if the tube is not filled correctly, discard and redraw.
    - After filling the vacuum tube, remove the tube from the adapter, gently mix the contents and set aside. Send to a referral lab that is able to test it within 4 hours.
    - If using venous blood for testing on the CoaguChek XS System, remove the adapter, attach a 3 cc plastic syringe, and collect about 1 cc of blood into the syringe. Pinch off the tubing or close the luer lock and remove the syringe.
    - Expel **the first four drops** of blood from the syringe. Then place one drop of blood (at least 8 µL) from the syringe directly on the strip sample target area.
    - Record the result from the CoaguChek XS System on the **Split Sample Log** (FORMS Section*).* For the purpose of this study, repeat any CoaguChek XS System result greater than 4.0 INR with a fingerstick sample from the opposite hand. Place the second result in parentheses after the first result in the **Split Sample Log**.
5. If the referral lab cannot test the venous samples within **four hours,** spin the samples according Clinical and Laboratory Standards Institute (CLSI) guidelines. Pipette off the plasma without disturbing the cell layer into an appropriately labeled tube. The referral lab may also require the original blue top to accompany the plasma.

- When results are returned from the referral lab, record on the **Split Sample Log**. A bias factor calculated on the **Split Sample Log**, is the average amount that results will differ when performed on the CoaguChek XS meter and the comparison instrument. The CoaguChek XS System results may be consistently lower or consistently higher than the comparison instrument. In evaluating results, as long as the bias factor remains consistent, the split-sample verification of results may be considered successful.

6. When the split sample study is complete, provide results to the anticoagulation management program director. The director will determine whether or not a clinically significant difference exists between the two methods and whether or not the results are acceptable.

Sources of Error in Split Sample Studies

Some inherent sources of error in split sample studies include differences in specimen collection between testing performed routinely on the CoaguChek XS System and the way specimens must be collected for the split sample analysis. Split sample sources of error are identical to those for method comparison, and are described further on page 3-2.

SECTION 9: FORMS

Forms Index

Form	When to Use	Page #
CoaguChek XS Operator Certification Checklist	Once, before new testing personnel are allowed to perform the test.	9-2
Operator Certification Test	Use when conducting in-services for new CoaguChek operators. Includes test key.	9-3
CoaguChek XS Operator Evaluation Checklist (Optional)	Use if periodic competency assessment of operators is requested.	9-5
CoaguChek XS Method Comparison (Optional)	Use to compare a new CoaguChek XS System with a previous method (optional).	9-6
CoaguChek XS Patient Test Log	Fill out for each patient tested.	9-7
Monthly QA Checklist	Monthly.	9-8
Split Sample Log	Use when a periodic external assessment of accuracy is required by state regulations.	9-9

COAGUCHEK XS OPERATOR CERTIFICATION CHECKLIST

Operator Trainee: _____ Date: _____

General

– Describe the intended use of the instrument.

– Review all manuals and reference materials (User Guide, package inserts, Policies & Procedures Manual)

Sample Handling

– Review the requirements for specimen collection, sample handling, and processing.

Instrument Components

– Identify and locate the following instrument components:

√ Display
√ On/ Off button
√ Test strip guide cover
√ Test strip guide
√ Battery cover and tab
√ Code chip slot and code chip(s)

– Identify the following icons and symbols:

√ Apply Blood Sample
√ Automatic QC successful
√ Results above or below instrument range
√ Battery Status
√ Error messages
√ Room or meter temperature outside acceptable range

Controls

– Review and assist as needed:

√ Importance of quality control
√ Interpretation of onboard controls

System Operation Overview

– Review and assist as needed:

√ Loading correct code chip
√ Handling test strips and preparing to test
√ Follow screen prompts to process samples
√ Interpret results

Daily Procedures

– Review and assist as needed:

√ Cleaning procedures
√ Log Sheets (see FORMS section)
√ Telephone troubleshooting Roche Technical Service 800-428-4674

General Lab Knowledge

– Trainee has read and signed the Policies & Procedures Manual

– Trainee knows how to report patient test results according to written procedures.

– Trainee can recognize system failures, unacceptable QC, PT and inconsistent or erroneous patient test results.

– Trainee can correctly document corrective actions associated with error messages.

– Trainee knows who to contact in the event of questions concerning testing or reporting.

– Trainee knows how to contact the FDA in the event of a device-related adverse event.

Trainer Name and Title: _____ Date: _____

OPERATOR CERTIFICATION TEST

Operator Trainee: _____ Date: _____

Mark "T" (true) or "F" (false)

___ 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.

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

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

___ 4. A venous sample must be collected in a plastic syringe free of anticoagulants.

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

___ 6. INR is a reporting format that stands for International Normalized Result.

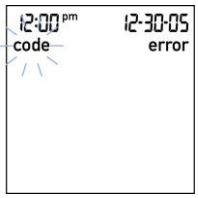
___ 7. Every time a blood test is performed, the meter also performs a built-in quality control test.

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

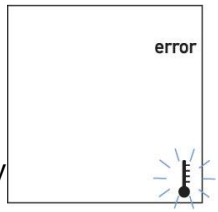
___ 9. The most recent patient result appears first when reviewing memory.

___ 10. The CoaguChek XS meter stores up to 300 results with time and date.

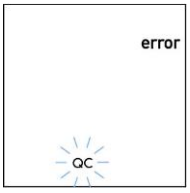
11. What is used to clean the exterior of the CoaguChek XS meter? _____

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?_____

Operator Certification Test Answer Key

1. T
2. T
3. T
4. T
5. T
6. F – International Normalized Ratio
7. T
8. F – If the built-in quality control does not pass, a flashing “QC” will appear on the display.
9. T
10. T
11. Use a 10% household bleach solution and 70% isopropyl alcohol
12. Code chip is damaged, missing, or not snapped firmly into place.
13. Meter was stored above or below the proper operating temperature. Turn meter off and let sit at room temperature for 30 minutes.
14. The test strip failed the internal quality control check. The test strip is unusable. Turn the meter off and remove the test strip. Repeat test using a new test strip and blood taken from a new fingerstick from the opposite hand.
15. Strips are stable for 18 months or the expiration date, whichever comes first, when stored at room temperature.

COAGUCHEK XS OPERATOR EVALUATION CHECKLIST (OPTIONAL)

CoaguChek Operator: _____ Evaluation Date: _____

Observe operator during testing and mark the following items "Yes" or "No":

Reviews Procedure

__ States when coding is needed
__ Turns meter off before inserting or removing code chip
__ Removes old code chip if one is installed
__ Inserts new code chip until it snaps into place

Performs Test Procedure

__ Washes hands and dons disposable protective gloves
__ Prepares lancet device or plastic syringe according to written procedures
__ Removes test strip from container and replaces cap tightly
__ Inserts test strip properly
__ Obtains blood sample correctly
__ Applies blood to test strip correctly
__ Reads and understands onboard control results
__ Reads and records results properly
__ Properly discards used test strip and blood-drawing supplies
__ Correctly recalls results stored in memory

Solves Problems

__ Refers to Error Messages in CoaguChek XS System User Manual when a problem occurs
__ Knows when to call the 24-hour Roche Technical Service (800-428-4674)
__ Contacts the appropriate person when questions arise concerning testing or reporting results

System Checks

__ Documents remedial actions associated with QC and error messages
__ States minimum cleaning frequency
__ Demonstrates exterior cleaning procedure as stated in the User Manual
__ Properly cleans test strip guide
__ Demonstrates removal and replacement of batteries

Reviewer Name and Title: _____ Date: _____

COAGUCHEK XS METHOD COMPARISON LOG (OPTIONAL)

Referral lab (name): _____ **Instrument used:** _____
Type of Thromboplastin: _____ **Reagent Lot:** _____ **ISI:** _____
MNPT: _____
CoaguChek XS System Serial Number: _____
Test Strip Lot #: _____ **Exp. Date:**_____

Day/ Date	Patient ID#	Patient on Warfarin? Y/N	Referral Lab Result		Internal Controls OK?	CoaguChek XS Result	Operator
Average Referral Lab Results = _____					**Average CoaguChek XS Results** = _____		

*Average of Method 1 minus Average of Method 2 = Bias Factor **Bias Factor:** _____

Comments: _____

Program Director Approval: _____ **Date:** _____

COAGUCHEK XS PATIENT TEST LOG

CoaguChek XS Meter Serial Number (if more than one meter used in this facility): _____

Date/Time Specimen Collected/Tested	Patient Name	Patient ID#	Test Strip Lot Number	Controls (OK?)	Test Results	Operator

MONTHLY QA CHECKLIST

Mark Yes, No, or N/A (Not Applicable). If you answer "No" to any item, explain on the reverse.

Check CoaguChek XS Operator Certification Checklists:

_____ Is a Checklist present for each CoaguChek XS system operator?

Check the Policies and Procedures Approval Form:

_____ Have all CoaguChek XS operators read and signed this form on page ii?

_____ Has the current anticoagulation management program director approved the CoaguChek XS procedure?

_____ Have any changes made to the Policies & Procedures Manual been are approved, signed, and dated by the current anticoagulation management program director?

_____ If any revisions have been made, have all affected personnel been made aware of them?

Observe one or two CoaguChek XS operators:

_____ Do operators follow the manufacturer's instructions for test performance and troubleshooting?

_____ Were patients properly identified using two distinct identifiers?

_____ Were test strips stored properly and within the “Use by” date?

_____ If personnel competency problems were identified or observed, was corrective action instituted to assist employees to improve performance?

Check CoaguChek XS Testing Log:

_____ Were all patient tests logged completely and correctly (including second identifier, QC acceptability, reagent lot numbers, etc.)?

_____ **Did any complaints or communication problems concerning testing or reporting patient specimens occur this month?**

_____ If so, were they resolved by the program director and documented on this Monthly QA Checklist?

_____ **Did any mix-ups occur this month with patient identification?**

_____ If an incorrect patient test result was reported, did the operator notify the person who ordered the test of the correction and submit a corrected report? Are both original and corrected reports being kept for 2 years?

Pull five patient charts and check the following:

_____ Written test requests are available for PT/INR tests ordered.

_____ Manually entered results were transferred accurately, located in the correct patient chart, and in the proper area of the patient chart.

_____ Caregiver saw test report and acted on it when necessary.

Attach any pertinent reports to this checklist (complaints, incidents, etc.). Also, explain any changes made to laboratory policies and procedures as a result of this Quality Assessment program. Describe corrective actions taken and how changes have improved quality of the testing process. Also, note how pertinent staff members were involved in this quality assessment process (discussions or active participation).

Comments: _____

_____

_____.

Program Director Approval: _____ **Date:** _____

SPLIT SAMPLE LOG (OPTIONAL)

Date	Operator	Sample #	CoaguChek XS Result	Second Result*	Difference**	Accept? Date Accepted
		1				/
		2				/
		3				/
		4				/
		5				/

Comments: ____

____

Date	Operator	Sample #	CoaguChek XS Result	Second Result*	Difference**	Accept? Date Accepted
		1				/
		2				/
		3				/
		4				/
		5				/

Comments: ____

____

Date	Operator	Sample #	CoaguChek XS Result	Second Result*	Difference**	Accept? Date Accepted
		1				/
		2				/
		3				/
		4				/
		5				/

Comments: ____

____

** Attach referral lab results to this form, if applicable.*
***Use the following formula to calculate percent deviation:*

$$\frac{\text{CoaguChek XS result minus comparison lab result}}{\text{comparison lab result}} \times 100 = \%\ \text{deviation}$$

Program Director Approval: ______________________________ **Date**: ____________________

SECTION 10: APPENDICES

Appendices Index

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APPENDIX A.
REGULATIONS GOVERNING TESTING

All laboratory tests that are performed on humans for the purpose of diagnosis, treatment or monitoring fall under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA'88 or simply CLIA). The CLIA program is administered by the Centers for Medicare and Medicaid Services (CMS). Each state, except for those that are "exempt" from federal standards (Washington state and certain testing facilities in New York), has at least one office where CMS surveyors are located. A listing of state CLIA contacts appears below.

State CMS Offices

AL	334-206-5120	**KY**	502-564-7963	**NY- POL**	518-485-5352
AK	907-334-2583	**LA**	225-342-9324	**NY - Other**	518-485-5378
AR	501-661-2201	**MA**	617-753-8438	**OH**	614-644-1845
AZ	602-364-0741	**MD**	410-402-8025	**OK**	405-271-6576
CA	213-620-6160	**ME**	207-287-9339	**OR**	503-693-4121
CO	303-692-3681	**MI**	517-241-2698	**PA**	610-280-3464
CT	860-509-7400	**MN**	651-201-4120	**RI**	401-222-4526
DC	202-727-1740	**MO**	573-751-6318	**SC**	803-545-4291
DE	302-223-1392	**MS**	601-364-1115	**SD**	605-773-3694
FL	850-412-4500	**MT**	406-444-1451	**TN**	615-741-7023
GA	404-657-5447	**NC**	919-733-0176	**TX**	512-834-6792
HI	808-692-7420	**ND**	701-328-2352	**UT**	801-965-2531
IA	319-335-4500	**NE**	402-471-3484	**VA**	804-367-2107
ID	208-334-2235 x245	**NH**	603-271-4832	**VT**	802-652-4145
IL	217-782-2343	**NJ**	609-292-0016	**WA**	253-395-6745
IN	317-233-7502	**NM**	505-222-8646	**WI**	608-261-0653
KS	785-296-3811	**NV**	775-684-1060	**WV**	304-558-3530 x2103
				WY	307-777-7123

Source: http://www.cms.hhs.gov/CLIA/downloads/CLIA.SA.pdf, accessed July 2011.

CLIA regulations divide testing sites into 3 categories depending on the complexity of the tests performed:

1. Waived
2. Moderate complexity, including the subcategory Provider Performed Microscopy (PPM)
3. High complexity

The CoaguChek XS falls into the CLIA waived category. Those facilities that perform only CLIA waived tests are required to:

1. Possess a valid CLIA certificate (see below for instructions to complete the form to obtain such a certificate).
2. Pay CLIA fees of $150 every two years.
3. Follow the manufacturer's instructions for performing the test.

If your facility needs to apply for a CLIA certificate, follow these easy steps:

STEP 1: Call your state CMS office (see list on previous page) and ask for Form CMS-116 and any additional forms that may be required in your state to either register a new laboratory for a certificate of waiver. Form CMS-116 is also available online at the CLIA website: http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf. Ask the CMS representative for the address (or fax number) and the contact person who will receive your completed CLIA application.

STEP 2: Complete **Form CMS-116** and any additional state forms required. In Section II of Form CMS-116, check "Certificate of Waiver".

STEP 3: Mail or fax Form CMS-116 and any additional required forms to your state CMS office. Note that Medicare/ Medicaid will NOT pay for tests performed before the effective date of the CLIA certificate, which is the day CMS enters the application in their database, not the day you complete the application. So, do not begin testing Medicare or Medicaid patients until receiving notification from your State agency or CMS with the CLIA number and its effective date.

Accredited Facilities: CAP, Joint Commission, COLA

Accrediting Agencies
Some testing facilities, especially those associated with hospitals or that are part of integrated delivery networks voluntarily choose to be accredited by an agency such as the Joint Commission (JC) or the College of American Pathologists (CAP). Many physician office-based testing programs opt for accreditation by COLA. To be accepted as agencies that can inspect testing facilities in lieu of CLIA inspectors, accreditation agencies must have requirements that are –overall- as stringent as the federal CLIA regulations. Accrediting agencies provide Checklists for their members that specify their actual requirements, and these Checklists are updated frequently. The following table contains a brief overview of quality requirements for three common accrediting agencies for non-waived tests as of January 1, 2011. Consult Checklists provided by the accreditation agency for more specific and updated information.

Waived Tests	CLIA/COLA	JC	CAP
Personnel educational requirements	None	None	None
Personnel Training/evaluation	None. Follow manufacturer's instructions.	Documented training initially + evaluation annually thereafter	Documented training initially + evaluation after first 6 months and annually thereafter
Quality Control (QC)	Follow manufacturer's instructions	Follow manufacturer's instructions	Follow manufacturer's instructions
QC Documentation	None required	Required	Not required for on board controls due to automatic lockout
Inspections/ audits	None	Every 2 years	Every 2 years
Split sampling	None	None	Yes
Method comparison**	No	No	No
Proficiency Testing	No	No	Split sampling

State Regulations That Differ From the Federal CLIA Regulations

Certain states have regulations that exceed the Federal CLIA regulations for certain kinds of testing facilities. Contact your state department of health for any state-specific requirements.

APPENDIX B.
HOSPITAL: NATIONAL PATIENT SAFETY GOALS

For the most current national patient safety goals, -refer to The Joint Commission publication, *National Patient Safety Goals for Hospital Accreditation Program*, available online at: http://www.jointcommission.org/