

# CoaguChek<sup>®</sup> XS System

**Professional**

**Training Manual**

**for Self-Testing**



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Rx only.

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On the packaging and on the identification plate of the instrument you may encounter the following symbols, shown here with their meaning:



Caution (consult accompanying documents). Refer to safety-related notes in the manual accompanying this instrument.



Temperature limitation (Store at)



Use by



Manufacturer



Batch code/ Lot number



Catalog number



In vitro diagnostic medical device



Consult instructions for use

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	<b>Introduction .....</b>	<b>1</b>
<b>1</b>	<b>Overview of Warfarin Therapy and the CoaguChek XS System .....</b>	<b>3</b>
<b>2</b>	<b>Materials for User Training .....</b>	<b>5</b>
<b>3</b>	<b>User Selection Guidelines .....</b>	<b>7</b>
	Overview .....	7
	Clinical Study .....	8
	Performance Characteristics.....	9
<b>4</b>	<b>Training Users for Self-Testing .....</b>	<b>13</b>
	Preparation .....	13
	Supplies .....	13
	Training Outline .....	14
	Testing the Trainees.....	20
	<i>Certificate of Completion</i> .....	21
	Follow-up Visits.....	21
<b>5</b>	<b>Proficiency Checks .....</b>	<b>23</b>
<b>6</b>	<b>Forms .....</b>	<b>25</b>

## Introduction

### Introduction

Roche Diagnostics is pleased to present this guide to assist you in training individuals in the use of the CoaguChek® XS System. The guide contains a variety of materials to help you plan the curriculum:

- an overview of the CoaguChek XS System
- a description of training materials available from Roche Diagnostics
- a guide to selecting appropriate individuals to participate in self-testing
- a suggested outline for the training class
- *Skills Checklist* and *Knowledge Test*
- *Certificate of Completion* to be given to trainees
- suggestions for refresher training.

If you have questions, please contact the Roche Diagnostics Technical Service Center 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

### Obtaining CoaguChek XS Meters for Users

Roche Diagnostics uses a network of certified national distributors to assist you with acquiring a CoaguChek XS System for your patients. Contact your Roche Account Manager or the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year. Potential users who will be self-testing must have a doctor's prescription for the CoaguChek XS meter and complete a training program offered through an approved Roche distributor.



### OVERVIEW

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The CoaguChek XS System from Roche Diagnostics measures blood-clotting time for people who are taking anticoagulation medications such as warfarin (for example Coumadin®). Warfarin is an oral anticoagulant that changes the formation of certain blood factors produced in the liver in such a way that the clotting time is slowed. (Refer to the latest warfarin package insert for contraindications.) The goal is to prevent clots from forming or moving. At the same time, however, it is important to avoid excessive anticoagulation, or blood thinning, which carries a risk of hemorrhage.

People on warfarin therapy must be monitored closely for two reasons. First, as indicated above, it is very important to keep blood coagulation time within an optimal therapeutic, or target range. Second, each individual reacts differently to warfarin, and the medication's ability to prevent a clot is affected by a person's metabolism, diet, and other medications.

The variability of laboratory results due to reagent differences is a common problem. The CoaguChek XS System minimizes the variability that is seen with traditional PT/INR assay reagents. Each lot of test strips is compared to a reference material by Roche Diagnostics. The strips are then assigned a "code," which standardizes the reported result via a mathematical algorithm, thus minimizing lot-to-lot variability. No manual calibration of the system is required; each lot of strips comes with a code chip that stores the information needed for automatic calibration.

The CoaguChek XS System offers significant advantages in both convenience and reliability. It is a hand-held, battery-operated system that can perform a PT/INR blood test on a fresh whole blood sample from a fingerstick. A test strip is inserted into the meter and a blood sample applied to the strip. The test result is displayed in about one minute. The need for trips to the laboratory or for venipuncture is virtually eliminated.

The CoaguChek System by Roche Diagnostics has been used successfully since 1994 by healthcare professionals in anticoagulation clinics, physicians' offices, and home health agencies and since 1997 for self-testing. Now, there is the CoaguChek XS System available for self-testing. The materials that follow are designed to help you select appropriate users and train them to use the CoaguChek XS System properly.



# 2

## Materials for User Training

Roche Diagnostics has developed the following materials, provided in the product care kit, specifically for your use in training new users to self-test with the CoaguChek XS System:

### Training DVD

This program, which runs approximately 15 minutes, provides step-by-step instruction in setting up the meter, preparing for and performing a fingerstick blood test, and cleaning the meter. It is intended to be the basis of the training session. You may also use the DVD as a trainee selection aid; individuals who are unsure of what self-testing involves may be shown the DVD to help them decide if they want to go through training and try self-testing.

### CoaguChek XS System User Manual

A copy of the manual is provided with each CoaguChek XS Meter. It is intended to be used as an ongoing reference guide by users, but should also be used in training to familiarize trainees with the content and structure of the manual and make them comfortable with referring to it.

### Getting Started Guide

A Getting Started reference guide is included in each CoaguChek XS System Care Kit. It provides an easy reference for testing.

### Package Inserts

Both the test strips and lancet device have package inserts with information about proper storage and use. It is important to call the users' attention to the inserts during training.



# 3

## User Selection Guidelines

### OVERVIEW

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It is important that users be screened carefully before beginning a self-testing program. The following questions are designed to guide the physician, clinic nurse, or other healthcare professional in determining an individual's suitability for self-testing.

**Are specific diagnoses more appropriate for self-testing?**

No, the specific diagnosis is not necessarily indicative of who should or should not self-test. However, prior to beginning self-testing, users should be stabilized on anticoagulation medications such as warfarin. People with chronic conditions (for example, congestive heart failure, atrial fibrillation, prosthetic heart valve replacement) who will need frequent monitoring over a long period of time are certainly candidates for self-testing.

**What personal characteristics must the potential user have?**

The person must be reliable, compliance-oriented, and able to follow instructions.

**What do I look for in judging these characteristics?**

Consider the following:

- Does the person keep appointments?
- Does he or she comply with medication dosing and other elements of the treatment regimen?
- Is he or she capable of understanding the importance of testing and the details of the testing procedure?
- Are vision and motor skills adequate?

**What else should I consider?**

Look for motivated individuals who want to take an active part in managing their condition. Lifestyle factors may be important; people who travel, work, or find it difficult to get to the laboratory may be especially motivated to learn self-testing.

**Which individuals probably should not self-test?**

- It is up to the attending physician to determine which individuals are eligible for self-testing.
- Refer to the test strip package insert for current limitations of procedure.

**Is it appropriate to train a third-party tester?**

Caregivers for other individuals (for example, a spouse) may be trained. The caregiver should be screened using the same criteria.

**Once the potential user has passed the initial screening, what do we do next?**

Explain to the person in general terms what will be involved and provide an opportunity to ask questions. If he or she expresses interest, send a copy of the training DVD home or show it in the office. Stress that this overview is only intended to give a better idea of what self-testing involves and that more detailed training and follow-up support will be provided. Each potential user will be instructed on the fingerstick procedure and perform a fingerstick as part of the screening. If the person wants to continue participation after seeing the DVD and performing a fingerstick, he or she should be enrolled in a training class.

**Clinical Study Information**

A clinical study was conducted by Roche Diagnostics consisting of four visits to the clinical site. Informed consent and randomization occurred at Visit 1. Testing began at Visit 2. Ninety-one individuals completed at least one visit after Visit 1. The following table outlines the demographic information for the users who completed at least one visit after Visit 1.

Demographic	Number	Percent
Total number of users	91	100%
Caregivers	4	4.4%
Males	51	56%
Females	40	44%
Age range	32 – 89	100%
Mean Age	64 years	N/A
Age 65 – 69 years	16	17.6%
Age 70 – 74 years	13	14.3%
Age 75 years and up	16	17.6%
Education Level- Eighth grade or less through advanced college degree	91	100%
Median Education Level	Some college	N/A
On warfarin 3 – 12 months	19	20.9%
On warfarin 1 – 2 years	22	24.2%
On warfarin 3 – 5 years	23	25.3%
On warfarin > 5 years	27	29.7%
Atrial fibrillation	38	41.8%
Valve replacement	25	27.5%
Stroke/stroke prevention	7	7.7%
DVT	5	5.5%
Other heart conditions	6	6.6%
Other clotting disorders	10	11%

There were 107 people enrolled. A total of 88 people completed all four visits to the site. The reasons for drop-outs were as follows:

Reason for Drop-Out	# of Subjects
Felt it was too stressful	2
Didn't have time	3
Didn't want to use meter on his own	1
Didn't think he could learn to use meter	1
Was having knee surgery	1
Study terminated prior to Visit 4	1
Unknown	7
Disqualified due to target INR range outside of study protocol	3

## PERFORMANCE CHARACTERISTICS

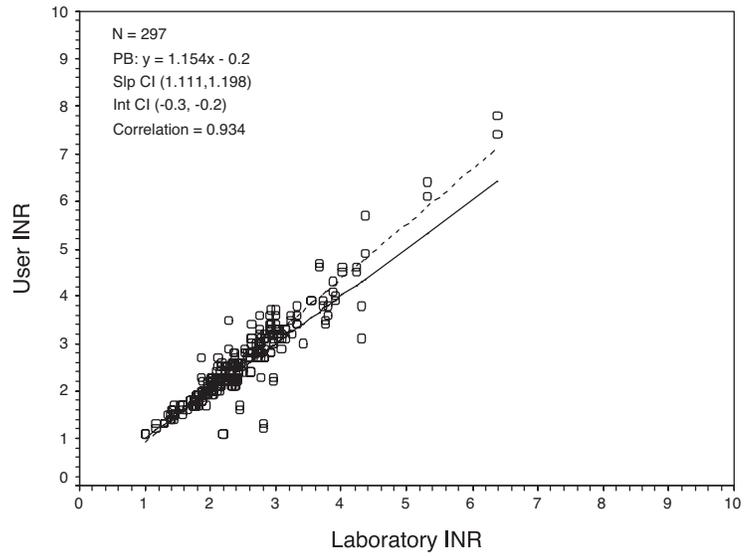
### Measuring Range:

The CoaguChek XS System has a PT/INR measuring range of 0.8–8.0 INR and 9.6–96.0 seconds.

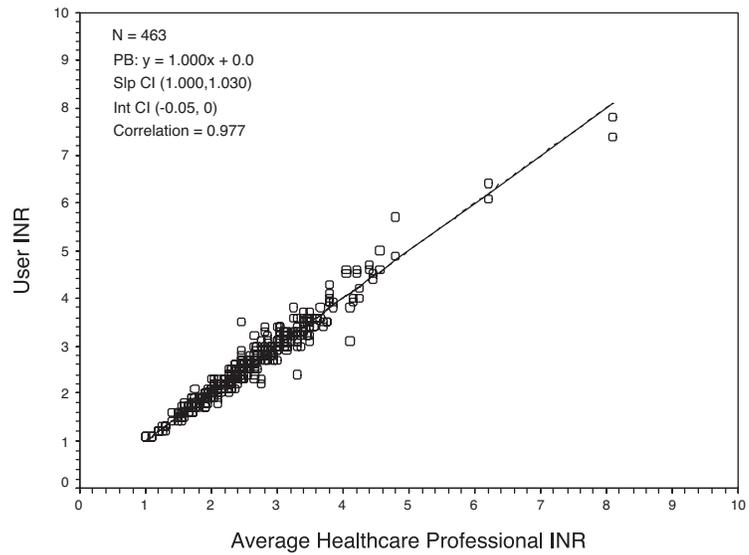
### Accuracy:

A study was conducted comparing test results obtained by trained users with those obtained by healthcare professionals, when both were using the CoaguChek XS System. The correlation was very good, as indicated by the following statistics: N=463, Slope=1.000, Intercept=0.0 and Correlation Coefficient=0.977. This study shows that trained users are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

Results Comparison: User vs Laboratory Result



Results Comparison: User vs Healthcare Professional



**Precision:**

A study was conducted and the precision of duplicates for capillary blood results was calculated for both trained users and healthcare professionals. The following results were obtained:

	<b>User Results</b>	<b>Professional Results</b>
N	214	249
Mean	2.57	2.52
SD	0.13	0.13
CV	5.13	5.36

This study shows that trained users are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

During the study, the following error rates were observed:

		<b>Visit 1</b>	<b>Visit 2</b>	<b>Visit 3</b>	<b>Overall</b>
Error 6	Test Strip Interference	0.8%	0.9%	0.5%	0.7%
Error 5	Blood Application	31.7%	23.9%	18.9%	25.2%
Error 4	Test Strip Unusable	0.8%	0.0%	2.8%	1.1%
Error 000	Time Exceeded	1.5%	1.3%	0.0%	1.0%
Error QC	Quality Control Failure	1.1%	0.0%	0.0%	0.4%
Unknown Error		1.1%	0.0%	0.5%	0.6%



# 4

## Training Users for Self-Testing

### PREPARATION

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The suggested time for each training session is two hours. If you prefer, you may break this into two one-hour sessions. Some trainers have found that it works well to have one educational session and one hands-on practice session. However the training is scheduled, it is important to allow plenty of time for trainees to practice the testing procedure and ask questions.

Training is mandatory. Users should not be permitted to take a meter home without satisfactorily completing a training session and passing the *Knowledge Test* and *Skills Checklist*.

Schedule training in a room free of distractions and with adequate facilities for trainees to take notes and practice with the meters.

Limit training classes to small groups so trainees can have individual attention during the practice session. It may be helpful to have an assistant.

Organize the presentation, gather the needed supplies, and make sure the meters are operational.

### SUPPLIES

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#### CoaguChek XS Testing Supplies

(one set for each trainee  
plus one for demonstration)

- CoaguChek XS System Care Kit, consisting of:
  - CoaguChek XS Meter
  - 4 AAA batteries
  - CoaguChek XS System User Manual
  - CoaguChek XS System Getting Started Guide
  - CoaguChek XS System Prothrombin Time Self-Testing Log Book
  - ACCU-CHEK® Softclix lancet device and lancets
  - CoaguChek XS System Training DVD

- CoaguChek XS PT Test Strips, consisting of:
  - A container of test strips
  - A test strip code chip
  - The test strip package insert

**Other Supplies**

- 70% isopropyl alcohol (rubbing alcohol)
- Or 10% bleach solution (1 part bleach to 9 parts water)
- Alcohol wipes
- Cotton balls or tissue
- Ordinary lint-free swabs/buds (available at pharmacies)
- Soft lint-free cloth
- Biohazard waste and sharps containers for disposal of supplies and lancets used during practice
- Disposable gloves for instructor and assistants to wear when assisting trainees in practicing fingersticks
- DVD player
- TV monitor
- Sufficient copies of the class outline, *Knowledge Test*, *Skills Checklist*, Log Book, *Certificate of Completion*, and key sections of the *CoaguChek XS System User Manual*, especially the *Error Messages* section

**TRAINING OUTLINE**

**User Training  
CoaguChek XS System**

Topic	Time
Introduction and Overview of Training Session	5 minutes
CoaguChek XS System Training DVD	15 minutes
Review of CoaguChek XS System and Operating Guidelines	10 minutes
Review System Set-Up	5 minutes
Testing Fingerstick Samples (including practice and completion of <i>Skills Checklist</i> )	40 minutes
Documenting Results on Log Book	5 minutes
Review Built-In Quality Control	10 minutes
Cleaning the CoaguChek XS System	5 minutes
<i>Knowledge Test</i>	10 minutes
Local Information and Wrap-Up	10 minutes

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**Introduction and Overview of Training Session**

1. Explain the importance of regular PT/INR testing.
2. Review the policy for certification. Explain that each trainee will be asked to successfully complete a *Knowledge Test* and *Skills Checklist*.
3. Review the agenda for the training session. (This outline may be copied and distributed to attendees as a detailed reference.)

**CoaguChek XS System Training DVD**

Show the 15-minute Training DVD, which gives an overview of the testing procedure, built-in quality control testing, and maintenance.

**Review of CoaguChek XS System and Operating Guidelines**

1. Review components of the CoaguChek XS Meter
  - Display panel
  - M (memory) button
  - ON-OFF button
  - Test strip guide cover
  - Test strip guide
  - Battery compartment cover
  - Code chip slot
  - SET button
2. Review contents of the CoaguChek XS PT Test Strips
  - A container of 6 test strips
  - The test strip code chip
  - The test strip package insert

3. Review operating conditions of the meter and proper storage conditions of test strips
  - Operate meter at room temperature, 59° to 90° F (15° to 32° C).
  - Operate meter with 10% to 85% relative humidity, without condensation.
  - Avoid bright sunlight.
  - Operate the meter on a flat surface, free of vibrations.
  - Use the provided carrying case.
  - Read the information packaged with the test strips regarding up to date product specifications and limitations.
  - Read the latest warfarin package insert for contraindications.

### Review System Set-Up

1. The CoaguChek XS System uses four AAA alkaline batteries, inserted into the battery compartment on the back of the meter. Explain the importance of entering the correct date and time. (Each time you run a test, the meter compares its date with the test strip's expiration date. If the test strip is expired, the meter displays an error message and prevents you from running a test.)
2. Discuss the purpose of the code chip included with each test kit. The code number on the test strip container must match the code chip number.
3. Review how to insert the code chip. Make sure the meter is off. Insert the code chip with the code number facing up until it snaps into place.
- 4 Explain that the meter has set-up options that users will not be asked to change. Appropriate settings have been programmed before they receive their meters.

### Testing Fingerstick Samples

(including practice and completion of *Skills Checklist*)

**Important:** If a caregiver assists with the testing procedure, it is recommended that the caregiver wash hands thoroughly and wear disposable gloves to prevent contact with the blood sample.

1. Review supplies needed for performing a self-test:
  - CoaguChek XS meter
  - Container of test strips
  - Test strip code chip
  - ACCU-CHEK Softclix lancet device and lancet

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2. Review how to prepare the lancet device.

Users pull off the cap and insert a new lancet. Provide these instructions: Twist off the lancet's protective cap. Put the cap back on the lancet device. To place the cap back on, line up the notch on the cap with the center of the semi-circle. Turn the dial so that the center of the semi-circle points to 5. (The lancet device has multiple depth settings, so the user can use the setting that works best. The higher the number, the deeper the penetration. The first time a person uses it, try a depth setting of 5. If the blood drop you get is not sufficient, try a higher setting.)

Instruct the user to press the plunger. A yellow dot appears in the release button, telling the user that the device is ready. Tell the user to set it aside while preparing for the fingerstick.

3. Review how to prepare for a fingerstick, instructing the user to:

- Wash the hand in warm, soapy water. This cleans and warms the hand.
- Massage the finger from its base.
- Let the hand hang loosely at his or her side for 10 to 30 seconds.
- Use these techniques until the fingertip has good color.

4. Review testing procedures, instructing the user to follow this process:

- The correct code chip must be in the meter. The code chip automatically provides the meter with the information that is specific to each lot of test strips. Each box of test strips comes with a matching code chip. Every time users open a new box of test strips, they will replace the code chip.
- Take a strip out of the test strip container. Close the container tightly.
- Slide the test strip into the meter's test strip guide in the direction of the arrows until it stops. The meter will turn on and the code number of the inserted code chip will flash on the display.
- Be sure the code number on the display matches the number on the test strip container, then press **M**.
- After **M** is pressed, an hourglass appears as the meter warms up. A flashing test strip, blood drop and a countdown appear when the meter is ready for a sample. The user has 180 seconds to apply a blood drop to the test strip.

5. Review collecting and applying the sample, instructing the user to follow this process:

- Massage the finger from the base until there is increased color in the fingertip. Keeping the hand down, press the tip of the lancet firmly against the side of the fingertip. Press the release button.
- The meter must be on a table. Find the target area on the test strip.
- **Within 15 seconds of sticking the fingertip, apply the blood drop from the fingertip to the target area from the side.** See the user manual for more information.
- Hold the blood drop to the test strip until the meter beeps. The flashing blood drop symbol will disappear and the result will appear on the display, which takes about a minute. **Do not add more blood or touch the test strip.**
- If the meter displays an error message rather than a test result, refer to the *Error Messages* section of the user manual to learn what to do next.
- To run a new test, use a new test strip and a different finger.

6. Review final testing steps, instructing the user to:

- Record the result in the Log Book. The meter will automatically store 300 results, with the date and time, in its memory.
- Clean up: remove the lancet from the lancet device. Place the used test strip and lancet in a puncture-proof waste container with a lid. Turn the meter off. If the meter is dirty, wipe it with a lint-free tissue and an approved cleaning solution.
- Always call the service provider with test results.
- If the result is outside the therapeutic range, call the doctor immediately.

7. Review the procedure to follow if the test results are not in the accepted PT/INR range:

- Explain to the user that a PT/INR result outside the therapeutic range is a result that is above or below the immediate follow-up values set by their doctor or designated healthcare professional. The user must contact his or her doctor immediately if this occurs. Include clear instructions on how the user is to contact his or her doctor and what the user is to do if the doctor is not immediately available. The user's

doctor should write these immediate follow-up values and follow-up instructions in the appropriate section of the user's Log Book.

*NOTE: Be sure the meter is properly set up, including date, time, and units of measurement, before the training session ends.*

### Review Built-In Quality Control

The CoaguChek XS System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality controls.

When the quality control test is finished, a check mark (✓) appears following the letters **QC**. Then the meter continues to run the blood test.

The built-in quality control helps you know that your test strip has not been damaged. If you receive a test error, look in the manual for an explanation of all test errors.

### Cleaning/Disinfecting the CoaguChek XS System

Review cleaning procedures with the user, instructing them to follow the process detailed in the following text. Failure to follow these procedures may cause malfunction of the meter.

- Clean the meter only when contaminated with blood.
- Do not use sprays of any sort.
- Ensure that swab or cloth is only damp, not wet.

*Useful tip: to prevent contamination, apply blood via side-dosing directly from the fingertip.*

To clean/disinfect the exterior of the meter:

- Use only the following items for cleaning/disinfecting the CoaguChek XS 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 disinfecting/cleaning solutions on the meter housing.**

1. With the meter turned off, wipe the meter's exterior clean.  
Apply cleaning agent for a contact time of >1 minute (refer to the corresponding product labeling)  
Do not let liquid accumulate near any opening. Make sure that no liquid enters the meter.
2. With a lint-free tissue, wipe away residual moisture and fluids after cleaning the exterior.  
Allow wiped areas to dry for at least 10 minutes before performing a test.

To clean/disinfect the 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.
2. Hold the meter upright with the test strip guide facing down.  
Clean the easily accessible areas with a cotton swab.  
Apply cleaning agent for a contact time of >1 minute (refer to the corresponding product labeling)  
Be sure the swab is only damp, not soaking wet, to ensure excess fluid does not enter the meter.  
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 cover and make sure it snaps into place.

## TESTING THE TRAINEES

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1. Complete the *Skills Checklist*, included in this package, after observing each trainee during the hands-on practice session. One or more assistants may be helpful in completing the checklists without slowing down the class.
2. Have trainees complete the *Knowledge Test*, included in this package, at the end of the training presentation and practice sessions.
3. Score the test with the answer key and review any areas of confusion.
4. Develop a plan before the training class for remedial action if trainees do not perform adequately on either of the tests. In some cases, it may be necessary to return the trainee to a laboratory testing regimen.

The *Skills Checklist* and *Knowledge Test* master forms can be copied as needed and are included in the back of this booklet.

## CERTIFICATE OF COMPLETION

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Each trainee who successfully completes the class and the tests should be given a certificate. A certificate that can be copied as needed is included in the *Forms* section at the back of this booklet.

## FOLLOW-UP VISITS

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Remind all trainees they are required to return for two follow-up visits where they will demonstrate their knowledge of self-testing with the CoaguChek XS System.



After completing the training class and beginning self-testing, users should be monitored periodically by a trained healthcare professional to be sure their testing technique is correct and the meter is performing properly. Suggested frequency for monitoring is every six months. The following procedure may be useful:

- Establish a reminder system that prompts you to contact each user at 6-month intervals.
- Make an appointment for the user to come to the clinic or office.
- Ask the user to bring the CoaguChek XS meter, testing supplies, and Log Book.
- During the interview, record your observations on the 6-month Performance Evaluation form.
- Inspect the meter thoroughly.
- Observe the user cleaning the CoaguChek XS meter. If necessary, stress the importance of maintaining a regular cleaning schedule.
- Observe the user performing a blood test. If necessary, offer suggestions for improvement. A 2-week follow-up is recommended whenever competency needs reassessment.
- The healthcare professional will perform a user blood test after the trainee performs a self-test. The test should match within 30%; this verifies that the meter is performing properly. If this test indicates a problem with the meter or test strips, repeat the test. If the result is still in question, please contact the Roche Diagnostics Technical Service Center 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.
- If the test result is within range and the user performs all tests satisfactorily, make an appointment for six months in the future.



# 6

## Forms

### OVERVIEW

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#### Introduction

The following forms are included as part of the CoaguChek XS System training for self-testing.

These forms should be used as originals. Please feel free to copy them as needed.

- *Skills Checklist*
- *Knowledge Test*
- *Answer Key*
- *Certificate of Completion*

# COAGUCHEK XS SYSTEM SKILLS CHECKLIST

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Trainer should check each activity as it is demonstrated or described.

## Assembles Equipment

- CoaguChek XS meter
- Container of test strips
- Test strip code chip
- ACCU-CHEK Softclix lancet device and lancet

## 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

- Properly prepares lancet device
- Turns meter on
- Inserts test strip
- Obtains blood sample correctly
- Applies blood to test strip correctly
- Reads result
- Records result
- Tries to correct any problem should there be an error message, using the solutions described in the user manual
- Is aware of the 24-hour Technical Service number at 1-800-428-4674 if problem persists
- Properly discards used test strip and blood-drawing supplies

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# COAGUCHEK XS SYSTEM SKILLS CHECKLIST

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## Recalls Results from Memory

- Correctly recalls results stored in memory

## Problem Solving

- Refers to *Error Messages* in the user manual when a problem occurs

## Cleaning

- States minimum cleaning frequency
- Demonstrates exterior cleaning procedure as stated in the user manual
- Properly cleans test strip guide

## Battery Replacement

- Demonstrates removal and replacement of batteries

Trainee Name: \_\_\_\_\_

Training Date: \_\_\_\_\_

Training Site: \_\_\_\_\_

Trainer Name: \_\_\_\_\_

Trainer Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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# COAGUCHEK XS SYSTEM KNOWLEDGE TEST

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**Mark “T” if the statement is true and “F” if the statement is false.**

- \_\_\_\_ 1. When coding the CoaguChek XS Meter, you must use the code chip from the same test strip container that you are using.
- \_\_\_\_ 2. After removing a 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 strip until the meter beeps.
- \_\_\_\_ 4. The sample must be applied to the test strip within five minutes of removing it from the container.
- \_\_\_\_ 5. INR is a reporting format that stands for International Normalized Ratio.
- \_\_\_\_ 6. Every time a blood test is performed, the meter also performs a built-in quality control test.
- \_\_\_\_ 7. If the built-in quality control test fails, the meter will still give a test result.
- \_\_\_\_ 8. The most recent user result appears first when reviewing memory.
- \_\_\_\_ 9. CoaguChek XS test strips may be stored at room temperature until the expiration date printed on the container.
- \_\_\_\_ 10. The CoaguChek XS Meter stores up to 50 results with time and date.

**Please answer the following questions:**

11. How do you determine when it is the correct time to perform the fingerstick and apply blood to the strip?

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12. What would cause Error 3 to appear on the display?

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13. What would cause Error 5 to appear on the display?

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14. After inserting a test strip, the code flashes on the display.

What is the next step?

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15. Why is it important to apply blood to the test strip within 15 seconds of sticking the finger?

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Trainee Name: \_\_\_\_\_

Training Date: \_\_\_\_\_

Training Site: \_\_\_\_\_

Trainer Name: \_\_\_\_\_

Trainer Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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# ANSWER KEY

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## For CoaguChek XS System Knowledge Test

1. T
2. T
3. T
4. F – The sample must be applied to the test strip within 10 minutes of removing the strip from the container.
5. T
6. T
7. F – If the built-in quality control does not pass, a flashing “QC” will appear on the display.
8. T
9. T
10. F – The CoaguChek XS Meter stores up to 300 test results with time and date
11. After the meter warms up, a flashing test strip and blood drop appear. A countdown of second also appears on the screen.
12. Error 3 indicates that the strip is expired. Ensure that the date is set correctly on the meter. If it is incorrect, set the correct date. If the date is correct, turn the meter off and remove the code chip and the test strip. Use the code chip and a test strip from a new box of test strips.
13. Error 5 indicates an error applying blood to the test strip. It is caused by not having a large enough drop of blood. When applying blood to the test strip, massage your finger until you have a good blood drop and hold your finger against the test strip until the meter beeps.
14. Confirm that the code flashing on the display matches the code on the container of test strips you are using. Then press the **M** button to continue the testing process.
15. After 15 seconds your blood may begin to clot, which could lead to an incorrect result.

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# CoaguChek<sup>®</sup> XS System



## *Certificate of Completion*

presented to

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for successfully completing Self-Testing training on the

*CoaguChek<sup>®</sup> XS System*

Dated: \_\_\_\_\_

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Certified Training Consultant

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