

# CoaguChek<sup>®</sup> XS Pro PT Controls

REF 04625382160

4 bottles each of Level 1 and Level 2 Quality Control lyophilized plasma, 8 diluent-filled droppers, 1 Quality Control Code Chip

For optional liquid quality control testing using CoaguChek XS PT Test [REF] 04625315160 with the CoaguChek XS Pro System [REF] 05530199160 or the CoaguChek XS Plus System [REF] 05021537001 by professional healthcare providers.

## Introduction

Roche Diagnostics has available optional liquid quality controls for the CoaguChek XS Pro System and the CoaguChek XS Plus System. These controls assist with meeting regulatory compliance requirements, as applicable to your facility. The term "System(s)" hereafter will refer to both the CoaguChek XS Pro System and the CoaguChek XS Plus System.

Read these instructions thoroughly before using the controls.

To ensure that you are using the test strips and the meter correctly, read the appropriate System *User Manual*.

## Reagent

- Each control bottle contains lyophilized non-human plasma with varied levels of coagulation factors, stabilizers, and preservatives.
- Each diluent-filled dropper contains a calcium chloride solution with preservatives.

## Precautions and Warnings

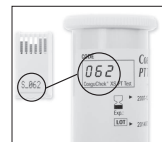
1. For *in vitro* diagnostic use. Do not take internally.
2. Incorporate the requirements of the appropriate licensing or accrediting body into your quality control program.
3. Exercise the normal precautions required for handling all laboratory reagents.

## Control Storage and Stability

- Store controls at 2 to 8 °C (36 to 46 °F). DO NOT FREEZE.
- Unopened, lyophilized controls that are stored at 2 to 8 °C are good until the expiration date.
- Controls are stable for 30 minutes after adding the diluent.

## Before Testing

If you are using test strips from a new unopened container, you will need to change the Test Strip Code Chip. The meter recognizes only those test strips that match the Test Strip Code Chip.



**NOTE:** The three-digit code on the test strip container should match the code on the Test Strip Code Chip.

To install the Test Strip Code Chip, follow the instructions in the appropriate System *User Manual*.

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

## Step 1: Getting Ready to Test

You will need the CoaguChek XS Pro meter or the CoaguChek XS Plus meter and these supplies:

- CoaguChek XS PT Test Strip(s) with matching Test Strip Code Chip
- CoaguChek XS Pro PT Controls: Level 1 and/or Level 2 with matching Quality Control Code Chip
- Diluent dropper(s): one for each control to be run
- Scissors

Refer to the appropriate System *User Manual* for more details about the components and procedures of the System.

## Step 2: Preparing the Control

1. Insert the Quality Control Code Chip into the meter. This tells the meter the acceptable ranges for this box of controls.
2. Remove the screw-cap and rubber stopper from the quality control bottle. Label the bottle with the **date and time** that you reconstitute it.
3. Using scissors, cut off the tip of the dropper at the **end of the stem**. Hold the dropper a safe distance from your face.

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

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

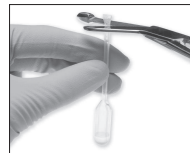
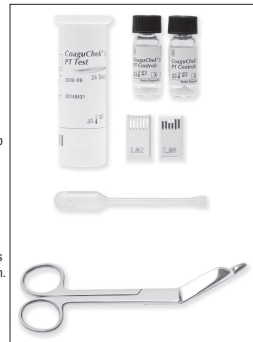
5. Gently squeeze the bulb to dispense all of the contents of the dropper over the dried material. Do not allow the dropper to touch the dried material. **IMPORTANT: Make sure you dispense ALL the diluent.**

6. Remove the dropper from the bottle. Do not discard the dropper. Replace the cap first and gently swirl the bottle to dissolve the dried material. Do not shake or invert the bottle. Let the bottle sit undisturbed for at least a minute to ensure that the dried material dissolves completely.

**Use the reconstituted quality control solution within 30 minutes** from the time the diluent is added.

## Step 3: Performing the Test

1. When you are ready to test, remove 1 strip from the container and **immediately close the container. Make sure it seals tightly.** **IMPORTANT:** Do not open a container of test strips or touch a test strip with wet hands or wet gloves. This may damage the test strips. You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test.
2. Insert test strip as far as you can into the meter. This powers the meter ON.
3. Press QC-TEST. The meter warms the test strip for about 30 seconds. Then the meter begins a countdown. You have 180 seconds to apply a liquid quality control solution to the test strip.
4. The meter automatically checks to see if you have the right Test Strip Code Chip. The three-digit code on the test strip container must match the number on the Test Strip Code Chip before the test can be run. If you are using test strips from a new, unopened container, you will need to change the Test Strip Code Chip.



5. When the meter is ready for the sample, gently swirl the control bottle once or twice to mix the control solution. Do not mix the solution with the dropper. Draw control solution into the dropper and put one drop of the liquid on top of the target area (clear area of the test strip). Do not add more control.



6. Do not touch or remove the test strip while the test is in progress. The flashing dropper symbol changes to an hourglass symbol when the meter detects sufficient sample. If the meter's beeper is enabled, a beep sounds as well.

If any control remains in the dropper after you dose the test strip, return the remaining control material to the control bottle. Save extra control until after the test result is obtained, in case the control test needs to be repeated.

- The result appears in approximately one minute.
7. Record the result. After you verify the validity of the control result, discard the test strip, dropper and the reconstituted bottle of quality control solution.
8. Remove the Quality Control Code Chip and store it with the opened box of controls. Re-insert the Test Strip Code Chip.
9. Power the meter OFF.

**NOTE: If you need to repeat a test, use a new test strip.**

## Expected Results

- The meter displays the acceptable control range and the result. The reading is automatically saved in the memory of the meter.
- The system is working properly and all handling has been done correctly when the test results obtained are within the acceptable control range.

## Unacceptable Results

An out-of-range result is indicated by an arrow. An arrow pointing up means the result is too high. An arrow pointing down means the result is too low. To resolve out-of-range results or error messages, check for the following:

- Controls may be expired or were stored improperly.
- The control may not have been used within 30 minutes of reconstitution.
- Make sure you run the test within 10 minutes of removing the test strip from its container.
- You may not be doing the test correctly. Repeat the control test, using a new test strip. Carefully follow the instructions in the appropriate System *User Manual*.
- If you follow all these guidelines and your results are still unacceptable, call Roche Diagnostics Technical Service Center at 1-800-428-4674.

## Performance Characteristics

Control precision was determined at three external sites. Operators at each site ran two levels of liquid controls upon opening a container of test strips, and again at the end of each container of test strips. The results are shown in INR.

Control Level 1	N	Mean	SD	CV
Site 1	202	1.17	0.05	3.87
Site 2	176	1.18	0.04	3.44
Site 3	160	1.19	0.03	2.22
Overall	538	1.18	0.04	3.37

Control Level 2	N	Mean	SD	CV
Site 1	202	2.95	0.14	4.61
Site 2	173	2.99	0.11	3.66
Site 3	160	2.91	0.09	3.27
Overall	535	2.95	0.12	4.10

## Additional Information

Refer to the appropriate System *User Manual* for additional information about your system. If you still have questions, call Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

## Return Policy

If there is a problem with the CoaguChek XS Pro PT Controls, you may be asked to return them, along with the Control Code Chip, to Roche Diagnostics. Before returning, call Roche Diagnostics Technical Service Center at 1-800-428-4674. You will be mailed a return authorization label which must be placed on the shipping carton.

## Limited Warranty

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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