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

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.
2. Remove the test strip from the cover and discard the cover into the trash.

This tells the meter the acceptable range for this box of controls.

3. Using scissors, cut off the tip of the dropper using the scissors provided.

This tells the meter to dispense the correct amount of sample.

4. Insert the dropper into the meter.
5. Dispense the reconstituted quality control solution into the test strip.

The meter begins a countdown. You have 180 seconds to apply a liquid quality control solution to the test strip.

**Step 3: Performing the Test**

1. Insert the test strip into the meter.
2. Insert the test strip into the meter.

You must use the last 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.

When the meter is ready for the sample, gently swirl the control bottle once in its original container. Do not open the solution with the dropper.

Drive control solution into the dropper and put one drop of the liquid on top of the target area (clean area of the test strip). Do not add more control.

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 buzzer is emitted, 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 bottles. Save extra control until after the test result is obtained; in case the control test needs to be repeated.

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1. 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.
2. Remove the Quality Control Code Chip and store it in the opened box of controls. Reinsert the Test Strip Code Chip.
3. Power the meter OFF.

**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 alarm. An arrow pointing up means the result is too high. An arrow pointing down means the result is too low. If one result is out-of-range results or error messages, check for the following:

- Controls may have expired or stored improperly.
- The control may not have been used within 30 minutes of reconstitution.
- Make sure you dose the test within 10 minutes of removing the test strip from the 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.

**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 1-800-428-4464. You will be asked to provide a description of the problem and the error code.

**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 1-800-428-4464. You will be asked to provide a description of the problem and the error code.

**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 throughout 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.