CoaguChek XS Pro PT Controls

CoaguChek XS Pro PT Test Kit (8452351510) with the CoaguChek XS Pro System (9550019160) or CoaguChek XS Plus System (9552153701) by professional healthcare providers.

Before using the test strips and the meter correctly, you should refer to the appropriate System User Manual for more details about the components and procedures of the System.

Step 2: Preparing the test
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 reconstituted 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 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.

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.
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.

CoaguChek XS Pro PT Test Kit (8452351510) with the CoaguChek XS Pro System (9550019160) or CoaguChek XS Plus System (9552153701) by professional healthcare providers.

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Step 2: Preparing the test
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 reconstituted 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.
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2. Insert test strip as far as you can into the meter. This powers the meter. 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.
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4. 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.

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”/“user” will refer to both the CoaguChek XS Pro System and 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, you should refer to the appropriate System User Manual.

Reagents
Each test strip contains lyophilized non-human plasma with varied levels of coagulation factors.
Each dried-filled dropper contains a calcium chloride solution with preservatives.

Precautions and warnings
For in vitro diagnostic use. Do not take internally.
Requirements of the appropriate licensing or accrediting body should be incorporated into your quality control program.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.
For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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.

Materials provided
4 bottles Level 1 Quality Control lyophilized plasma
4 bottles Level 2 Quality Control lyophilized plasma
4 dried-filled droppers
1 Quality Control code chip

Materials required (but not provided)
CoaguChek XS Pro System (9550019160)
or CoaguChek XS Plus System (9552153701)
CoaguChek XS PT Test (8452351510)

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. To install the test strip code chip, follow the instructions in the appropriate System User Manual.

NOTE: The three-digit code on the test strip container should match the code on the test strip code chip.

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

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