CoaguChek XS Pro Medical Mobile Unit: Quality Control Test Procedure

PURPOSE:

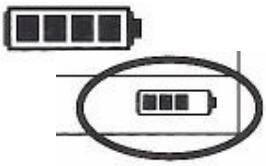
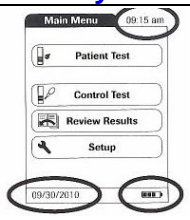
This procedure provides instruction on how to perform the liquid quality control testing for PT INR using the CoaguChek XS Plus / Pro instruments.

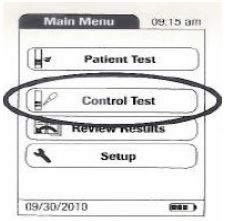
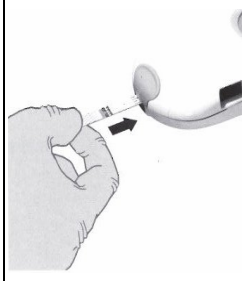
REQUIRED MATERIALS:

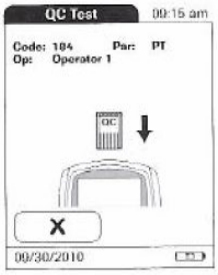
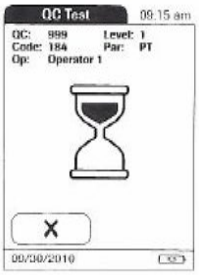
- CoaguChek® XS Plus / Pro Instrument
- CoaguChek® XS PT Test Strips with supplied code chip marked "S" and code number
- CoaguChek® XS PT Lyophilizaed Control with supplied code chip marked "C" and code number, diluent-filled dropper
- Scissors
- Gloves
- Sharps container
- Paper towel for working surface
- Caviwipes disinfectant wipes

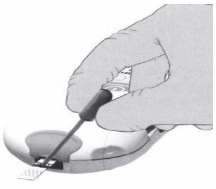
Note: One Level of Quality Control Solution is used at PHSA for the Coaguchek XS / XS PLUS / XS PRO

	Action	Related Documents
	Note: Liquid Quality Control is run at a minimum once per week on the CoaguChek XS System, or with a new vial of test strips	
1.	**Assemble supplies.** o Remove control vial and diluent filled dropper from refridgerated storage. o Allow to sit at room temperature for 10 minutes. o Quality control (QC) code chip supplied with the QC matches the number on the lyophilized control bottle.	CoaguChek XS Pro Medical Mobile Unit: Appendix B - CoaguChek XS PT Quality Control
2.	**Check that the Test Strip Code is Current.** o Each Lot number of Coaguchek XS PT Test Strips has a specific Code number. o Each box of test strips is supplied with a code chip with the corresponding code number. o *Test strip code chips are marked with an "S".* 	
3.	**Test strip chip code in the meter is current.** o When switching to a new lot number of test strips it is mandatory to insert the new code chip into the meter before you perform the first test (patient or quality check). o Insert the code chip into the code chip slot, with the "S" facing up, until it snaps into place. 	
	Note: The manufacturer recommends that a code chip is left in the meter to protect the electrical contacts from becoming dirty.	

4.	**Press the On/Off button.** o Instrument initializes and performs electronic checks.	
5.	**Check the battery level.** ***If battery level shows*** o 1 bar left in battery icon proceed to the next step o < 1 bar left in battery icon, you can perform a patient test. o Replace batteries for next test or place on charger base once testing is complete. 	
6.	***If*** / ***then*** Coaguchek XS — Proceed to step 9. Coaguchek XS Plus — Proceed to step 8. Coaguchek XS Pro — Proceed to next step.	
7.	**Operator ID entry page appears.** o Manually enter or scan POCT OPID. o Press "√" to accept if a manual entry. o IR scanner on right side of meter.   **Scan from a distance of approximately 10 cm. The meter beeps once the barcode has been read successfully.**	
8.	**Main Menu screen appears** o Check that the date and time are correct. o Make any corrections to the date or time if required at this time, before proceeding to the control test. 	
9.	**To prepare CoaguChek® XS PT Control - match control code chip with vial.** o CoaguChek XS PT Control is at room temperature for a minimum of 10 minutes. o Open the lid of the control vial and carefully remove the rubber stopper. o Be careful not to remove any of the lyophilized control plasma. o Set cap and rubber stopper aside on paper towel. Do not discard. o Hold the pipette with the sealed pipette neck pointing upward. Ensure that the diluent contents are in the bulb. o Cut off the end of the pipette cap with scissors. o Gently squeeze the bulb of the pipette to dispense the entire contents of the dropper onto the lyophilized control plasma. o Do not allow the dropper to touch the dried material. o Set pipette aside on paper towel. Do not discard. Close the container. o Swirl the vial 2 to 3 times using a circular motion to completely dissolve all of the control plasma. Do not shake the vial or turn it on its side o Control solution is ready in one minute. Use within 30 minutes.	

	 **Match Control Code Chip**	 **Cut end of diluent pipette**	 **Add contents of pipette**	 **Replace lid, swirl Allow to sit 1 minute**	
10.	***If***			***then***	
	Coaguchek XS			Proceed to step 12	
	Coaguchek XS Plus / Pro			Proceed to next step	
11.	**Press Control Test** o Hourglass icon appears briefly followed by the Test Strip icon. o Test strip icon prompts you to insert a test strip. o Remove test strip from vial. o Touch only the end of the test strip. o Place face up onto the paper towel to avoid o contamination of the sample area. o Immediately replace the container lid. o Use the test strip within 10 minutes of removing it from its container. *Note: Exposure to external influences such as humidity may deteriorate the test strips and can lead to error messages or incorrect results. Always close the strip container immediately after removing a test strip. If a test strip vial is found open – discard. Do not use.*			 	
12.	**Insert the test strip into the meter** o CoaguChek XS PT lettering on the test strip is facing upwards. o Test strip is inserted in the direction indicated by the arrows. o Test strip is inserted as far as it will go. o Beep tone detects that the test strip is in place. *Note: If test strip is not detected, remove the test strip and reinsert into the meter.*				
13.	***If***	***then***			
	Coaguchek XS	Confirm Current Test Strip Code is correct. • Press “M” button to accept. • Proceed to step 16.			
	Coaguchek XS Plus / XS Pro	Proceed to next step.			

14.	**Control Code Chip** o Select the QC Code Chip number from the list on the screen o The QC Codes currently in the memory of the Coaguchek XS Pro will be displayed. **New Lot number and New Control Code** o Select "New Code" when a new Lot number with new Code Number of QC is being used. The Control Chip icon prompt will appear. o To program the Coaguchek XS Pro meter with a new Control Code, remove the Test Strip Code Chip currently in the meter. o Replace with the new Control Code Chip. Note: Control Chips are marked "C" with the corresponding code number.	  **Screen with Control Code Chip Icon.**	
15.	**QC Test screen appears** o QC lot number, QC Code number, Level 1 and Operator ID number appears at the top of the screen. (Coaguchek XS Plus / Pro instruments) o The hourglass icon shows that the test strip is warming up. o Do not apply Aqueous Control solution at this stage or an error code will appear and the control test process will need to start from the beginning with a new test strip. *Note: Once the warming-up process is complete, a further beep tone indicates the instrument is ready for QC sample application.*		
16.	**Apply control solution to the CoaguChek XS PT test strip.** o Pipette icon flashes to indicate that the monitor is ready. o Simultaneously a 180 second countdown begins. o Swirl the Control solution in the vial well 2 to 3 times in both directions for adequate mixing. o Using the pipette, draw up the dissolved contents of the vial, and further mix the control solution by drawing up solution into the pipette and dispensing into the vial. Perform this step at least twice. o Apply a large hanging drop (approximately 8 uL) of control solution from the pipette to the sample application area of the test strip. o The monitor beeps when enough control solution is applied. o The test cycle starts and the hourglass icon replaces the flashing pipette icon.		

	 180 second count down	 Draw up control contents into pipette	 Apply large drop – approx. 8 uL required	 Test incubation	

17. QC Result is displayed.

If	*then*
Coaguchek XS	QC results is displayed on the screen. There is no indicator that this is a QC or a Patient Test result. Refer to current QC range for an indication of pass or fail. Proceed to step 18.
Coaguchek XS Plus / XS Pro	See below.

- o INR units. (chosen unit of measure)
- o QC lot number, QC Code number, Level 1 and Operator ID number appears at the top of the screen as before.
- o QC range is displayed for the specific Lot number of Control solution.
- o QC test saved in memory with date and time.

18. Review the QC Result

If result is	Then
within QC range	o Report result on QC Record sheet. o CoaguChek XS Pro is ready for patient testing. o Proceed to next step.
not within QC range	o Report result on QC Record sheet. o For the Coaguchek XS Pro, the displayed result flashes with an arrow up (too high) or arrow down (too low). Review and confirm the following: o Is the control material properly stored? o Was the control material at room temperature before preparation? o steps taken to prepare the quality control material. o was the control test performed after 1 minute and within 30 minutes of control solution preparation? o Are the test strips stored correctly? o Is the test performed within 10 minutes of removing the test strip from the container? o Was the test strip stored in an air tight container with the stopper on correctly? o Is the test strip guide dirty? Clean the test strip guide as per instruction if required. o Repeat with a new test strip. o Correct any actions taken to perform QC testing as required.

19.	**To Add a Comment (Coagucheck XS PLUS / PRO)** o **Not mandatory** o To add a comment do not remove the test strip o In the Test Screen touch the "bubble" icon on the bottom right of the screen o In the Comments screen select the appropriate canned comment o Touch the checkmark to save *Note: Once the test strip is removed a comment cannot be added or edited.*		
20.	**To Remove the test strip from the meter** o Touch the menu icon at the bottom of the patient result screen (Diagram Step 14) o You will be prompted to remove the test strip. o Discard the test strip and lyophilized Control solution as per institutional guidelines for biohazardous waste disposal.		
21.	**Turn the monitor off.**		
22.	**Replace the Control Code Chip if previously inserted into the meter with the Test Strip Control Code.**		
23.	**Clean the surface of the meter with 2% Chlorhexidine in 70% isopropyl alcohol prep pad or Caviwipe disinfectant Wipes.**		CoaguChek XS Pro Medical Mobile Unit Appendix G - CoaguChek XS Pro Meter Cleaning

References:

- CoaguChek® XS Plus Operator Manual, Roche Diagnostics GmbH D-68298 Mannheim, Germany 2009-11
- CoaguChek® XS PRO Operator Manual, Roche Diagnostics, 201 Boul, Armand-Frappier, Laval, Quebec, H7V 4A2 Canada 2010-10
- CoaguChek® XS Operator Manual, Roche Diagnostics, 201 Boul, Armand-Frappier, Laval, Quebec, H7V 4A2 Canada 2011-03
- CoaguChek® XS PT Test Strip Directional Insert, Roche Diagnostics, 201 Boul, Armand-Frappier, Laval, Quebec, H7V 4A2 Canada 2010-05
- CoaguChek® XS PT Controls Directional Insert, Roche Diagnostics, 201 Boul, Armand-Frappier, Laval, Quebec, H7V 4A2 Canada 2009-12

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0		New document	10 Dec 2012	Elvira Kozak	Dr. Cathy Halstead
1.1		Addition Coaguchek XS PRO		Elvira Kozak	
1.2		Manual review & update	16 Sept 2013	Elvira Kozak	
1.3	Minor	Document title and number change. Upload to QMS document control	28 Dec 2016		Dr. Benjamin Jung

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