CoaguChek XS Pro Medical Mobile Unit: Quick Reference Guide

Assemble on a paper towel

Supplies
-Coaguchek XS Pro meter
- Coaguchek XS PT Test strips
- Test Strip Code Chip
- Capillary puncture device or
- Venous collection non-additive syringe
- Disinfectant swab
- Gauze/Tape

Patient Test

QC is completed within a one week period prior to a patient test.

QC is not complete then:

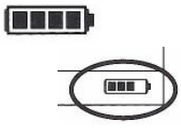
- Prepare QC solution Level 1
- Proceed to Patient & QC Testing
- Test the QC solution and document QC PTINR on QC Record.

Coaguchek XS Pro Patient Test

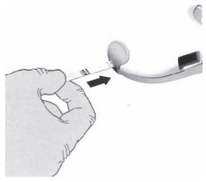
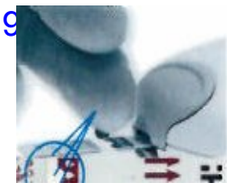
- **Check that the Coaguchek XS PT Test Strip is within expiry & the current Lot # in use.**

Note: For Patient Testing, identify & ready the patient first before proceeding

Patient & QC Test Preparation - Steps 1-5

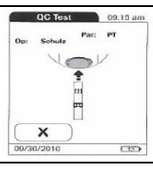
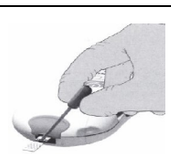
1	2	3	4	5
				
MATCH Coaguchek Test Strip vial & code chip. Remove test strip & place on paper towel. Up to 10 min before use. Hold bottem of test strip.	**CHECK:** Current Lot number and corresponding Code Chip is in the meter. Code Chip marked "S" with corresponding #	**PRESS ON/OFF** button On meter initialization - **CHECK** battery level, if <1 segment replace 4 x AA batteries - back of meter.	**ENTER POCT Operator ID #** (barcode) Manually Enter or Scan Press "√" to save.	**Main Menu Screen** Press Patient Test or Control Test

Patient Test – Steps 6-10, 21 & 22

6	7	8	9	10
				
Identify Patient with a minimun of 2 identifiers Name, DOB, MRN Enter Patient ID – Medical Record Number Press "√" to save. **Test Strip incubation** Hourglass icon appears briefly followed by Test Strip icon.	**Insert Test Strip** Test Strip Icon prompts to insert a Test Strip Insert into the strip guide, bottom of meter. Hold test strip at the bottom end only. DO NOT TOUCH clear sample application area or top end with arrows.	**Test Strip incubation** Hourglass icon: Test Strip is warming @ 180 sec countdown: meter is ready for application of patient sample. *You can only now perform the puncture – capillary or venous – per institutional guidelines.*	**Perform puncture** & apply sample drop (min 8 uL) within 15 sec of the puncture. **Capillary** direct or non-additive capillary rod – use 1st drop **Venous** - non-additive syringe – dispense 4 drops – use 5th drop.	**Sample incubation** Hourglass icon appears Patient information retained on the screen QC symbol appears & indicates internal QC OK **INR displays <1min** Range = 0.8-8.0 Reportable= 0.8-4.0 Alternate method if>4.0 HCT is within 0.25-0.55

Quality Control Test – 11-22 (QC Test is within QC range prior to patient testing.)

11	12	13	14	15
You will need to: - Remove from 2-8^{0}C storage - Bring to Room Temp. Approx 10-15 minutes. - Level 1 QC lyophilized material in vial - Pipette/Dropper with Diluent - QC Code Chip - scissors				
	MATCH QC code with code # on QC vial. Remove lid & rubber stopper from vial. Place on paper towel Avoid loss of QC material	**HOLD PIPETTE** upright with diluent in the bulb end. Cut off the end of the pipette cap with scissors	**DISPENSE** bulb contents from pipette onto the lyophilized QC material Set aside pipette on paper towel.	**RECAP QC** with rubber stopper and lid. Gently swirl 2 – 3 times. Do not shake. **Control ready in 1 min.** Use within 30 min.

16	17	18	19	20
				
Test Strip incubation Hourglass icon appears briefly followed by Test Strip icon. **Insert Test Strip** into the strip guide, bottom of meter. Hold test strip at the bottom end only.	**Select QC Code Chip #** To program a new Control Code # Remove strip code chip PRESS NEW Insert New Control Code Chip "C".	**SWIRL VIAL 2-3 times** in one direction, and repeat in opposite direction. Hold pipette & gently squeeze the bulb, insert into the control vial. Draw up solution.	**Apply large drop – approx. 8 uL** onto the test strip application area. Coaguchek Pro will beep. Hourglass icon appears. QC symbol appears for internal QC check.	**QC result is displayed** If QC within range given you can proceed to a patient test. If QC not within range proceed to the trouble guide

This is a controlled document for CW use only. Any printed copies are uncontrolled unless specified. Please refer to Lab QMS

21

Example Patient Test

To add a Comment for either patient or control

Not Mandatory

Touch "bubble" icon bottom right of screen

22

Choose a Comment

Select appropriate canned comment

Press "√" to save.

Touch Menu Icon to Remove test strip.

Clean up

Discard Test Strip and Control Vial in biohazardous waste.

Ensure Test Strip Code Chip is left in the meter to protect electrical contacts.

Clean surface of the meter with 2% Chlorhexidine in 70% isopropyl alcohol prep pad or Caviwipes. Wipes are damp to the touch – avoid pooling of solutions.

Patient Result Review

If "c" is displayed along with the result – low hematocrit (<25%) or blood contamination of water or residual disinfectant can be the cause. Repeat with a new puncture site, test strip and sample application.

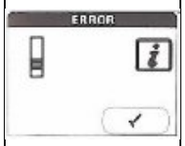
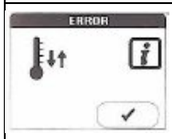
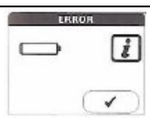
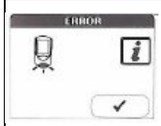
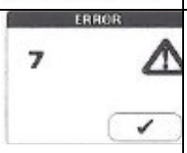
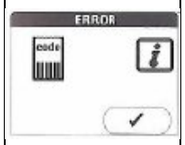
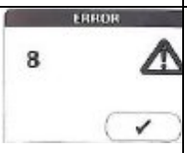
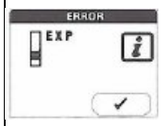
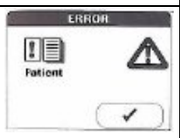
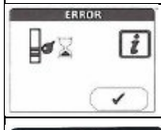
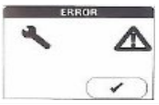
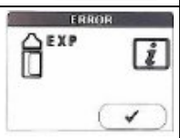
Battery Change – 4 x 1.5 volt "AA" alkali-manganese batteries

Meter if off. Open tab on the reverse side of the Coaguchek XS Pro.

Slide the battery compartment cover upward and remove. Replace the batteries, following the guide inside the cover. Close the compartment cover.

Troubleshooting Guide

Limitations of Heparin is 0.8 U/L; Low Weight molecular Heparin up to 2 IU/L antifactor Xa activity is acceptable for testing with Coaguchek XS System. HCT is within 0.25-0.55

ERROR	DESCRIPTION	SOLUTION	ERROR	DESCRIPTION	SOLUTION
	**Error: Test strip** Test strip already in meter when the meter was turned on. Test strip unusable. Test strip is not a CoaguChek XS PT test strip. *Note: Confirm correct test strip in use*	Remove test strip. Error message disappears, meter is ready. Reinsert test strip when prompted. Error appears, discard the test strip & repeat.		**Error: Measurment** Measurement error. Note: Product alert may indicate an INR > 8.0 RR2013-16/PAN13-06_d June 2013	Turn the meter off. Remove test strip. Repeat test using a new test strip. Do not touch strip during test cycle. If persists, consult physician for LAB INR
	**Error : Ambient temperature.** Meter is too cold or too warm to measure correctly. *Note: With continuous use, may still error if < 32°C.*	Turn the meter off Allow it to stand for about 30 minutes at room temperature. (18°C to 32°C).		**Error: Quality Control (QC)** Test strip failed the internal QC check. The test strip is unusable.	Turn the meter off. Remove the test strip. Repeat the test using a new test strip.
	**Error: Battery** Battery level too low.	Insert new batteries.		**Error: Quality Control (QC)** QC must be performed with a new lot number of test strips.	Perform QC with the new lot number of test strips before performing the patient test.
	**Error: Cover** Measurement chamber cover is not closed properly.	Close the measurement chamber cover. Error message disappears, meter is ready to use.		**Error: Measurement** Blood sample measurement error. *Note: ??? Heparin contamination. Use alternate method; use only non-additive collection devices.*	Turn the meter off. Remove test strip. Repeat patient test with new test strip. Apply blood from a new puncture site. Do not touch strip during test cycle If persists, consult physician for LAB INR
	**Error: Test Code Chip** Code chip is missing, not properly inserted or damaged.	Insert test code chip Remove test code chip, re-insert. Acquire new test code chip from a different package, same code number.		**Error: Diagnostic test** Internal diagnostic test error for the meter. If the error persists, the meter has a fault.	Turn the meter off. Remove batteries. Wait min.[1] minute. Re-insert batteries. Set date and time. Repeat the test. *Note: Notify POCT technologist.*
	**Error: Test Strip** Test strip is beyond expiry date.	Meter date is incorrect: Reset Meter date correct Turn meter off, remove code chip & test strip. Use new code chip.		**Error: Memory test (patient)** Memory contains faulty data.	Meter has a fault. *Note: Notify POCT Technologist.*
	Error: Test strip Test strip is unusable.	Turn meter off. Remove strip, re-insert. If error message appears again, repeat with new strip		**Error: Memory test (QC)** Memory contains faulty data.	Meter has a fault. *Note Notify POCT Technologist.*
	**Error: Time for application exceeded.** Maximum allowed time for applying blood is 180 seconds.	Turn the meter off. Remove test strip. Start a new test. Use the same test strip.		**Error: Memory test (setup)** Memory contains faulty data.	Meter has a fault. *Note: Notify POCT Technologist.*
	Error: Blood application Blood application error to the test strip. *Note: Either Error screen may display.*	Turn the meter off. Remove the test strip. Review patient testing procedure. Repeat the test using a new test strip.		**Error: Quality Control** Control solution is beyond the expiry date.	Use a new control solution with corresponding code chip.

For Assistance contact the Point of Care Technologist Room 2J8. Monday – Friday ext: 7521 Pager: 41-02190.

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	Dec 2010	Elvira Kozak	Dr. Cathy Halstead
1.1		Document Review – addition of Coaguchek XS Pro	23 Aug 2012	Elvira Kozak	
1.2		Error 6 update; "Error 6" may indicate an INR > 8.0. June 2013 RR2013-16/PAN13-06_D	20 June 2013	Elvira Kozak	
1.3	Minor	Document title and number change. Upload to QMS document control	28 Dec 2016		Dr. Benjamin Jung

Attention: This document is published on the BCCW SharePoint website

Revisions made to this document require an update to the corresponding document published on BCCW SharePoint website