


CoaguChek XS Pro Medical Mobile Unit: Patient Test Procedure



I. Purpose:

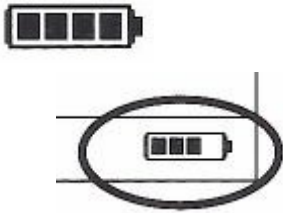


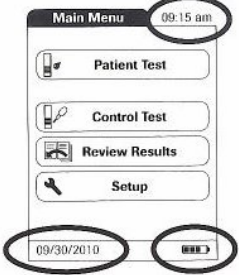


This procedure provides instruction on how to perform a patient test for PT INR using the CoaguChek XS Pro instrument.

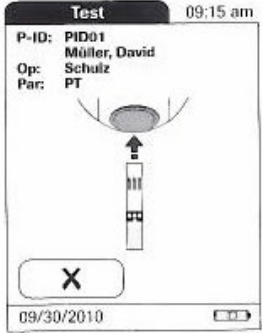
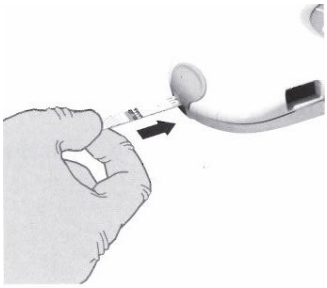
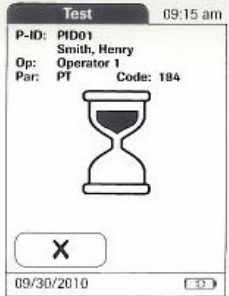
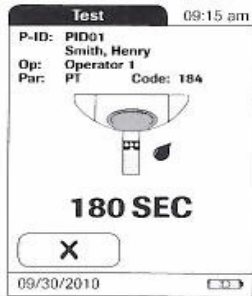
II. Materials:

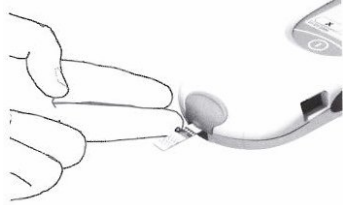
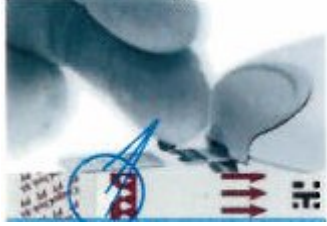

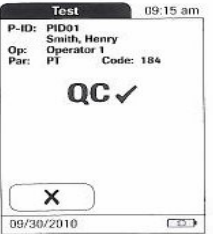
<ul style="list-style-type: none"> ○ CoaguChek® XS Pro Instrument ○ CoaguChek® XS PT Test Strips with chip code ○ Appropriate Capillary Lancing Device or non-additive syringe with needle. ○ 2% Chlorhexidine in 70% Isopropyl alcohol Prep Pad ○ Cotton Gauze ○ Tape ○ Gloves ○ Sharps container ○ Paper towel for working surface ○ Caviwipes Wipes 	
--	--


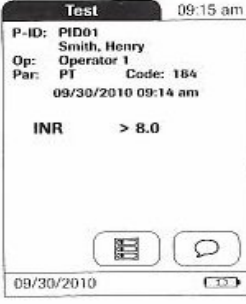
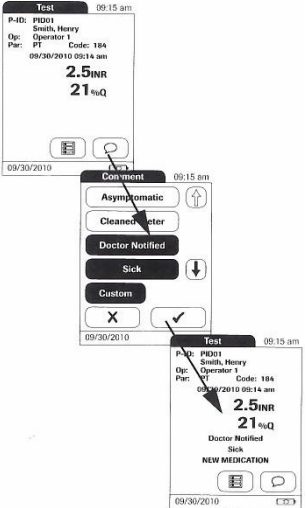
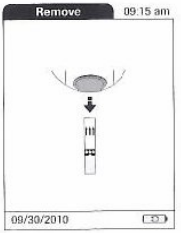
III. Procedure:

	Action	Related Documents Title Number
	<p><i>Note:</i></p> <ul style="list-style-type: none"> ○ Perform Aqueous Quality Control once weekly prior to a patient test, or with a new vial of CoaguChek XS PT Test Strips ○ Capillary whole blood or venous whole blood with a non-additive syringe. 	
1.	<p>Assemble supplies.</p> <ul style="list-style-type: none"> ○ CoaguChek Pro and supplies are set up at the bedside on a paper towel, ready for use. 	
2.	<p>Check that the Test Strip Code is Current.</p> <ul style="list-style-type: none"> ○ Each Lot number of CoaguChek XS PT Test Strips has a specific Code Chip number. ○ Each box of test strips is supplied with a code chip. ○ <i>Test strip code chips are marked with an "S".</i> 	
3.	<p>Test strip chip code in the meter is current.</p> <ul style="list-style-type: none"> ○ 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). ○ Insert the code chip into the code chip slot, with the "S" facing up, until it snaps into place. 	

	Action	Related Documents Title Number
	<p><i>Note: The manufacturer recommends that a code chip is left in the meter to protect the electrical contacts from becoming dirty.</i></p>	
4.	<p>Press the On/Off button.</p> <ul style="list-style-type: none"> ○ Instrument initializes and performs electronic checks. 	
5.	<p>Check the battery level bottom right on screen.</p> <p>If battery level shows</p> <ul style="list-style-type: none"> ○ > 1 bar left in battery icon proceed to the next step ○ < 1 bar left in battery icon, you can perform a patient test. ○ Replace batteries for next test 	
6.	<p>Operator ID entry page appears.</p> <ul style="list-style-type: none"> ○ Manually enter or scan POCT OPID. ○ Press “√” to accept if a manual entry. ○ IR scanner on right side of meter. 	  <p>Scan from a distance of approximately 10 cm. The meter beeps once the barcode has been read successfully.</p>
7.	<p>Main Menu screen appears</p> <ul style="list-style-type: none"> ○ Check that the date and time are correct. ○ Make any corrections to the date or time if required at this time, before proceeding to the patient test. 	 <p>CoaguChek XS Pro Medical Mobile Unit Appendix E - CoaguChek XS Pro Setting Date and Time e</p>
8.	<p>Press Patient Test</p> <ul style="list-style-type: none"> ○ Manually enter or scan the patient identifier (PID) number. ○ Use the institutional medical record number or PHN. ○ Press “√” button to save. 	  <p>Enter Patient ID Press “√”</p>

	Action		Related Documents Title Number
<p>9.</p>	<p>Test strip icon prompts you to insert a test strip.</p> <ul style="list-style-type: none"> ○ Remove test strip from vial. ○ Touch only the end of the test strip. ○ Place face up onto the paper towel to avoid contamination of the sample area. ○ Immediately replace the container lid. ○ Use the test strip within 10 minutes of removing it from its container. <p><i>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.</i></p>	 <p>Patient information with date and time is retained on each of the pages during the patient test process.</p>	<p>CoaguChek XS Pro Medical Mobile Unit: Appendix A - CoaguChek XS PT Test Strip</p>
<p>10.</p>	<p>Insert the test strip into the meter</p> <ul style="list-style-type: none"> ○ Hold the test strip so the lettering “CoaguChek XS PT” is facing upwards. ○ Insert the test strip in the direction indicated by the arrows. ○ Slide the test strip as far as it will go. ○ Beep tone indicates that the test strip is detected. <p><i>Note: If test strip is not detected, remove the test strip and reinsert into the meter.</i></p>		
<p>11.</p>	<p>Hourglass icon is displayed</p> <ul style="list-style-type: none"> ○ Hourglass icon indicates that the test strip is warming up. ○ Do not apply patient sample at this stage or an error code will appear and the testing process will need to start from the beginning with a new puncture. 		
<p>12.</p>	<p>Blood drop icon flashes to indicate that the meter is ready for a patient sample</p> <ul style="list-style-type: none"> ○ Instrument is now ready to perform a patient test and is waiting for blood to be applied ○ Simultaneously a 180 second countdown begins. ○ Drop of blood is applied within the 180 seconds or an error message will occur. 		

<p>13.</p>	<p>Perform the capillary finger or heel puncture, (or for venous sample collection use a non-additive syringe)</p> <ul style="list-style-type: none"> ○ Put Gloves on. ○ Clean the puncture site with soap and water if necessary. ○ Disinfect puncture site with 2% Chlorhexidine in 70% isopropyl alcohol. ○ Air Dry. ○ Capillary Puncture is performed on the side of the fingertip, or at the appropriate site on the heel with approved lancing device. ○ Venous collection is in a non-additive syringe. 	
<p>14.</p>	<p>Capillary puncture Whole Blood (8 uL) is applied within 15 seconds of collection. <i>Applying blood after 15 seconds may lead to an erroneous result as the coagulation process would already have started.</i></p> <ul style="list-style-type: none"> ○ Whole blood is free flowing. ○ Apply a slight pressure to the punctured site to form a drop of blood if necessary. ○ Do not press or squeeze the area (interstitial fluid may enter the capillary sample with excessive pressure). ○ Use the first drop of blood formed. ○ Apply to the side or top of the semicircular transparent sample application area. ○ When adequate sample is applied the flashing blood drop icon disappears. ○ The monitor beeps and the test starts. <p><i>Note: Capillary blood - Diagrams show finger collection only. Venous blood – Discard first 4 drops of blood from the syringe before application to the test strip.</i></p>	 <p>Blood application to side of test strip – blood is drawn up by capillary action.</p>  <p>Blood application to top of test strip – blood covers entire area.</p>
<p>15.</p>	<p>Blood drop symbol disappears and the test starts</p> <ul style="list-style-type: none"> ○ Patient information is retained on the screen ○ Do not add additional blood ○ Do not touch the test strip until the result is displayed ○ Place and keep the meter on a flat surface during the test cycle. 	
<p>16.</p>	<p>“QC” appears in the display.</p> <ul style="list-style-type: none"> ○ The meter performs an automatic quality control test on the test strip before it displays the test result. ○ If successful a checkmark appears after “QC”. <p><i>Note: If the internal QC is not successful an error code will display. Turn the meter off and repeat the process with a new puncture and new test strip</i></p>	 <p>CoaguChek XS Pro Medical Mobile Unit Appendix H - CoaguChek XS Pro Error Messages</p>

<p>17.</p>	<p>INR Result is displayed in INR units</p> <ul style="list-style-type: none"> ○ Range of measurement INR = 0.8-8.0 ○ Reportable range INR = 0.8-4.0 <p><i>Note: if “c” is displayed along with the result – low hematocrit (<25%) or blood contamination of water or residual disinfectant. Repeat the test with a new puncture site and sample.</i></p>			<p>CoaguChek XS Pro Medical Mobile Unit: Appendix A - CoaguChek XS PT Test Strip</p>
<p>18.</p>	<p>Report result on patient chart as per institutional protocol.</p> <p>If the INR result is > 4.0</p> <ul style="list-style-type: none"> • Repeat with a new capillary collection to confirm the resulted INR on an alternate site. ○ Repeat the test to confirm the result with venous INR on an alternate method – Hematology reference analyzer - when possible. Consult with Physician. 			
<p>19.</p>	<p>To Add a Comment</p> <ul style="list-style-type: none"> ○ Not mandatory ○ To add a comment do not remove the test strip ○ In the Test Screen touch the “bubble” icon on the bottom right of the screen ○ In the Comments screen select the appropriate canned comment ○ Touch the checkmark to save <p><i>Note: Once the test strip is removed a comment cannot be added or edited.</i></p>			
<p>20.</p>	<p>Remove the test strip from the meter</p> <ul style="list-style-type: none"> ○ Touch the menu icon at the bottom of the patient result screen (Diagram Step 17) ○ You will be prompted to remove the test strip. ○ Discard the test strip as per institutional guidelines for biohazardous waste disposal. 			
<p>21.</p>	<p>Turn the monitor off.</p>			
<p>22.</p>	<p>Clean and disinfect the surface of the meter with 2% Chlorhexidine in 70% isopropyl alcohol prep pad, or Caviwipes.</p>	<p>Appendix H Monitor Cleaning</p>		

IV. References:

<p>Medical Approval: Dr Benjamin Jung Version: 1.1 Folder Name: CW\Point of Care\PT INR</p>	<p>Medical Approval Date: 28 Dec 2016 Implementation Date: 1/4/2017 11:10:09 AM</p>
<p style="text-align: center;">This is a controlled document for CW use only. Any printed copies are uncontrolled unless specified. Please refer to Lab QMS</p>	

- 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	08 Aug 2012	Elvira Kozak	Dr. Cathy Halstead
1.1	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