| **Ridgeview Medical Center Laboratory Services** | **Department of Origin** | **Effective Date:** |
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|  | Point of Care |  | 10/2009 |
| **Purpose** The CoaguChek XS test strip, when combined with the meter, will provide an electrochemical measurement of prothombin time following activation of blood coagulation with human recombinant thromboplastin. |
| **Specimen**Capillary or venous whole blood can be used to perform this test. |
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| **Reagents** | **Supplies** | **Equipment** |
| * CoaguChek XS test strips with matching code chip
 | * Lancet
* Gauze and alcohol wipe for use in obtaining blood specimen
 | * CoaguChek XS Plus meter
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| **Quality Control**Two levels of quality control will be run monthly, when opening a vial of test strips from a different shipment,or when opening a vial of test strips of a different lot number. |
| **QC Procedure: (Review cleaning/disinfecting procedure prior to performing quality control.)** |
| **Step** | **Action** |
| 1. **Preparation**
 | If using test strips from a new vial, change the test strip code chip. The three digit code on the vial should match the code on the chip. |
|  | Be sure to have the quality control code chip available. This tells the meter the acceptable ranges for this box of controls. |
|  | Reconstitute the control bottles by carefully removing the cap, cutting the end from the pipette stem, and carefully squeezing the contents into the bottle. Save the dropper for application to the test strip. |
|  | Replace the cap and gently swirl to dissolve the quality control material. Write the date and time on the vial. Use the control within 30 minutes of reconstitution. |
| 1. **Performance**
 | With dry hands or gloves, remove a test strip from the vial and immediately close the container. Make sure that it seals tightly. Test strips must be used within 10 minutes of removal from the container. |
|  | Turn meter on; choose QC test. When prompted, insert a test strip into the meter.  |
|  | Choose the QC code. If this a new lot number of control solution, remove the strip code chip from the meter and insert the control code chip. |
|  | Choose the level that will be tested. The meter will warm the test strip; when it begins a countdown, there are 180 seconds in which to apply the sample. Swirl gently to mix before application. |
|  | The meter should be on a flat surface during testing. |
|  | When the meter detects sufficient sample, the flashing dropper symbol changes to an hourglass. |
|  | Record the results, verify their validity, and discard the test strip, dropper, and reconstituted bottle of quality control material. |
|  | Remove the QC code chip, store it in the QC material box, and replace the strip code chip. |

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| **Patient Testing Procedure:** |
| **Step** | **Action** |
|  | Routine blood collection procedures apply to the sample collection. |
|  | When ready to test, remove the test strip from the container; close the vial immediately. |
|  | Turn the meter on, either by touching the power button or by inserting a strip.  |
|  | Press PATIENT TEST. Enter the patient identification data, which for Home Care and Coumadin Clinic will be the Visit ID number. In the case of RMC clinics the accession number should be used. |
|  | The meter warms the test strip for about 30 seconds and then begins a countdown. There are 180 seconds during which the blood specimen must be applied to the strip. |
|  | Lance the finger. |
|  | Apply the first drop of blood to the target area on the strip. Blood must be added within 15 seconds of lancing the finger. Do not add more blood.  |
|  | The meter should be on a flat surface during testing. |
|  | The flashing drop symbol changes to an hourglass when the meter detects sufficient sample. |
|  | The meter performs an automatic quality control test on the test strip before it displays the test result. “QC” will appear in the display, followed by the patient result.  |
|  | Record the result. |
|  | Properly dispose of the used lancet and test strip. |

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| **Result Reporting**The INR should be logged in the patient record per protocol.The target range for INR results will be determined individually by the physician on an individual basis, but Ridgeview Medical Center’s therapeutic ranges for INR are generally as follows:* Orthopedic cases, 1.6-2.2
* Internal Medicine patients, 2.0-3.0
* Heart valve replacement patients, 2.5-3.5
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| **Limitations*** The valid measuring range for CoaguChek XS PT test strips is an INR 0.8–8.0.
* Results outside the measuring range are indicated by the symbols > (greater than) or < (less than). Repeat the test.
* An INR of >5.0 is a critical value and must be repeated with a venous draw.

**Troubleshooting*** The CoaguChek XS Plus User Manual contains troubleshooting advice in the Error Messages section.
* Contact Roche Diagnostics Point of Care Technical Service at 1-800-428-4674 if an error 9 appears on the meter.
* Notify the RMC Point of Care Coordinator of any issues with the meter or supplies.

**Cleaning/Disinfecting the Meter**It is important to follow these procedures for cleaning and disinfecting. Failure to follow these procedures may cause malfunction of the meter.* Do not use sprays of any sort.
* Ensure that the swab or cloth is only damp, not wet. Remove excess moisture before use.

Use only the following solutions for cleaning/disinfecting the CoaguChek XS meter for a contact time of >1 minute.* 70% isopropyl alcohol
* 10% sodium hypochlorite (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours).
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| **Step** | **Action** |
| **Meter Housing****(Daily)** | Clean at the end of the day; this will allow sufficient time for the meter to be disinfected and completely dry before use. |
| **1.** | With the meter powered off, wipe the exterior clean. |
| **2.** | Do not let liquid accumulate near any opening. Make sure that no liquid enters the meter. |
| **3.** | With a lint-free tissue, dry the meter. |
| **4.** | Wipe away residual moisture and fluids after cleaning the housing. |
| **5.** | Allow wiped areas to dry for at least 10 minutes before performing a test. |
|  **Test Strip Guide** **(Monthly)** | Perform this procedure as needed or at least monthly, prior to performing quality control. |
| **1.** | With the meter powered off, use your thumbnail to remove the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter, then rinse the cover with water or wipe it clean. |
| **2.** | Hold the meter upright with the test strip guide facing down. |
| **3.** | Clean the easily accessible areas with a cotton swab. |
| **4.** | Ensure that the swab is only damp, not wet. Wring excess moisture from swab before use. |
| **5.** | Apply cleaning agent for a contact time of >1 minute. |
| **6.** | Wipe away residual moisture and fluids. |
| **7.** | Do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide. |
| **8.** | With the cover off, allow the test strip guide to dry for at least 10 minutes.  |
| **9.** | Close the cover; make sure that it snaps into place. |
| **10.** | Perform quality control before resuming patient testing. |
| **Note**For outpatients requiring periodic INR testing for the management of anticoagulation, testing with the CoaguChek is acceptable. On all other patients a venipuncture is the preferred specimen; the CoaguChek may be used if the venipuncture fails.**Safety**Standard biohazard precautions should be followed in the performance of this test.**Backup Procedure**In case of meter failure, a critical value, or a result outside the measuring limits, a sodium citrate tube should be drawn and sent to RMC lab for analysis. |
| **References*** CoaguChek XS Plus System User Manual
* CoaguChek XS PT Test Strip Insert
* RMC Policy 5580 INR Testing with the Coaguchek XS Plus
* CoaguChek Analyzer Bulletin 09-206
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| **Date:** | **Author:** | **Date:** | **Validated by:** | **Date:** | **Approved by:** |
| 11/2009 | Sue Allison  | 12/02/09 | Joan Goetteman | 4/2/10 | Dr. Paul Weatherby |
|  |
| **Annual Review** |
| **Date:** | (7/21/10) | 3/19/13 |  |  |  |  |  |  |  |  |  |  |
| **Initials:** | (RPW) | SA |  |  |  |  |  |  |  |  |  |  |
| **Date:** | **Initials:** | **Revision and Reason** |
| 2/14/10 | SA | Addition of target ranges |
| 6/15/10 | SA | Addition of meter cleaning instructions |
| 7/18/11 | SA | Change from 120 to 180 seconds for sample application time |
| 3/19/13/ | SA | Addition of note about the use of the CoaguChek meter |
| **Discontinued** |
| Date: | Reason: | Initials: |