TITLE: QE POC INR Procedure	Doc #: 4452
Section: Kernel Root\PLM\Hematopathology\Coagulation\	Version: 1.4 CURRENT
Prepared by: Technical Specialist - Coagulation	Revision Date: 2010/05/08

Approved by: Dr. Irene Sadek

Purpose This procedure provides instructions for obtaining an INR result via a finger prick.

Abbreviations

International Normalized ratio (INR)	Prothrombin time (PT)
International Sensitivity Index (ISI)	Quality Control (QC)
Oral Anticoagulation therapy (OAT)	World Health Organization (WHO)

Materials

Reagents
Test strip with supplied code chip
Liquid control with supplied code chip

Reagents stability and storage: The test strips can either be stored at room temperature or in the refrigerator as the range is 2 – 30 °C. The test strips are good until their expiry date as long as they have not been exposed to humidity. When a test strip is removed from the container, the cap must be placed back on the container immediately to prevent the rest of the strips from deteriorating.

Supplies
Micropore tape
Cotton ball
Band aids
Alcohol pad
Gloves
Capillary tube and bulb
Lint free swab
Brown absorbant cloth
Distilled water
Scissors
Accu-Chek Softclix Pro Lancing device
AA batteries
Backup battery pack

Equipment
CoaguChek XS Plus monitor

Sample

Sample type	Amount required	Transport and Storage	Stability
Whole blood	10 ul drop		

Limitations: The drop of blood must be applied to the test strip within 15 seconds after the finger has been punctured.

Special Safety Precautions

All samples must be regarded as potentially infectious.
Refer to Health Laboratory Safety and Waste Management Manual for safety considerations.

Maintenance

Clean the plastic housing if it appears dirty or contaminated.

Step	Action
1	Clean the outside of the monitor with a cloth that has been moistened with warm water.
2	Dry the monitor with a fresh cloth.

Clean the test strip guide if it appears dirty or contaminated.

Step	Action
1	Remove the measurement chamber cover by pressing upwards from the front and rinse with distilled water.
2	Clean the white area with a lint free swab moistened with distilled water. Make sure that no liquid enters the monitor. If the area needs to be disinfected then moisten the swab with an alcohol swab.
3	Let this area dry for 10 minutes and then re-attach the chamber cover by snapping into place.

Calibration

Each lot number of test strips has been calibrated to a reference lot that is traceable to the WHO. For the purpose of providing universal INR results, the mean normal range

has been established at 12 seconds using healthy donors and the ISI value is 1.0.

Quality Control

Control	Level	Stability	Frequency	Preparation (y/n)
Liquid	1	2 – 8 °C until expiry date	Every 30 days	Y

Control preparation: Open the lid of the vial and remove the rubber cap. Cut the end off of the sealed pipette with the neck pointing upward and transfer the contents of the pipette into the vial. Do not allow the pipette to come in contact with the dried control plasma. Close the vial and swirl 2 to 3 times in a circular motion so the plasma is completely dissolved.
Note:
Do not shake the vial or turn it on its side. Let the vial sit at least 1 minute before testing. Use within 30 minutes of preparation.

Procedure

Testing quality control material must be performed every 30 days or the instrument will lock the user out and prevent the monitor from being used. Ideally, perform at the beginning of the month.

Step	Action
1	Place the monitor on a level surface and turn it on.
2	Check the battery level display in the lower bottom right hand corner of the monitor. If there are no bars left then the backup battery pack should either be inserted, the AA batteries should be replaced or the monitor should be plugged into the wall.
3	Select the QC TEST button.
4	The test strip icon will prompt to have a strip inserted. Hold the strip so the lettering “CoaguChek XS PT” is facing upward and slide the strip into the monitor as indicated by the arrows on the strip.
5	If this is a new test strip lot and the code chip has not been previously inserted then it must be done now. Failure to perform this step will not allow quality control to be done.

6	If it is a new code select the button “new code” and insert the code chip that came with the control solution. There will be a “C” on the code chip and an “S” on the strip chip in case there is a mix-up.
7	An hourglass icon will appear indicating that the strip is warming-up. When the strip is warmed up there will be an audible beep.
8	A pipette icon flashes to indicate to apply the control solution to the strip. At the same time a 120 second countdown begins during which time the control solution must be applied or an error message will occur.
9	Using the pipette apply a hanging drop of control solution to the sample application area on the test strip. An audible beep will be heard when there is enough control applied to the strip and the testing will start.
10	The result of the control will appear on the screen along with the range and this will be stored into the memory of the instrument.
11	There is a Quality control log sheet in the CoaguChek XS binder that must be filled out with lot numbers (strips and controls), expiry dates, results and ranges.
12	Remove the test strip and dispose of in a biohazard container. Turn off the instrument.

Testing patients

Step	Action
1	If this is a new lot number of strips then the code chip matching the strips must be inserted while the instrument is off. Once the new one is in place turn on the monitor so the information can be retrieved off of the chip and stored into the internal memory. If this is the first time the strips will be used perform the liquid control on the strip as per instruction above.
2	Place the monitor on a level surface and turn it on.
3	Check the battery level display in the lower bottom right hand corner of the monitor. If there are no bars left then the backup battery pack should either be inserted, the AA batteries should be replaced or the monitor should be plugged into the wall. Please note: if a QC BLOCK is displayed instead of the PATIENT TEST button then perform the liquid control on the strip as per instructions above.
4	Select the option “Patient ID” and keypad in the patient’s name.

5	The test strip icon will prompt to have a strip inserted. Hold the strip so the lettering "CoaguChek XS PT" is facing upward and slide the strip into the monitor as indicated by the arrows on the strip. Make sure that the cover is put back on the container housing the strips so the humidity does not cause them to deteriorate.
6	An hourglass icon will appear indicating that the strip is warming-up. When the strip is warmed up there will be an audible beep.
7	A blood drop icon flashes to indicate to apply the blood to the strip. At the same time a 120 second countdown begins during which time the blood must be applied or an error message will occur.
8	Using the Accu-Chek Softclix Pro Lancing device, obtain a capillary blood drop from the patient from the side of the fingertip. Massage this area until a good size drop appears. Do not press or squeeze the finger. **Apply the first drop of blood from the finger within 15 seconds. A delay of more than 15 seconds will falsify results as the clotting process will have been initiated after that time frame.**
9	There are 3 ways to apply the drop: a) Draw the blood up in a capillary tube with a bulb on the end and transfer drop onto the strip. b) Apply the blood directly from the finger to the top of the test strip. If this method is used then the entire sample area must be covered. c) Apply the blood directly from the finger to the side of the sample application area and the blood will be drawn by capillary action. Hold the finger there until an audible beep is heard. **An audible beep indicates that enough blood has been added, the blood drop icon will disappear and the test will start.**
10	Watch the monitor display screen as the monitor will perform an automatic quality control check on each strip that is inserted and once the QC has passed "QC" with a tick mark beside it will appear on the screen. **Failure of the tick mark means the strip is not valid for the patients test. If this is the case the test must be repeated with a new finger prick.**
11	The result of the patient will appear on the screen along with the patient's name, date and time of testing. This information will be stored into the memory of the instrument.
12	Remove the test strip and dispose of in a biohazard container. Turn

		off the instrument.
	13	Return to Coagulation Lab with the instrument and patient requisition. Order the POC INR in Millennium (SOP #??) and verify the patient result. Be sure to book the next POC INR appointment as requested by the pharmacist. (Refer to HEM-TP-151)

Calculation

$$INR = \left(\frac{PT\ sec}{Mean\ of\ patient\ normal\ range} \right)^{ISI}$$

Result Interpretation

Results that are outside the measuring range, which is 0.8 – 8.0, will be indicated with > or < symbols.

Expected Values

INR normal range 0.8 – 1.2
Most medical and surgical thromboembolic states 2.0 – 3.0
Artifical heart valves and recurrent embolism 2.5 – 3.5

Limitations

Bilirubin up to 513 umol/l (30 mg/dl)
Hemolysis up to 0.31 mmol/L (500 mg/dL)
Triglycerides up to 11.4 mmol/L (1000 mg/dL)
Heparin >1.0 u/ml
Low molecular weight heparins > 2 IU/ml antifactor Xa activity
Hematocrit <.250 or >.550

Procedural Notes

1. Using the wrong chip code can produce inaccurate results.
2. Not applying the drop of blood within 15 seconds can produce inaccurate results.
3. Using a test strip that has been exposed to the air for more than 10 minutes can produce inaccurate results.

4. If the monitor produces an "error 7", this could indicate a prolonged INR result. Repeat testing and if this message appears again then send the patient for a venous collection.
5. Certain drugs taken in conjunction with coumadin can falsely lower or increase the INR result.
6. INR testing, via this method, is not recommend for patients that have anti-phospholipid antibodies or patients on Hirudin.
7. If for any reason you need to collect a second sample on the patient, be sure to use a different finger from your original sample. The clotting process will have been initiated in the first finger and may interfere with your recollect.

Principle	Electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin.
Clinical Utility	Allows patients to self- test their INR result from the fingertip without performing a venous collection. Provides an immediate result.
Related Procedures and Documents	Doc # 1324: QE ACL TOP PT/INR Procedure [Para-Link] Doc # 4502: QE Appointment Booking Process [Para-Link] Doc # : Department Order Entry.
Reference	CoaguChek XS Plus Operator's Manual, January 2006. CoaguChek XS PT Test Package Insert, February, 2007. CoaguChek, XS PT Controls Package Insert, August, 2006.