STANDARD OPERATING PROCEDURE FOR COMMUNITY PHARMACY ANTICOAGULATION MANAGEMENT (CPAM) SERVICES

Version 1.3

EQUIPMENT

CoaguChek XS Plus Meter

The CoaguChek XS Plus meter tests the INR from a finger prick blood test using 8µL of capillary whole blood. It conforms to the WHO PT standardisation scheme (INR).

CoaguChek XS Plus meters must be stored suitably, protected from dust and extreme temperatures, and cleaned according to instructions.

Each meter has the ability to store the Operator and Patient ID alongside 1000 test results and up to 500 Quality Control Results.

The base unit is used for data transfer of the patient result directly into INR Online and also used to charge the meter.

Test strips

Test strips should be stored at room temperature. Always keep test strips in the original container, replacing the vial cap after removing a test strip (as exposure to moisture, heat and humidity will damage the strip and cause an error message on the CoaguChek XS Plus).

The test strips will come with a code chip in the bottom of the box which also hold all the test strip calibration, lot and expiry information. The code chip should be inserted into the CoaguChek XS Plus meter when a new lot of strips are being used. The code chip should be kept in the meter even after the meter has read the information as this will protect the contacts from any dust. Protect the code chip from any electromagnetic fields.

Capillary Blood Lancing Devices

In order to prevent cross infection and minimise the risk of sharps injury a disposable single-use lancing device called the Accu-Chek Safe-T-Pro Plus is used for all individual patients.

All pharmacy staff should be aware that pen lancing devices are also available for single patient use, and are often provided with CoaguChek XS meters for patient self testing and also blood glucose meters purchased over the counter. However, such lancing devices are NOT suitable for use on multiple patients.

Quality Control Testing

Quality control refers to the routine testing of the CoaguChek XS Plus. This will ensure the device is working correctly and assure the operator of the reliability of patient results.

Quality control testing must be performed on a monthly basis and with every new lot of test strips. The CoaguChek XS Plus will be programmed with a QC Lockout which will require the operator to run the quality control test successfully before proceeding with patient testing. The result will be stored in the meter.

The CoaguChek XS PT Control solution must be stored in the refrigerator and must be used within 30 minutes of reconstitution.

The quality control results are interpreted on the basis of whether they fall within or outside acceptance limits. If the results of the control solution fall within its acceptance limits, then the performance of the meter and the current test strip can be said to be adequate.

If the result falls outside the quoted limits the quality control test procedure should be repeated using a fresh vial of QC material.

If the results are still found to be outside the acceptable limits, then the performance of the meters and strips must be deemed unacceptable and the meter should not be used pending further investigation. Withdraw the CoaguChek XS Plus from use, label with a "do not use notice", and contact Roche Diagnostics on 0508 69 5433.

SPECIMEN REQUIREMENTS

The blood drop must be a minimum of 8µL in volume. Low sample volume will cause an error message. Possible interferences include:

- Presence of Anti Phospholipid Antibodies
- Haematocrit <0.25 or >0.55
- Triglycerides >5.7 mmol/L
- Haemolysis >0.31 mmol/L
- Bilirubin >513 µmol/L
- The presence of alcohol or soap at the lancing site
- Hirudin

The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU/mL antifactor Xa activity.

Please refer to CoaguChek XS PT Test Strip package insert for details.

TRAINING

It is essential that both the correct equipment is used and the pharmacist is trained and accredited by attending an approved training programme for the delivery of Community Pharmacy Anticoagulation Management Services. The current training provider is the College of Pharmacists, Pharmaceutical Society of NZ.

A competency assessment must be successfully completed before staff use the CoaguChek XS Plus and INR Online.

PROCEDURAL GUIDELINE – PHARMACY BASED ANTICOAGULATION MANAGEMENT SERVICE

Equipment

- CoaguChek XS Plus
- Base Unit
- Test Strips and Code Chip
- Quality Control Material
- Safe-T-Pro Plus Lancing Device
- Computer with Internet
- Printer
- Cotton swabs
- Disposable gloves

Procedural Guideline – Patient Testing & Dosing

Action	Rationale
1. Access INR Online via the internet and login using your name and password in the morning to check the clients due and overdue for an INR test under **Due Test** tab. Contact overdue patients.	Ensures patients are having their INR tests at the necessary intervals for best management.
2. Patients attend the pharmacy for their INR test. If it is the patient's first consultation they must receive full warfarin counselling. Document any patient counselling given in INR Online.	The patient is aware of all aspects of their Warfarin Management.
3. Gather items for testing: CoaguChek XS Plus, test strips and code chip, Safe-T-Pro Plus lancing device, alcohol wipes, plasters, gloves and tissues.	Ensures you have everything ready before testing will enhance workflow.
4. Take the CoaguChek XS Plus off the Base Unit and place in front of the patient on the edge of the table so when the strip is inserted it will be hanging over the edge of the table. (You may leave the meter in the base unit dock for testing as long as patient is close enough) Make sure the patient is facing the meter.	This is the best position for testing successfully, giving you room for placing the drop of blood on the side of the strip.
5. Enter the Patient NHI or name into INR Online.	To access the patient's file.
6. Click to add a test result and work your way through the INR Online requirements (asking the patient all the safety questions) until you	This records any necessary information for the patient file i.e. Missed tablets, Bleeding or

Action	Rationale
come to the instructions for testing. Check for possible drug interactions in MIMS.	Bruising, New Medication and Hospital Admissions.
7. Touch and hold down the power button until the CoaguChek XS Plus beeps.	This will turn the machine on.
8. Enter your initials as your operator ID.	This ensures a record of who did the testing is kept in the CoaguChek XS Plus next to each result.
9. Touch the Patient Test button and the patient name, and NHI Number will appear on the screen. Touch this to proceed.	The NHI number is a unique identifier which INR Online will use for each patient to transfer patient results.
10. Insert the test strip and code chip. (If using a new lot of strips the meter will request this automatically, and you will be required to perform a Quality Control Test – see **Procedural Guideline – Quality Control Testing**). The meter will then warm up displaying an egg timer.	The code chip holds all the test strip lot information, expiry date and calibration information necessary to perform the test.
11. Put on gloves.	To minimise the risk of cross-infection.
12. Select the finger for lancing. It is recommended you use either the index finger or middle finger. If necessary, swab the patient's finger with an alcohol swab and tissue it dry, or get them to wash their hands with warm soapy water for a good 30 seconds making sure they wash off all soap residue.	These fingers are usually the easiest to obtain a sample from and move to the test strip. Minimises the risk of infection. Washing hands in warm water increases circulation. (Also warming hands with a heated wheat pack is helpful to increase circulation if necessary). Any alcohol or soap residue left on the lancing site could affect the INR result.
13. Prepare the patient's finger for lancing by massaging gently from the base of the finger to the tip, making sure you get good colour in the tip.	Enables a good blood sample size.

Action	Rationale
14. Adjust the disposable Accu-Chek Safe-T-Pro Plus dial to the most appropriate setting and twist off the end cap.	The deepest setting enables a good blood sample size.
15. When the meter beeps and the 180 second countdown begins, prick the side of the patient's finger at the top, holding their hand upright as though they were about to shake someone's hand.	The side of the fingertip is less painful, and by pricking the top side you can then balance the drop of blood easily.
16. Milk the finger from the base to the tip until you obtain the biggest drop of blood you can balance on the top side of the finger. Always use the first drop of blood for testing and apply the drop to the test strip within 15 seconds of lancing.	Obtaining the biggest drop ensures you have enough blood for testing and avoids a blood application error. As soon as you lance the finger the clotting process has begun. By using the first drop of blood and applying the drop within 15 seconds you eliminate any shortened INR results.
17. Making sure the patient is relaxed and you are in control of the finger, take the drop of blood to the strip and touch it to the edge of the transparent area of the strip until you hear the CoaguChek XS Plus beep. Take care not to bump the meter or test strip or move the patient's finger during this process as the test could error out.	Allows control of dosing the strip. Side dosing gives you full view of dosing and more control. The beep tells you the strip has a sufficient dose of blood.
18. Dispose of Safe-T-Pro Plus into a biohazardous waste bin.	To comply with waste regulations.
19. Wipe blood off the finger with a tissue and apply a plaster if required.	To minimise contamination and ensure patient comfort.
20. The INR Result appears within a few seconds and is stored in the meter memory. Touch the 'speech bubble' symbol if you would like to add comments.	Then enables data to be transferred electronically to INR Online.
21. Dispose of the used test strip, gloves, and tissues in the biohazardous waste bin.	To comply with waste regulations.
22. Dock the meter back onto base unit and click on **Upload result** in INR Online.	Enables transmission of result from the CoaguChek XS Plus to INR Online.

Action	Rationale
23. Confirm the NHI number, result and date and time, and click on **Next**.	This records the result in the patient file.
24. Follow the instructions on INR Online and as per the Standing Order. Educate the patient on the result, and record any specific advice in the patient's file as necessary.	Allows appropriate dose recommendation.
25. Add any comments relevant to the result, if necessary. Confirm the result by clicking on the **confirm** button.	Enables a record of all relevant information related to the patient's results and treatment. Takes you to the current result page.
26. If a review of the result is not necessary click on **Contacted.** If the result has gone off for GP review click on **Contact later.** If a review is necessary, communicate to the patient that they will be contacted *only if* their GP has changed their dose. It is the Pharmacist's responsibility to contact the patient with any dose changes.	This will prompt you to follow up any results that need to be reviewed.
27. Click on the **treatment calendar** and print this off for patient. Discuss the dose they are to take each day, and when they are due back for their next test. Advise them to keep the calendar somewhere visible, and mark off each day that they have taken their medication.	Gives the patient a visual prompt on when to take their medication.
28. Log out of INR Online.	Ensures no unauthorised use of INR Online and access to patient files.
29. On a daily basis make sure you 'clean up' the **Due Test, Need Review** and **Uncontacted** tabs in INR Online.	This ensures all patients under these tabs receive appropriate action.

Procedural Guideline – Quality Control Testing

Action	Rationale
1. Take the CoaguChek XS PT Controls out of the fridge.	Storing the controls in the fridge ensures stability.
2. Remove 1 vial of CoaguChek XS PT Control, 1 dropper of diluent, and the code chip.	These are necessary items to perform the Quality Control test.
3. Carefully remove the screw cap and rubber stopper from the vial of QC material and make sure none of the dried powder is removed with the stopper.	Removing any powder could lead to an erroneous result.
4. Holding the dropper at the bottom of the stem, use scissors to cut off the tip of the dropper at the marked upper end of the stem. Do not squeeze the bulb of the dropper.	Allows a measured amount of diluent to be added to powder.
5. Insert the dropper tip first into the control solution bottle. Gently squeeze the bulb to dispense the entire contents of the dropper onto the dried powder. Do not touch the dried material and the dropper.	To reconstitute the QC Material.
6. Gently swirl a number of times and allow to stand for at least 1 minute before testing. **Do not shake. Once reconstituted the QC material must be used within 30 minutes.**	Shaking may cause the formation of foam which could lead to an error on the CoaguChek XS Plus.
7. Take the CoaguChek XS Plus off the Base Unit, and touch and hold down the power button until the CoaguChek XS Plus beeps.	This will turn the meter on.
8. Enter your initials as your operator ID.	This ensures a record of who did the QC testing is kept in the CoaguChek XS Plus next to each result.
9. Touch the **Control Test** button and either select the corresponding code in the list that appears, or touch **NEW CODE** and insert the QC code chip. The code number of the lot of control you are using can be found on the side of the box and also on the side of the vial of QC material.	The code chips holds the lot specific information to perform a QC test including the QC range the result should lie within. The CoaguChek XS Plus must read this code chip with every new lot of QC material.

Action	Rationale
10. The meter will then warm up displaying an egg timer. While it is warming up gently swirl the QC material again.	Ensures the QC material is properly mixed.
11. The meter is ready to perform the test when the dropper icon flashes and you see the 180 second countdown begin. Draw the solution into the dropper and apply one large hanging drop of QC solution to the clear target area of the strip.	The INR measurement will then begin.
12. The result will appear and the QC range will be underneath in brackets. You can add comments by touching the 'speech bubble' button. If the result is out of range (depending on the meter software version it will be indicated by an up arrow or down arrow next to the result, or a Fail comment) repeat the test mixing a fresh vial of QC material. If it is still out of range with the repeat test, withdraw the CoaguChek XS Plus from use, label with a "do not use notice", and contact Roche Diagnostics on **0508 MY LIFE (0508 69 5433).**	The likely cause of a QC result to be out of range is inadequate mixing of the QC material. Roche Diagnostics need to find the cause of the problem and the meter must NOT be used until the cause has been found and remedied.
13. The result will be stored in the CoaguChek XS Plus memory alongside the Operator ID and QC lot information.	This is an important record of the QC data for audit purposes.
14. Dispose of the used test strip, gloves, QC Material and dropper into the biohazardous waste bin.	To comply with waste regulations.

Supporting Documents

- CoaguChek XS Plus Operator's Manual
- CoaguChek XS Plus Quick Reference Guide
- INR Online Quick Guide
- Standing Order for Warfarin Management, Dose Adjustment and INR Testing Frequency
- CMDHB Warfarin Education Flipchart. (NB: For other Warfarin Education resources and information visit: http://www.cmdhb.org.nz/warfarin/default.htm)
- CoaguChek XS PT Test Strip Package Insert

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APPROVAL

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