Point of Care Testing for INR using CoaguChek XS Plus

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INTRODUCTION

0.1 Scope and purpose
This document details the procedure for performing a Point of Care normalised prothrombin time (INR) using the Roche Coaguchek XS Plus meter.

0.2 Responsibility
It is the responsibility of the local management team to ensure that the content of this document is applied to the performance of this test in order to ensure best practice, quality of results and health and safety.

It is the responsibility of all suitably trained staff to comply with the guidance set out in this document.

It is the responsibility of the device owners to ensure the equipment is demonstrably fit for purpose e.g. by participation in an External Quality Assurance scheme.

0.3 References
1. Roche Coaguchek XS Plus operation manual – Q-PULSE POC-EXT-39
2. Roche Coaguchek Test Strip kit insert – Q-PULSE POC-EXT-18
5. Point of Care Testing – Requirements for quality and competence, ISO 22870:2006

0.4 Definitions
INR International Normalised Ratio, the result when a Prothrombin Ratio has the International Sensitivity Index applied.
ISI International Sensitivity Index. Method specific correction factor designed to make all Prothrombin Ratios comparable.
QC Quality Control, the material/process used to check a system is functioning satisfactorily on a routine basis.
QA Quality Assurance, the overall measures in place to maintain satisfactory system performance.
EQA External Quality Assurance, quality assurance materials/processes periodically provided by a source outside the organisation/area where the system is used.
PoCT Point of Care Testing, using devices outside the Pathology Laboratory setting to produce results.

0.5 Related documents
Trust Medical Devices Policy – Accessed via Trust Intranet
Infection Control Policy – Accessed via Trust Intranet
Pathology Sample Acceptance Policy – Q-PULSE TRUST-POLICY 1
1 INDICATIONS FOR ASSAY
The Prothrombin ratio can be used to monitor oral anticoagulant therapy (after conversion to an International Normalised Ratio (INR)). The provision of Point of Care Testing INRs allows greater convenience for patients, immediate dosing and decreases risk. PoCT is not suitable for all patients and is in general for those cases on warfarin that are uncomplicated and stable.

2 PRINCIPLES OF ASSAY
Thromboplastin is contained in the test strip and triggers clotting, the time from addition of sample to the formation of a clot is detected electrochemically and gives the Prothrombin Time (PT) and hence the Prothrombin Ratio (PR). The ISI is automatically applied to the PR and the resultant INR is displayed. The test is intended for capillary samples but any fresh whole blood sample can be used as long as it contains no additives and the test is performed immediately.

3 PERSONNEL PERMITTED TO PERFORM ASSAY
All suitably trained staff who have undergone the necessary training and competency assessment.

4 PRECAUTIONS AND WARNINGS
- Only use the meter if it has been maintained, quality assured and you have been assessed as competent.
- Follow infection control and device policies.
- Always wear gloves when performing invasive procedures and dispose of sharps safely.
- Results must be recorded in such a way that a patient result can be traced back to the meter and operator that generated them.
- The meter is best operated on a level surface or whilst being held horizontally and at ambient temperatures between 18°C and 32°C.
- Make sure relevant information is gathered and discussed with patients and passed to whoever is doing the dosing.

5 PERFORMING ASSAY
(see appendix 1)
Ensure timings are adhered to reduce the risk of erroneous results.

6 QUALITY CONTROL

6.1 Internal Quality Control
(also see appendix 2)
The quality control (QC) should ideally be performed prior to each clinic/once a week, but must be performed when a new box of test strips is first used and at least once a month.
also when the operator has any concerns regarding the meters performance e.g. as a check when unexpected patient INR results of >4 or <1.5 are obtained. Meters that have not been QC checked or have failed a QC check must not be used. All QC results must be recorded in the log book kept with the meter and this must be signed and retained by the device owners for audit purposes. If the QC result/s is out-with the stated range then,

   1. Repeat the QC check
   2. Repeat with fresh QC
   3. Open a new pot of test strips and repeat QC check
   4. Remove the meter from service and seek advice from PoCT or Roche helpline.
   5. Use a different meter that has passed its QC check or send venous patient samples to Pathology.
   6. Record your actions in the log book and sign clearly.

6.2 External Quality Control
All PoCT users must be signed up to an approved external quality assurance scheme (EQA) which will send samples periodically for testing on each meter e.g. Wales External Quality Assurance Scheme (WEQAS). The results should be returned as per the scheme instructions. The performance reports sent by the scheme providers need to be reviewed and signed off on arrival then stored by the device owners for audit purposes. If the reports show poor performance the actions required to resolve this can be discussed with the scheme providers or the PoCT Manager and all actions should be recorded.

6.3 Comparison Checks
As an additional QC check every 25-30 patients a venous sample should also be collected and sent to Haematology, the request form should be marked QC check and have the meter result clearly written on it. The results from the lab’ must be reviewed and significant discrepancies investigated (see appendix 3). NB Meter results below 4 are suitable candidates for comparisons those above 4 should not be used for this QC purpose.

7 CALIBRATION
The meter is factory calibrated and this is adjusted via the calibration chip supplied with each box of test strips, it is therefore essential that the correct chip is used i.e. that chip lot number corresponds to the test strip lot number.

8 REPORTING RESULTS
All results must be clearly recorded according to local protocol so that patient identification is unambiguous. It is recommended that the results are recorded with two digits e.g. 0.5 not .5 and 5.0 not 5. If possible avoid telephoning results but if they must be ‘phoned record to whom and have them repeat back the result to minimize the risk of transcription errors.

9 VALIDATION
If an INR is unexpectedly elevated a repeat sample should be performed.

INR > 4.0 It is recommended that a venous sample is taken and sent to the local Pathology lab for confirmation testing. NB this is not a comparison check, as high results show significant variation to lab’ results.
The local protocol for notification and referral should be followed for all INRs out with the therapeutic range.

10 LIMITATIONS OF ASSAY
Direct thrombin inhibitors and Lupus anticoagulants may falsely elevate results. Many commonly administered drugs and other supplements/remedies can effect the action of warfarin. PoCT is not suitable for all patients. Values above 4.5 show increasingly poor correlation with laboratory and reference methods and consequently should not be used as a basis for treatment.

11 REFERENCE RANGES
INR 0.9 – 1.1 (non-anticoagulated)
INR 2.0 -3.6 therapeutic Range (actual range depends on clinical disorder but a target value of 2.5 is common).

12 INTERPRETATION OF RESULTS
In the absence of anticoagulation therapy the prothrombin time may be prolonged in,
Congenital Deficiencies of factors I,II,VII,X
Disseminated Intravascular Coagulation (DIC)
Hepatic problems- e.g. primary disease of the liver or drug induced damage.
Lupus Anticoagulant

13 HEALTH AND SAFETY/COSHH
Follow Universal Precautions when handling patient specimens as detailed by the Infection Control Manual. Handle all components and all patient samples as recommended for any potentially infectious human serum or blood specimen in the HHS Publication No. (CDC) 93-8395, Biosafety in Microbiological and Biomedical Laboratories, U.S. Government Printing Office; Washington, DC. Use supplied personal protective equipment. Wipe up spills promptly and decontaminate affected surfaces. Avoid generation of aerosols. Follow appropriate waste handling regulations applicable to your area. See associated COSHH sheets for details of individual reagents and link below.

MSDS Roche XSPlus QC POC-EXT-34
MSDS Coaguchek Test Strips POC-EXT-36
http://physchem.ox.ac.uk/MSDS/
14 APPENDIX 1
(for full information see device manual)

1. Check the meter has been QC checked and the results are within limits.
2. Check the meter is clean, if not clean using detergent wipes.
3. Prepare all equipment, check expiry date, lot number of strips and that the meter has been coded with the correct code chip.
4. Gain consent from the patient.
5. Perform hand hygiene and wear gloves as per infection control policy.
6. Wash patient's hands in warm water to clean skin and to promote blood flow, if required, or just clean the chosen finger prick site with water.
7. Enter operator ID (only for meters with this function activated)
8. Remove test strip from the container and immediately re-stopper it.
9. Select “Patient Test” and enter patient ID using case number, NHS number or name (max 20 characters).
10. Insert the strip into the instrument so the lettering “Coaguchek XS PT” is facing up, the meter will beep when it detects the strip (if the beep tone is on), wait for the meter to beep a second time to indicate that it has warmed the strip and is ready.
11. Prick the side of the finger, with a single use lancing device, no lower than the nail bed. If possible avoid using the thumb and index finger.
12. Obtain a sufficiently large hanging drop of blood, avoid squeezing the finger as this can adversely affect the result, and apply it to the semicircular, transparent sample application area of the strip (this must be within 15 seconds of lancing). If a drop has not been applied within the three minute window (counted down on screen) an error message will be generated.
13. Once sufficient blood has been applied the meter will beep and the timer icon will replace the blood drop one. **N.B.** Use only the first drop of blood and do not add more blood after the test has begun.
14. Encourage the patient to apply pressure to the finger prick site with cotton wool until bleeding ceases.
15. If the test fails for any reason or the blood was not applied within 15 seconds of lancing repeat steps 6 onwards and **use a different finger**.
16. Dispose of sharps safely, remove gloves and perform hand decontamination.
17. Record the result, always use a decimal point and two digits e.g. record a result of five as 5.0 not 5

18. If possible avoid telephoning results but if they must be ‘phoned record to whom and have them repeat back the result to minimize the risk of transcription errors.

19. Clean the meter.

15 APPENDIX 2
(extract from Roche manual)

6 Quality Control

The CoaguChek XS Plus meter has a number of built-in quality control functions:

- A check of the electronic components and functions every time the meter is powered on.
- A check of the test strip temperature while a test is in progress.
- A check of the expiration date and lot information on the test strip carried out by the code chip.
- A two-level, on-board quality control test and patient result determination within a single test chamber.

Roche offers optional liquid quality controls for the CoaguChek XS Plus system. These controls are provided to assist with regulatory compliance requirements as applicable to your facility.

To perform an optional liquid quality control test using control solutions, you need:

- CoaguChek XS Plus meter
- The test strip code chip supplied with the test strip container you are using. A code chip is provided with every test strip pack.
- Test strips that came with the code chip mentioned above
- Bottles of CoaguChek XS PT Controls (not available in the United States) or CoaguChek XS Pro PT Controls, diluent droppers, and the quality control code chip provided.

You can choose the frequency of liquid quality control tests in the meter setup. (Refer to the chapter entitled Meter Setup/QC (quality control) Lockout starting on page 65). If the control results in the display are in the specified range, this confirms that the liquid control test was performed correctly.
Preparing to run a liquid quality control test

Prepare for a liquid quality control test in the same way you would prepare to perform a test with a capillary blood sample. The only difference is the use of control solution instead of blood.

1. Have the test strip container at hand.
2. If you are using the test strip lot for the first time, make sure that the code chip that came with these test strips is at hand.
3. Make sure the bottle of freeze-dried (lyophilized) control plasma and the dropper for making the control solution are at hand. This bottle should remain refrigerated (not frozen) until use.
4. Make sure that the quality control code chip that came with the control solution is at hand.
5. Open the lid of the bottle and remove the rubber cap.
6. Hold the dropper with the sealed dropper neck pointing upward, then cut off the end of the cap with scissors. Do not hold the dropper close to your face.

To avoid loss of diluent, hold the dropper by the stem, do not squeeze the bulb of the dropper while cutting the tip.
7 Apply gentle pressure to the reservoir to transfer the entire contents of the dropper to the bottle. Make sure that the dropper does not come into contact with the dried control plasma.

8 Close the bottle again.

9 Make sure the dropper is at hand for the next steps in the liquid quality control test.

10 Swirl the bottle using a circular motion to completely dissolve all of the control plasma inside. Do not shake the bottle or turn it on its side. Doing so can cause components in the control plasma to stick to the sides of the bottle. Please refer to the control solution package insert.

The control solution is now ready to be applied to the test strip.

The control solutions may be reconstituted (mixed) after removal from the refrigerator. The resulting solution may be used up to 30 minutes after reconstitution.
Performing a liquid quality control test

1. Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal.

2. Power on the meter by pressing the button for approximately 1 second. You can also power on the meter directly by inserting a test strip or connecting the power adapter.

3. Wait until the Main Menu is displayed or log on as described on page 78.

4. Check the battery level. If there are no bars left in the battery icon, you cannot perform any more tests.

5. Check that the date and time are correct. Correct any wrong entries as described in the chapter entitled "Meter Setup/Setting the date."
6 Touch Control Test.

7 The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

8 Hold the test strip so the lettering with the test name is facing upward.

9 Slide the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go. A beep tone indicates that the meter has detected the test strip (provided the beeper is enabled).

Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, always close the container immediately after removing a test strip.
If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now. Otherwise you cannot perform a quality control test.

As with the test strips, a quality control code chip is also provided with the control solutions. This chip informs the meter about the acceptable ranges of results for that lot of controls. The information on the code chip is retained in the memory so you can use the same control solutions at any time.

10 Select the code stored for your current control solution, or touch New Code to use a new control solution.

The first time you run a control, the meter skips this QC Test screen option because there are no code chip parameters in memory yet. The next time you use the control, this screen will display, offering you a pick of the code(s) already stored as well as the option New Code.

If you are using a new control solution, remove the strip code chip from the meter and insert the code chip that came with the control solution instead.

If the code chips get mixed up, check the letter on the code chips to tell them apart. The code number on the code chips that came with the test strips starts with the letter S, and the code number on the control solution code chips starts with the letter C.
If performing more than one level, select the level for this measurement.

The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply the control solution.

The dropper icon flashes to indicate that the meter is ready to perform the test and is waiting for the sample to be applied.

At the same time a 180-second countdown begins. You must apply the sample within this time, otherwise you will receive an error message.
12. Using the dropper, draw up the dissolved contents of the bottle.

13. Apply a single drop of control solution directly from the dropper to the semicircular, transparent sample application area on top of the test strip. Do not add more control solution.
You hear a beep when you have applied enough control solution (provided the beeper is enabled). The dropper icon disappears and the test starts.

The result of the liquid quality control test is displayed. It is automatically saved to memory. The acceptable range of results for the liquid control is displayed below the current result.

If a quality control test fails, an up arrow (too high) or down arrow (too low) is displayed and flashes.

**Note:** The arrow (next to the result) refers to the INR result only.

If you have selected to display INR and Quick or INR and seconds, the (up or down) arrow next to the result refers only to the INR value.

The printer icon only appears if the printer function is activated. Otherwise it is not displayed.
14 If you want to add a comment, touch 

15 Select the desired predefined comment(s) from the pick list (if configured) or

16 Touch Custom to enter your own custom comment. Use the keypad (as with login) to enter your comment. A comment may be up to 20 characters in length.

17 Once you have selected the desired comment(s), touch ✓ to return to the results screen.

After the test result is displayed, touch 

18 Remove the test strip from the meter.

If you are performing a 2-level control, you will now be asked to proceed with the second level.

19 Power the meter off.

20 Remove the quality control code chip from the meter and store it with the controls.

21 Clean the meter if this becomes necessary (see chapter 9, Cleaning and Disinfecting the Meter).

Dispose of controls and used test strips from control testing in accordance with the disposal policy of your facility. The control solution contains animal material, which should be considered as potentially infectious.
16 APPENDIX 3

When GP and Lab INRs are compared the resulting point should fall between the lines as in the example below GP 3.1 Lab 2.9