Policy and Procedures for Point of Care Testing using the Coaguchek® device for INR monitoring
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1.0 INTRODUCTION

Point of care testing (POCT) refers to the analysis of samples by non laboratory staff at sites near to the patient. POCT has developed in an attempt to improve patient safety and care by providing immediate access to results of investigations. This allows prompt decision making about patient management and appropriate initiation or adjustment of treatment. The use of POCT is associated with improved time in the INR target range and a significant reduction in risk of thromboembolic events and death (SIGN 129 Antithrombotics: Indications and Management).

International Normalised ratio (INR) measurement for control of anticoagulation therapy with warfarin is an area where a number of analysers have been developed to perform the analysis. The majority of the analysers use a finger prink sample applied to a reagent strip that contains the reagent for analysis. The reaction is read on an analyser which measures the prothrombin time and calculates INR.

This guidance only applies to the Roche Coaguchek® systems for point of care testing in primary care settings. For management of adult patients in primary care receiving warfarin anticoagulation refer to Prescribing Guidelines for the Management of Patients on Warfarin in Primary Care November 2014.

1.1 Aim of the Policy

The aim of the policy is to ensure high quality, safe and effective POCT using Roche Coaguchek® systems in primary care settings for patients and health care professionals in compliance with national guidance.

1.2 Policy Objectives

The objectives of this policy are to:

- Provide guidance on the use of POCT for INR measurement for patients on warfarin in primary care settings in NHS Lothian including: staff training, INR control, identifying and managing clinical events related to anticoagulant therapy, relevant and accurate record keeping, continuity of care when transferring patients between the sectors, health and safety and quality assurance.
- Provide advice on best practice.
- Describe the responsibilities of healthcare professionals when providing POCT for INR measurement for patients on warfarin.

1.3 Scope

To offer standardised, clinically safe, effective and timely measurement of INR and dosage advice for patients on warfarin in primary care settings.

This does not include the use of POCT for self management and self monitoring for patients on warfarin in primary care.

2.0 PHILOSOPHY, PRINCIPLES AND OBJECTIVES

This policy supports high quality, safe and appropriate use of POCT across NHS Lothian in line with national guidance. It describes good practice and provides support for healthcare professionals in the use of POCT in primary care settings.
3.0 ROLES AND RESPONSIBILITIES

3.1 Patients
Informing the specialist team, GP or other healthcare professional if he or she does not have a clear understanding of the treatment.

Reporting any adverse effects to the specialist team, GP or other healthcare professional involved in their care.

Sharing any concerns about their treatment and compliance with the specialist team, GP or other healthcare professional involved in their care.

3.2 Carers and Relatives
Carers have a responsibility to support the patient in fulfilling their roles and responsibilities as outlined above.

3.3 NHS Lothian Staff
Only health care professionals who have received approved training may use POCT equipment to include registered staff and suitably trained and supervised health care staff.

3.4 General Practice or Other Clinical Area
Nominate and document a clinical lead for POCT to supervise and monitor/audit POCT.
Appendix 1.

Responsible for following procedural guidelines.

Responsible for ensuring staff undertaking or supervising POCT have the appropriate clinical expertise and competence to provide comprehensive advice on anticoagulant use and dosage adjustment to patients as appropriate.

Responsible for ensuring non registered staff using POCT are suitably trained and supervised.

Document staff authorised to use POCT Appendix 1.

Responsible for ensuring that appropriate arrangements for initial and ongoing staff training are in place. Manufacturers may be involved in staff training following commissioning of new POCT equipment and may also provide subsequent refresher courses.

Responsible for overall governance for their own patients.

Responsible for agreeing Practice/Clinical Area policy for inclusion/exclusion criteria of patients selected for POCT.

Responsible for ensuring recommended internal and external quality assurance is undertaken.

Responsible for ensuring that clinical and decision support software is available and used and kept up to date.

Responsible for the purchase of the Coaguchek® XS Plus machines for professional use unless purchased by external organisation ie CHP where it remains the property of the external organisation and should be returned when no longer required.

Acquisition of Coaguchek ®XS test strips either on GP10A or other approved supply route.
4.0 TRAINING

In general training will include the following:

- Patient preparation and sample collection techniques
- Contra-indications and limitations of the method
- Familiarisation with policy and procedures to ensure good practice
- Interpretation of results
- Maintenance of equipment and corresponding log
- Recording of patients results
- Use of decision support software for dosage adjustment
- Internal quality control and log
- External quality assessment
- Waste disposal and health and safety aspects
- Responsibility for ensuring continuing competence
- Logging and reporting adverse events

5.0 QUALITY ASSURANCE

5.1 Reagents

CoaguChek® XS PT Test strips:
- Ref 04625358019 (x24)
- Ref 04625315019 (2x24)

All reagents for the test are contained in the test strip (thromboplastin and a peptide substrate).

CoaguChek® XS PT Control Solution
- Ref 04696522190 (x4)

5.2 Storage and Shelf Life

CoaguChek® XS Plus meter and CoaguChek® XS PT Test reagent strips – to be stored at room temperature (15 – 32°C). Expiry date indicated on each pack of test strips.

The lid of the test strips container must be replaced immediately to ensure the strips can be used up to their expiry date.

CoaguChek® Control Solution – to be stored in a refrigerator (2 – 8°C). Expiry date indicated on each pack of solution.

5.3 Calibration

Each box of CoaguChek® XS PT test strips comes with its own code chip. This is inserted into the meter and is stored within the memory of the machine. The code chip calibrates the meter to read and report information provided by the strips during tests.

5.4 Internal CoaguChek® Quality Control

The CoaguChek® XS Plus System has a number of quality-control functions:
- A check of the electronic components and functions every time the meter is switched on
- A check of the meter temperature while a test is in progress
- A check of the expiry date and lot information on the test strip carried out by the code chip
- A quality control function is incorporated into the test strip.

The integrity of each strip is checked prior to a result being produced. When the quality control test runs, the letters “QC” flash on the display screen. When the quality control test is complete a checkmark appears after the letters “QC” and the meter continues to analyse the blood test.
No result will be produced if an error message is displayed. Refer to Error Messages section in the manual for further explanation and relevant action or Roche Technical Support Tel: 0808 100 19 20

5.5 Internal Quality Control

- The CoaguChek® XS PT Control Solution should be used to assess meter readings are within the acceptable range.
- The Coaguchek® XS PT control solution will be stored in a refrigerator maintaining a temperature between 2-8°C
- This should be carried out each time a new box of test strips with a new code chip is commenced or at least once a month or before a large clinic as per manufacturers recommendation or if there is some doubt about the storage/integrity of the strips or if an unexpectedly high or low INR result is obtained on a patient or if anything happens to the machine e.g. dropped, before it is used again to run a patient test.
- It is good practice for the Coaguchek® XS Plus to be set up for “QC lock-out” on a monthly basis to ensure that internal QC checks are completed.
- All quality control results must be documented in either the Quality Control Record Book or on other similar documentation this record should be kept for 7 years (Appendix 2)
- If a quality control test fails it should be repeated and if the second test fails contact Roche Technical support on 0808 100 19 20 and do not use the machine until the problem has been successfully resolved.

5.6 External Quality Control

- It is appropriate that the same regulations in relation to quality assurance apply to POCT as to laboratory based analysis to ensure a valid result is produced to guide patient care.
- Annual registration of UK NEQAS scheme must be maintained for each device.
- Registration with NEQAS should be for their web-based service with results being entered on-line.
- Every CoaguChek® XS Plus System must be checked quarterly via the national NEQAS quality assurance scheme for POCT. The identified Lead clinician must ensure that systems are in place to check the results of each test returned by NEQAS and to take action on any result that is out with the national range.
- For all communications regarding external quality control assessment contact the NEQAS scheme manager, UK NEQAS for Blood Coagulation, Rutledge Mews, 3 Southbourne Road, Sheffield S10 2QN

Appendix 3 provides details of how to run the NEQAS QA test for CoaguChek® XS Plus Monitors and how to enter the results onto the internet system.

The NEQAS test should be run as a patient test.

6.0 METHODS FOR PERFORMING A PATIENT TEST

All personnel should also refer to the CoaguChek® XS Plus System Operator’s Manual as operation can be dependent upon set-up options chosen.

6.1 Limitations of Procedure

Patient selection criteria for POCT should consider the following:
There are a number of possible physiological test interferences, for example, haematocrit, bilirubin, haemolysis, triglycerides, heparin and LMWH (Low Molecular Weight Heparin) levels etc which are outlined in the training manual.

Please refer to the test-strip inserts for more detailed and up to date information.
The blood drop must be a minimum volume. Low sample volume will cause an error message.

There are a number of possible physiological test interferences.
- Bilirubin > 513 µmol/L (30mg/dl)
- Hemolysis > 0.62mmol/L (1000mg/dl)
- Hematocrit ranges below 25% and above 55%.
- Triglycerides > 5.7mmol/L (500mg/dl)
- Heparin concentrations > 0.8 U/ml
- The Coaguchek® XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2IU/ml antifactor xa activity.

Anti-phospholipids antibodies (APA) like Lupus antibodies LA may falsely prolong coagulation times, i.e. they may cause false high INR values and false low Quick values. Where APA are known to be present it is imperative that a result be obtained using an APA insensitive laboratory method for comparison.

Hirudin is not neutralised and leads to false – high INR values and false low Quick values.

6.2 Equipment
- CoaguChek® XS Plus meter using rechargeable battery pack or mains power supply.
- CoaguChek® XS PT Test reagent strips
- Appropriate lancets.
- Gloves
- Non sterile swabs / cotton wool
- Biohazard Container – orange stream bin container with orange lid
- 4x 1.5 volt AA batteries as back-up to rechargeable battery.
- Power supply unit
- Operator’s manual

Each box of test strips contains a code chip. Each time a new box of test strips with a different lot number is commenced the new code chip must be used.

6.3 Procedure
Staff should wash their hands and have a clear and tidy work area.
Staff should wear gloves and follow appropriate infection control guidelines.

All patients should be instructed to wash and dry their hands thoroughly to ensure that hands are clean and free from potential contaminants prior to testing, the use of alcohol gel should be avoided.

Prepare the lancet device, Switch on the CoaguChek® XS Plus monitor and place it on a flat, vibration free surface.

Check the battery level, check the time and date.
All CoaguChek® XS Plus Monitors should set up with the Patient ID, the Patient CHI number should be entered when required. - For patients who are temporary residents, their DoB should be used as ID.

Take one test strip out of container. Close the container immediately after removing the strip. Do not open a pack of test strips or touch a test strip with wet hands or wet gloves as this may damage the test strips.

You have 10 minutes to use a test strip after removing it from the container.
Insert the test strip into the monitor in the direction indicated by the arrows and the lettering “Coaguchek® XS PT” is facing upward. Slide the test strip in as far as it will go. A beep tone indicates that the monitor has detected the test strip.

If you use a new lot of test strips and have not inserted the chip code, you will be prompted to do so.

The hourglass icon shows that the test strip is warming up. Another beep tone indicates that the meter is now ready to have sample of blood applied.

A flashing drop of blood appears on the display and the monitor starts counting down from 180 seconds, only then should the finger be pricked. The blood sample must be applied to the test strip within this time or an error message will be displayed.

Prick the side of the finger (middle or little finger) using lancet device and wait a couple of seconds. If bleeding does not occur using thumb and forefinger move blood from the base of the hand down to the puncture site. This may be carried out as many times as necessary to obtain sufficient blood sample.

Apply the first drop of blood directly to the semicircular, transparent sample application area of the test strip within 15 seconds of pricking the finger. Alternatively a blood drop can be touched against the side of the sample application area. The test strip draws up blood by capillary action. The blood drop must be held against the test strip until the machine bleeps or the transparent strip starts to fill with blood and the flashing blood drop icon disappears.

If insufficient blood is obtained, start again with a different finger and fresh test strip. You will hear a beep when enough blood has been applied. The blood drop symbol will disappear from the display and the test will start.

The CoaguChek® XS Plus meter performs an automatic quality control test on the test strip before it displays the test result. “QC” appears on the display. Following a successful outcome of quality control test, a tick appears after “QC”.

If a cross appears in the QC box the strip is unusable and has failed the internal quality control. Remove the test strip and repeat the test with a new strip. If the test fails for a second time, repeat the test and using a control solution.

The result is displayed in the unit of measurement chosen when setting up the meter. The result is displayed and should be recorded in the patient’s medical / nursing notes and oral anticoagulation booklet in accordance with local protocol.

If an error message appears at any time refer to the Operator’s Manual for details of the error and appropriate action to be taken to either repeat test or contact Roche technical support for assistance.

Remove the test strip and dispose of this and the lancet in an appropriate biohazard container (orange lidded sharps bin).

Wash or clean hands with alcohol gel between patients.

7.0 RESULTS

7.1 Reference Range

The therapeutic range for INR (dependant on the patient’s diagnosis) is patient specific and must be documented in the patients notes but will usually lie between 2.0 and 4.5.
The CoaguChek® XS Plus PT Test strips measure INR within the test range of 0.8 – 8.0.

Results that are out with the measuring range of the strips are indicated by the symbols > (greater than) or < (less than) on the meter. If a greater or less than result is obtained the test should be repeated once using the meter. If the second test returns a greater or less than result, then a GP should be consulted, with consideration given to taking a venous sample of blood to be sent to the laboratory to confirm the result.

In the event of a confirmatory sample being sent to the laboratory this MUST be labelled CONFIRMATORY SAMPLE, GP and PATIENT AWARE. This will avoid unnecessary workload and confusion for laboratory and LUCs colleagues.

7.2 Recording of Results

The INR result should be recorded in the patient’s medical and nursing notes where required and in their oral anticoagulation booklet (yellow book). The recording and documentation system in place must include cumulative records of INR and warfarin dosage. The practice record should serve as the patient’s primary and permanent record.

7.3 Interpreting and Reporting Results

The result of the INR test is assessed against the patient’s previous results and target INR and an adjustment made to the patient’s warfarin dosage, if necessary. The patient must be informed of the dose they are to take and when their next test is to be carried out. The patient should be asked if they have a sufficient supply of warfarin at the correct strengths. Use of decision support software is recommended for warfarin adjustment advice.

7.4 Limitations of Results

If an INR result of greater than 5.1 is obtained from the CoaguChek®XS Plus monitor, this should be repeated with the same technique to ensure that the prolonged result is not a consequence of poor sample quality. The second result should be within 0.5 of the first result, a venous sample may not be necessary in the first instance, but the GP must be informed.

7.5 Abnormal Results

The agreed GP emergency arrangement with the labs for a confirmatory test on a very abnormal result should be followed as a matter of urgency. The GP may need to be in contact with haematology about confirmatory testing and provide access to records of previous INR results held for the patient when POCT has been used.

8.0 CLEANING AND DECONTAMINATION

8.1 Recommended Cleaning /Disinfecting Solutions

Use only the following Solutions for cleaning / disinfecting the meter
70% ethanol or isopropyl alcohol
a mixture of 1 – propanol (400 mg/g), 2 propanol (200mg/g) and glutaraldehyde (1.0mg/g) sold in some countries under the name Bacillol Plus.
1% sodium hypochlorite solution (1 part bleach (10% sodium hypochlorite solution) to 9 parts de-ionised water made fresh every 24 hours)

8.2 Clean the Exterior (Meter Housing)

- Ensure the meter is turned off and using only the recommended solutions wipe the meters exterior clean. Ensure that the blue test guide cover remains tightly closed while cleaning the meter house. **Do not let liquid accumulate near any opening.** Ensure that no liquid enters the meter. Excess moisture can cause malfunction of the equipment.
• With a fresh dry cloth or lint-free tissue wipe away any residual moisture and fluids after cleaning the housing.
• Allow wiped areas to dry for at least 10 minutes before performing a test.

8.3 Cleaning / Disinfecting the test strip guide

Using the solutions recommended previously. Apply the solutions for a contact time of greater than one minute using lint-free cotton swabs / bud. Ensure that no liquid enters the meter. Excess moisture can cause malfunction of the equipment. Do not insert any object in the test strip guide as this may damage the electrical contacts

• Remove the test strip guide cover to clean it. Move the cover safely away from the meter. Then rinse the cover with warm water or wipe it clean using the solutions recommended. Let the test strip guide cover dry for at least 10 minutes before re-attaching it.
• Hold the meter upright with the test strip guide facing down. Clean the easily accessible white area with a moistured cotton swab / bud. Ensure that swab / bud is only damp not wet. Wipe away residual moisture and fluids. With the cover off let the test strip guide dry for at least 10 minutes. After this time re-attach the test strip guide cover to the housing make sure that the cover is properly closed. You will hear it snap into place.

9.0 HEALTH AND SAFETY

9.1 Risk Assessment

Each Clinical Area has to perform their own risk assessments for point of care testing (POCT).

9.2 COSHH

See Roche for safety data sheets. Each Practice has to write their own COSHH assessment. (appendix 4)

10.0 REFERENCES / FURTHER READING

Coaguchek® XS PT Test Method Sheet
Coaguchek® XS Plus Operators Manual
Coaguchek® XS Plus Training Manual


NHS Lothian Prescribing guidelines for the Management of Patients on Warfarin in Primary Care Nov 2014


NHS Lothian Policy on Point of Care Testing Sept 2015
Appendix 1

Procedural Guidance:
MEASUREMENT OF INR USING ROCHE COAGUCHEK ® XS PLUS SYSTEM
NHS Lothian

Practice /Clinical Area: ____________________________

Lead GP or clinician for above Practice/ Clinical Area who is authorising Guidance for use within area: Name____________________ Designation________________ Signature__ Date__

I have read and understood this Guidance : Use of Coaguchek® XS Plus System. I agree not to act beyond my professional competence or out with the recommendations of this Guidance.

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Appendix 2

Procedural Guidance:
USE OF COAGUCHEK® XS PLUS SYSTEM
NHS Lothian
Record of Internal Quality Control Tests Carried Out.

CoaguChek® XS Plus Serial Number___________________________________________

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Test Strip</th>
<th>QC Solution</th>
<th>Person Testing</th>
<th>Result</th>
<th>Comments e.g. within range Yes/No</th>
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Quality Assurance must be carried out using the NEQAS quality assurance scheme in addition to the Internal Quality Controls. Results of the NEQAS tests should be kept along with this sheet or QC Record Book supplied by Roche to provide a comprehensive history of Quality Control Testing on this CoaguChek®XS Plus monitor.
Appendix 3

NEQAS Quality Assurance for CoaguChek® XS Plus Monitors
Point of care testing scheme – web-based participation.

All CoaguChek® XS Plus meters must be registered with the NEQAS (National External Quality Assurance Scheme) quality assurance scheme.

NEQAS send out samples four times a year which must be tested on the appropriate CoaguChek® XS Plus. The test results are sent to NEQAS who compare them with results from all the other CoaguCheks in the scheme. The participant is then informed if the CoaguChek® XS Plus tested produced a result that is within an acceptable range and therefore confirming accuracy of CoaguChek®XS Plus results.

In the interest of Patient Safety all CoaguChek® XS Plus machines MUST have a record of NEQAS Reports confirming it is producing acceptable readings.

It is now possible for participants to enter results and download survey reports online, using the UK NEQAS (Blood Coagulation) website (www.ukneqasbc.org). This system is accessed by a participant-specific secure password which was sent out with your registration documents. Please keep this password in a secure place, as it will not be provided with survey documentation for data security reasons. A reminder of the password can be sent to the registered participant email.

To enter results, proceed as follows:-

- Log in to www.ukneqasbc.org
- Click on the “survey data entry system” button (at the bottom left of the screen).
- Enter your 5 digit participant number (without any letters).
- Enter your password.
- This opens a list of recent surveys with the most recent at the top. If you are trying to enter results the survey needs to be active.
- Select the current survey and click to open the results page.
- Enter your results.
- Click on the “complete” button to send your results to the database.
- After the survey has closed and the analysis has been performed (usually 1-2 weeks) you can print reports through this system by opening the required survey and clicking on the report button. If you provide us with a email address, we can alert when this is available.

Please note the following points:

1. Participants registered for web-based reporting will not receive result sheets with their samples, but will be expected to return results on-line.
2. Hard copies of reports will be sent, but participants will be able to download and print survey reports and other information directly from the website.
3. Reports will be posted to the web approximately 1 week after the survey closing date. Participants can be alerted to the availability of reports if a valid email address has been provided – please check and/or amend the appropriate section of the enclosed re-registration form.
Control of Substances Hazardous to Health Regulations 1989 (COSHH)

General rules for Primary care personnel.

The control of substances hazardous to health regulations 1989 (COSHH), were established to make employers consider more carefully the health problems caused by work activities.

Therefore an employer should not carry out any work which is liable to expose employees to any substances hazardous to health unless:

- They have made a suitable and sufficient assessment of the risks created by the work to the health of those employees.
- Documented the steps needed to be made to reach the requirements of these regulations.

For primary care personnel undertaking laboratory procedures the following SOP has been produced to ensure safe practice and adherence to the COSHH regulations.

Deification of any substances hazardous to patients or researchers

- Whole blood – patients samples – risk of needle stick injury to researchers
- Lyophilised plasma samples – risk of contamination onto skin, eyes and mouth

Potential Hazard

Contact with dangerous micro-organisms including Hepatitis B and HIV

Instructions to protect researchers and patients

- No eating or drinking in the area where blood test or quality control procedures are being performed.
- Ensure that any cuts or grazes on hands are covered by a waterproof dressing.
- Patients must wash and dry hands thoroughly prior to performing finger prick blood test.
- If assisting patients with finger prick blood test one should wear protective gloves to avoid contact with the patients blood.
- Change protective gloves and wash hands between patients to ensure no contamination between patients.

Cleaning, Storage and Disposal

- Any spillages of blood must be cleaned up immediately.
- All tissues / cotton wool used to clean up blood should be disposed of in a clinical waste bag.
- All used sharps must be disposed of immediately in the sharps bins provided.
- All test strips should be disposed of in the sharps bin provided.
- All EQA equipment including used pipettes and glass vials should be disposed of in the sharps bin.
- All surfaces used for training should be washed down at the end of each training session.
- All sharps bins should be locked shut when the contents reach the manufacturers recommended level.
Emergency procedures for needle-stick or contamination injuries

These include:
- Puncture of the skin with a dirty needle
- Exposure to blood or blood product through cuts or breaks in the skin.
- Splashes of blood or blood products in the eye or mouth. E.g. during pipetting of human plasma (EQA)

For a Wound
- Encourage bleeding by gently squeezing the site. **DO NOT SUCK.**
- Wash in warm running water with soap for at least three minutes and dry.
- Apply a waterproof dressing.

For a Splash in the Eye
- Irrigate thoroughly for at least five minutes with eyewash or sterile water if available (if not available use tap water). Remove contact lenses.

For a Splash in the Mouth
- Irrigate thoroughly for at least five minute with drinking water. Do not swallow this water.

All of the above injuries should be reported to:
- Health & Safety Officer, using an Accident / Information report form, Line Manager.
- If patient is known to be HIV or Hepatitis B positive contact an Occupational Health adviser immediately for advice.
- All Primary Care Personnel must be immunised for Hepatitis B. If unsure of current status with regard to Hepatitis B, the Occupational Health Adviser should be contacted for advice.