Procedure for Point of Care Testing using the CoaguChek® Device to monitor INR

Purpose of this procedure:

This procedure is to support Point of Care Testing using the CoaguChek® device for INR monitoring.

The Procedure:

1. 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 prick 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 February 2018.

1.1. Aim of the Procedure

The aim of the procedure 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. Procedure Objectives

The objectives of this procedure 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. Philosophy, Principles and Objectives

This procedure 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. Roles and Responsibilities

3.1. Patients, Relatives and Carers

The responsibility of the patient is to ask if they do not have a clear understanding of the treatment. The responsibility of the patient is also to report any adverse effects to the specialist team, GP or other healthcare professional involved in their care.

Relatives and carers are integral to supporting their family member. The relatives and carers are responsible for sharing any concerns about their treatment and compliance with the specialist team, GP or other healthcare professional involved in their care.

3.2. NHS 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.

3.3. General Practice or Other Clinical Area

Nominate and document a clinical lead for POCT to supervise and monitor/audit POCT (Appendix 1).

The clinical lead will be responsible for following procedural guidelines.

The clinical lead will be 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.

The clinical lead will be responsible for ensuring non registered staff using POCT are suitably trained and supervised.

Document staff authorised to use POCT Appendix 1.

The clinical lead will be 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, may also provide subsequent refresher courses and/or specialised training to selected individuals to allow them to provide in-house training ('super trainers').

The clinical lead will be responsible for overall governance for their own patients.

The clinical lead will be responsible for agreeing Practice/Clinical Area policy for inclusion/exclusion criteria of patients selected for POCT.

The clinical lead will be responsible for ensuring recommended internal and external quality assurance is undertaken.

The clinical lead will be responsible for ensuring that clinical and decision support software is available and used and kept up to date.

The clinical lead will be responsible for the purchase of the CoaguChek® machines for professional use unless purchased by external organisation i.e. Health and Social Care Partnerships where it remains the property of the external organisation and should be returned when no longer required.

Acquisition of CoaguChek® test strips via Roche.

4. 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
- Maintenance of equipment and corresponding log
- Recording of patients results
- Internal quality control and log
- External quality assessment
- Waste disposal and health and safety aspects
- Responsibility for ensuring continuing competence

Training will not include interpretation of results or the use of decision support software for dosage adjustment. Practices should discuss this with staff at a practice level.

5. Quality Assurance

5.1. Reagents

Machine	Test Strip	Control Solution
CoaguChek® XS Plus	CoaguChek® XS PT Ref 04625358019 (1 x 24) Ref 04625315019 (2 x 24)	CoaguChek® XS PT Control Solution Ref 04696522190 (1 x 4)
CoaguChek® Pro II	CoaguChek® PT Ref 06688721019 (2 x 24) All reagents for the test are contained in the test strip (thromboplastin and a peptide substrate).	CoaguChek® PT Control Solution Ref 06679684190 (1 x 4)

5.2. Storage and Shelf-life

CoaguChek® Pro II meter, CoaguChek® XS PT meter, CoaguChek® XS test strips and CoaguChek® 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 after removing a test strip 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® 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® meters have 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 testNo 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® Control Solution should be used to assess meter readings are within the acceptable range.
- The CoaguChek® 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® 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® meter 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, Shefffield S10 2QN

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

The NEQAS sample should be run as a patient test.

6. METHODS FOR PERFORMING A PATIENT TEST

All personnel should also refer to the CoaguChek® 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® PT Test is insensitive to low molecular weight heparis (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 is 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® meter using rechargeable battery pack or mains power supply.
- CoaguChek® Test reagent strips
- Appropriate lancets
- Gloves
- Non sterile swabs / cotton wool
- Biohazard Container – orange stream bin container with orange lid
- 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® monitor and place it on a flat, vibration free surface.

Check the battery level, check the time and date.

All CoaguChek® Monitors should be set up to require the Operator ID, 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; hold the test strip where the lettering is. 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.

Scan operator barcode to log in to the CoaguChek, touch patient test and scan or enter CHI number via the touchscreen.

Insert the test strip into the monitor in the direction indicated by the arrows and the lettering "CoaguChek® 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® 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.

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. 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 patient's notes but will usually lie between 2.0 and 4.5.

The CoaguChek® and 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 taking into consideration any lifestyle factors which will influence the INR. 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® 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. 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. 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).

Associated materials/references:

Appendices

Appendix 1	Measurement of INR using Roche CoaguChek Pro II System- Clinical Lead and Practice Staff Agreement
Appendix 2	Record of Internal Quality Control Testing
Appendix 3	External Quality Assurance- NEQAS
Appendix 4	Control of Substances Hazardous to Health Regulations (COSHH) 2002

Further Reading

SIGN 129: Antithrombotic: Indications and Management June 2013
NHS Lothian Prescribing guidelines for the Management of Patients on Warfarin in Primary Care 2018
Management and use of IVD point of care test devices: MHRA Management and use of in vitro diagnostic(IVD) point-of-care test(POCT) devices.pdf Dec 2013
NHS Lothian Point of care testing Policy