STANDARD OPERATING PROCEDURE
ANTI-COAGULATION NEAR PATIENT TESTING IN PRIMARY CARE

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Author/Lead **Job Title**	Dr Sergio Raise General Practitioner
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Consultation:	Dr Chris Buswell, General Practitioner Maggie Bean, Primary Care Matron Caroline Fuller, Practice Nurse Helen Clarke, Practice Nurse
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VALIDITY – All local SOPS should be accessed via the Trust Intranet

CHANGE RECORD

Version	Date	Change details
1.0	*16/06/20*	*New SOP* *Reviewed and approved at Primary Care CNG*
1.1	*28/08/20*	*CoaguChek XS Plus Analyser Internal Quality Control Log Sheet added as Appendix*
1.2	*12/10/21*	*INR result changed from 6.0 to 5.0 on page 8.* *Clinical Lead 'or designated GP' to lead on INRstar* *Virtually approved by the Primary Care CNG 15/10/21*
1.3	*12/06/24*	*Duties and responsibilities of Qualified and Non-Qualified Staff Training updated on page 3. Appendix 7 Training and Development Application Form added. 7.1 Anti-Coagulation for Housebound Patients added. INRstar Annual Review added to 4.2 CDSS. CoacuChek Pro II device added. Approved by the Primary Care Clinical Network Group (12/06/24).*
1.4	*14/08/24*	*Internal and external audit added to Device Quality Control Assurance* *Approved at PMHD Group (14 August 2024).*

Contents

1. INTRODUCTION

This Standard Operating Procedure (SOP) has been developed to guide practice staff working in Humber Teaching NHS Foundation Trust Primary Care services to deliver optimum anti-coagulation control with a reduction in International Normalised Ratio (INR) tests resulting in improved patient convenience, patient safety, and efficient use of resources and contributes to practice finances.

2. SCOPE

This SOP will be used across all Primary Care services within the Humber Teaching NHS Foundation Trust. It will be used by all clinical staff who undertake anti-coagulation Near Patient Testing (NPT).

3. DUTIES AND RESPONSIBILITIES

GP Clinical Forum
Develop, approve, implement and review the effectiveness of this SOP.

Service Managers, Matrons and Clinical Leads or Designated GP
Review and update this SOP. Ensure dissemination and implementation of this SOP.

Qualified and Non-Qualified Staff Training
All prescribers must undertake INRstar training. Only trained clinical staff are authorised to undertake NPT and will be designated 'authorised users' on the INRstar CDSS. **The minimum training is LEVEL ONE** for anyone using the CoaguChek machine and **LEVEL TWO** for everyone running an INR Clinic using CDSS.
INRstar refresher training should be completed there is a change in the CoaguChek machine or if staff are not fully proficient in using INRstar.

To apply for INRstar training, staff must complete a Training and Development Application (Appendix 7) form for consideration / approval by the Primary Care Clinical Network Group.

Training will be carried out under the supervision of the Clinical Lead or designated GP and will incorporate the following points (depending on the Level achieved):

Basic theory of anti-coagulation
- Clinic aspects of warfarin: side effects, contraindications, interactions, dosing schemes
- Detailed training on the use of the coagulometer apparatus in use at the practice
- Detailed training on the use of INRstar CDSS in use
- Practice-based protocol for the clinic (e.g. who to ask if there is a problem with the equipment, who to ask if INR is out of range etc.
- Achievement of HTFT Competency Requirements for Level 4 Anti-Coagulation monitoring 2010/2011
- Health and Safety procedures (including infection control)
- Quality control procedures
- Record keeping and audit

The taking and testing of blood samples and the use of chemical reagents are activities with Health and Safety at Work implications and these need to be evaluated and documented. Many of these are already in place and documented.

The main implications include written protocols for:
- Safe venesection/finger-prick blood tests
- Glove/eye protection policy

- Pipetting/transfer of samples from specimen bottles to test strips (if applicable to your testing machine)
- Sharps disposal
- Spillages
- Needle-stick injury procedure
- Hepatitis vaccination and antibody testing
- Safe use of reagents (manufacturer will advise).

Health Care Assistants are responsible for taking blood samples, obtaining the INR result, entering the result into the software, generating the dosage recommendation.

Staff will need to have completed the following courses:

- BMJ e-learning
- e-Learning for Health
- INRstar https://help.inrstar.co.uk/Article/ae761248-dc3b-4157-9815-8232ced48530

4. PROCEDURES

4.1. Equipment

The CoaguChek XS Plus and the CoaguChek Pro II are the devices used within Humber Teaching NHS Foundation Trust.

The EQA scheme with NEAQAS UK for Blood Coagulation registers each device and undertakes quarterly checks on the device and the user.

Each device has On-Board Control System ensuring accuracy throughout day-to-day use *in addition* to an external quality control check at the beginning of each clinic.

The test strip reagent is insensitive to heparin, allowing continuous monitoring throughout the heparin to warfarin transition.

Ongoing training support is available from Roche Diagnostics.

4.2. Computer Decision Support Software

CDSS in the form of INRstar software is fully implemented onto our clinical systems.

Recording results and imparting results to patients will be via INR-Book and clinical record.

Individual practices will be sent an INRstar Annual Review which is to be forwarded to ESTATESINFORMATION (HUMBER TEACHING NHS FOUNDATION TRUST) hnf-tr.estatesinformation@nhs.net who will raise a purchase order.

4.3. Device Quality Control Assurance

External Quality Control

A NEQAS external audit is undertaken every 3 months.

Each CoaguChek machine in use will be registered with NEQAS. Each quarter an external quality check will be carried out using samples supplied by NEQAS according to their protocol (see appendix 4).

Results will be monitored and audited and action taken as appropriate.

Patient Control Reagent Test Strip – weekly check

Once a week the following checks will be undertaken:

- Using a new sealed human recombinant test strip, test the device and record the result.
- If the test result fails the expected value, carry out a second test after 5 minutes. Record the result.
- If the device fails a second quality control test, its use is to be discontinued until the manufacturer investigates, repairs and re-certifies the device.
- Where the device passes the daily external quality control test it is ready for use.
- Where the device fails quality control checks, the backup CoaguChek S device is to be used and the main unit sent for check/repair/recalibration by Roche Diagnostics
- Recombinant test strips are to be stored refrigerated (vaccine fridge) and expiry dates checked prior to use.

<u>Internal Quality Control</u> – daily check

- Ensure the device used is clean and free from contaminant
- For the CoaguChek XS Plus and CoaguChek Pro II – check the on-board memory software is working and the correct user is showing
- Check the batch of patient test strips have been stored correctly with lid sealed, in a dry environment free from frost and humidity and are in-date. Discard any incorrectly stored or out-of-date test strips.
- Check the test strip identifier chip matches the identifier number of the carton and insert the strip into the device, ready for use.
- Ensure the batch number has been added to the software and check this each time the software is used on a patient.

An internal audit is undertaken once a week and results are added to the INRstar database.

5. ANTI-COAGULATION INR TEST

- Ensure all required Quality Assurance Checks have been made and check Safe T-Pro lancets and consumables (non-woven cotton wool balls) are available
- Check the INRstar software is loaded / functioning and the clinical programme is running with adequate printer paper
- The CoaguChek device has continuous monitoring of strips and measurements of sufficiency of blood samples – these checks are to be monitored throughout the clinical session
- Patients are to be seated throughout the INR procedure
- A new lancet and a new test strip are to be used for each patient

- Confirm patient ID, check records for special information, instructions (new meds etc.), relevant INR history and consent for this INR procedure

- Enter the patient's identification number on the device, this is the same number used by the practice clinical system

- Enter the patient identification number into the CDSS and confirm current warfarin dose and other medication are as expected. Where this differs, note the patient's regime within appropriate CDSS section

- Insert a new test strip and ensure the device is operating (hourglass displayed)

- When the strip is ready and the device beeps, a 180 second countdown begins. Blood must be loaded to the test strip during this time frame

- Use the lancet to produce a sample of capillary blood from the fourth or fifth finger (either hand). If necessary, the finger can be milked to ensure a sufficient droplet of blood is available. Ensue the finger is generally clean but DO NOT USE AN ALCOHOL WIPE as this may affect the result

- Load the test strip with blood either from the side or the top. The device will beep when sufficient blood is present

- Check the device is testing the blood (hour glass displayed)

- Using non-woven cotton wool ball (ask patient to) apply pressure to the finger to stop any blood flow. Apply adhesive dressing if required.

- The device beeps when the result is displayed with date and time. If an error is reported the test procedure must be re-started with a new test strip.

- The test is complete – follow the next steps according to INR result.

6. ANTI-COAGULATION - INR RESULT

6.1. Using the CDSS for Dose and Recall – In-Range Results

An 'in-range' (therapeutic) result is within 0.5 INR units of target INR

1. Where calculated INR result falls within the therapeutic range **and there is no change in the recommended dose** the CDSS can be used to advise the patient of dose and re-test interval

2. Enter the new INR result into the CDSS

3. Explain to patient the result, dose and re-test period. Minimal dose changes of less than 0.5mg are ignored by the system. **Half tablets are not used.** Multiple tablets (0.5mg. 1mg. 3mg. 5mg.) are used and the system indicates both quantity in mg *and* tablet description regime for the patient to follow. **Print out** starts on the current day of the test so the patient begins new dose immediately. To avoid any confusion for patients the printed diary lists the dose to be taken on a day to day basis. The prescribing of 5mg warfarin tablets will be restricted to those patients needing a dose of 8mg or more.

4. NOTE: **Prosthetic valve patients maximum recall period is 70 days** therefore where the system recall is in excess of this following two INRs within therapeutic range – the recall date should be altered accordingly before the diary is printed.

5. Save the results in the CDSS and complete the INR Isis in the clinical notes.

6. Book the patient's next appointment to the **nearest** INR clinic to that suggested – if necessary, alter the printed diary date depending on result.

6.2. Using the CDSS for Dose and Recall – Out of Range Results

An 'out-of-range' (non-therapeutic) result is more than 0.5 INR units difference to the target INR

1. Where the calculated result falls outside the therapeutic range **the CDSS cannot be used by the HCA or Nurse to calculate the dose** or re-test period and the **result must be referred to the duty doctor**

2. Enter the new INR result into the CDSS and complete the clinical system INR Isis

3. Ask the patient about any recent changes in lifestyle / medication / diet etc. and enter these comments into the CDSS

4. Use the 'REFER' option to store the results / comments

5. There should be no need for receptionists to contact patients outside of the clinic. In exceptional circumstances where the patient needs to be contacted later, the HCA will record an agreed time to contact the patient

6. **If the INR result is 5.0 or higher (or if you have concerns over the result regardless of in-range or not – the patient must remain in the surgery whilst you seek immediate advice from the Duty Doctor**

7. The Practitioner will review the results at the end of the clinic and record dose and re-test interval in the CDSS – either by accepting the CDSS suggestions and printing the diary for each patient – or by manually changing the dose/recall period before printing the diary.

Where the INR is OUT-OF-RANGE
Relevant details will be added by the Nurse Practitioner when the Duty Doctor has reviewed the results. The patient will be informed immediately and asked to wait until the revised dosage has been decided. This ensures any changes to INRstar are not inadvertently omitted from the clinical records.

6.3. Transfer of INR Results from CDSS to Clinical System

INRstar has the ability to communicate with TPP SystmOne which is our clinical system and any results are able to be captured and entered on both. The patient record in SystmOne will be updated with all of the INR, treatment and dosing details from INRstar.

Having entered in the patient's current INR into the CDSS, it will generate a warfarin dose and appropriate review period which can then be saved to the CDSS patient database. A copy of this information will be sent to SystmOne under the relevant read coded entries.

The staff performing INRstar will need to book in the patient's next appointment date into the relevant appointment system as per the normal procedure to ensure the patient is appropriately reviewed.

INRstar has the functionality to amend review dates, if appropriate, to specific dates when warfarin clinics are being performed. The patient can then be booked in for a review as normal.

The following guide (BSH Guidelines) is to be used to supplement the CDSS by the doctors. It is provided for information only for HCA and nurses.

The CDSS has been set within these limits. Only where the suggested recall using the CDSS differs from this should the software be over-ridden. In all such instances the recall period is to be reviewed by the Duty Doctor using the CDSS 'refer' option.

Patients seen after discharge from hospital with prosthetic valves may need more frequent INRs in the first few weeks.
(Based on data from Ryan et al (1989) British Medical Journal 299, 1207-1209)

When a condition known to cause alteration in the dose requirement of warfarin occurs (e.g. a potentially interacting drug), or the patient has an acute intercurrent illness, frequency of monitoring should be increased.

The following conditions cause warfarin sensitivity (i.e. need for reduced dose):

i. liver dysfunction
ii. heart failure
iii. hyperthyroidism
iv. some drugs
v. acute pyrexial episode

Some conditions cause warfarin requirements to be increased (i.e. need for greater than normal dose)

i. hypothyroidism
ii. vitamin K containing remedies, e.g. some herbal remedies and enteral feeds
iii. some drugs (see BNF)

7. CLINIC PATIENT SELECTION

The Clinical Lead or designated GP will decide which of the practice patients are suitable for INR Clinic and what their therapeutic range is and what the time frame for warfarin treatment should be. This information will be used to populate INRstar.

Exceptions will include:

1. Patients whose last INR result is not within therapeutic range
2. Patients under 16 years
3. Patient known to suffer frequent falls
4. Patients with severe Hypertension
5. Patients with known Alcohol Abuse problems
6. Patients with memory impairment without supervision of medication
7. Bacterial Endocarditis
8. Gastro-intestinal disease with high risk of bleeding
9. Severe liver or renal disease
10. Pregnancy
11. Patients newly warfarin-ised until three stable standard INR blood checks have been obtained (either by the practice or by the hospital)
12. Patients who are 'unwilling or unable to cooperate'

N.B: Housebound patients will continue to be seen by the District Nurse team and tested in the conventional way using the Pathology Lab.

We will however undertake to provide the anticoagulation service to these groups should the need arise.

IN ADDITION TO PROTOCOL

All patients who produce an INR of 5.0 or above must be seen by the Duty Doctor before leaving the surgery.

Duty Doctor to consider clinical action and to give clear advice to patient regarding warfarin dose and recall.

7.1. Anti-Coagulation Housebound Patients

1. On initial presentation arrange GP review to patient record to review if patient is unable to attend for blood tests and if Warfarin or a DOAC is appropriate.
2. Practice to contact community team to request visit for INR with advised date.
3. Practice to ensure that virtual appointment slots are in assigned for designated HCA to follow-up patients post community INR date.
4. On return of INR from hospital pathology, HCA to review INR of these patients and add to INRstar. Appropriate same-day clinician to be contacted to review INRstar and authorise / amend as appropriate.
5. Patient to be contacted by HCA Lead and advised of dose and due date for next blood test. This should be confirmed by Accurx if consented.
6. HCA Lead to contact community team or liaise with the practice to contact community team to arrange follow up INR check.
7. Failure for INR to be completed should be discussed with Duty Clinician to advise on appropriate next action.

8. NPT ANTI-COAGULATION CLINIC – AUDITS – CRITICAL INCIDENTS

The Practice will complete a Critical/Significant Event Report for all relevant occurrences. Such occurrences should also include *positive* outcomes.

Outcome events such as thrombosis/embolism or bleeding can be audited as can the actual INR result over time.

The currently preferred method of auditing INR results is that described by Rosendaal et al. in which the total amount of time that each patient has an INR within the therapeutic range is estimated. This is then calculated for the practice population as a whole and presented in terms of number of patient-days (or patient-years) within defined variations from the target INR.

The other recognised method (called point prevalence) is to measure the proportion of patients with INR results that are within, above or below the therapeutic range at any given time.

INRstar software produces these audits automatically, as well as other functions such as identifying patients who are overdue for an INR test.

Results of each Critical Incident / Audit are to be reviewed by the Lead Clinician – and a copy to be sent to the HTFT Risk Management team within 48 hours – and discussed with the clinical team involved in the INR Clinics and communicated to relevant members of the Practice.

Any changes that are identified to improve the performance of the clinics will be implemented through revised protocols.

Appendix 1: CoaguChek XS Plus / CoaguChek Pro II System Competency Checklist

Name:.....

Work Location.....

Date.....

Preparation of equipment	Achieved	Comments
Storage & working temperature of meter & test strips		
Batteries		
Code chip calibration		
Meter set up		
Meter reading range/limitations		
Preparing to test	Achieved	Comments
Preparation of patient – consent/hand washing		
Preparation of nurse - handwashing		
Preparation of meter – positioning and verification of code number		
Lancet device – single use/depth setting		
Test strips – storage/stability outside container/handling		
Carrying out a patient test	Achieved	Comments
Confirming identity of patient		
Correct site and method for sampling		
Obtaining correct amount of blood within 15 seconds		
Application of blood to test strip – top/side dosing		
Reading & recording of result		
Carrying out a quality control test	Achieved	Comments
Automatic on board quality control test		
Failed quality control tests		
Using a control solution – required to test against solution range on a CoaguChek XS and XS Plus / Pro II		
External Quality Assurance (where applicable)		
Safety	Achieved	Comments
Correct disposal of equipment		
Cleaning of meter	Achieved	Comments

General/decontamination		
Interpretation of results	Achieved	Comments
Interpretation of results – lower & upper ranges		
Reviewing stored results (not applicable for multi patient device use)		
Test limitations and interferences (test strip insert)		
Display and error codes		
Additional Comment		

Signature of Trainee...... **Date**.....

Role/Work location.....

Signature of Assessor..... **Date**.....

Role/Work location.....

Appendix 2: CoaguChek XS Plus / Pro II Analyser Internal Quality Control Log Sheet

Date	Time	Machine No.	Person Completing	INR Result	Date	Time	Machine No.	Person Completing	INR Result

Appendix 3: Anti-Coagulation Therapy Audit

STANDARD 1	TARGET	ACTUAL
Each patient on anticoagulation therapy will have documentation recording the following:		
• **Target INR**	YES	
• **Monitoring frequency**	YES	
• **INR measurements**	YES	
50% of last INRs will be within target +/- 0.5 units	YES	
80% of last INRs will be within target +/- 0.5 units	YES	
For all INRs outside their ranges, further actions have been documented	100%	
STANDARD 2		
A monitoring process will be regularly applied to monitor the frequency of patients reviews and DNAs and DNA follow-ups		
• **Percentage of patients reviewed within 8 weeks**	**75%**	
• **Percentage of patients DNAs not followed up**	**10%**	
STANDARD 3		
For each patient with relevant complications a critical incident process will be adhered to		
• **A process to monitor and review complications is in place**	YES	
• **Critical incident reports exist for all patients with a complication**	100% completed	
A critical incident report was completed because		
• **INR <1.5 or >6.0**	**… %**	
• **Signs or symptoms of bleeding**	**… %**	
• **Signs or symptoms of thrombo-embolism**	**… %**	
• **Patients requiring other medical attention**	**… %**	
• **Other complications** (please specify)	**… %**	
STANDARD 4		
A suitable competency based training scheme will be implemented and monitored		
• **Clinical personnel have documented evidence of competence training**	**YES**	
• **Clinic personnel have documented evidence of ongoing appraisal**	**YES / NO / N/A**	
Key competencies will include		
• **NPT Clinic protocols**	**YES**	
• **Haematological testing**	**YES**	
• **Adjustment of anticoagulant dosing using CDSS**	**YES / NO / N/A**	
• **Giving information and advice to patients**	**YES / NO / N/A**	

Appendix 4: Anti-Coagulation Audit Review Sheet

Date of Audit	
Reason for Audit	HTFT Initiated Audit (delete as appropriate) Other Audit (specify reason)
Objectives for Audit	
Who undertook the Audit	
Results	
Learning points	
Changes planned as a result of the Audit	
How were results disseminated with the Practice	
What went well	
What was inadequate	
How could things be improved	
New education needs identified	

Appendix 5: Anti-Coagulation Critical Incident Analysis

Date of Incident	
Description of what happened	
Effect on: The Patient(s)	
Effect on: The Clinician (yourself)	
Effect on: Individuals within the Practice	
Effect on: The Practice as a whole	
Why do you think it happened?	
Steps taken to avoid repetition if UNDESIRABLE	
Steps taken to ensure repetition if DESIRABLE	
Learning needs revealed by the event What was learned / by whom i.e. individuals / practice / patient / HTFT	
New education needs identified	
Date of Review Meeting and Attendees	

Appendix 6: NEQAS Protocol

UK NEQAS
Blood Coagulation

2020/21

UK NEQAS FOR BLOOD COAGULATION

General Information for Participants Registered in the Point of Care Testing EQA Programme For INR Monitoring

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UK NEQAS for Blood Coagulation
3rd Floor Pegasus House, 463a Glossop Road, Sheffield, S10 2QD
Tel: +44 (0)114 267 3300
E-mail: negas@coagega.org.uk
Web site: www.uknegasbc.org

WHAT IS EXTERNAL QUALITY ASSESSMENT (EQA)?

- ❖ EQA is provided by UK NEQAS for Blood Coagulation (BC), an organisation within the NHS and independent from point of care testing (POCT) device manufacturers.
- ❖ EQA is the way your test system can be compared with all other registered participants performing the same test on the same sample using the same device.
- ❖ 4 sets of EQA samples (testing kits) are scheduled for distribution per year; approximately every 3 months.
- ❖ Each participant receives one package of the EQA material with full instructions, for each device registered in the scheme.
- ❖ 2 lyophilised human plasma samples (produced by a subcontractor of UK NEQAS BC) is provided together with a pre measured volume of diluent and a disposable plastic pipette. Samples have passed homogeneity and stability testing prior to analysis.

These are identified by a sample number and also have different coloured lids (purple and yellow).

- ❖ The tests are simple to perform but require approximately 10 minutes dedicated time to complete.
- ❖ Participants are usually allowed approximately 17 days to complete the tests and return results to UK NEQAS BC.
- ❖ Results are entered through our secure website using the participant number and password issued at the point of registration.

Please note the following requirements of laboratory participation in EQA under ISO15189: *"The laboratory shall not communicate with other participants in the interlaboratory comparison programme about sample data until after the submission date", and " The laboratory shall not refer interlaboratory comparison samples for confirmatory examinations before submission of the data, even if this would be routinely done with patient samples". Where evidence of collusion is found, participant performance will be scored as a fail for that survey.*

After the survey closing date, all the INR results received are analysed and a median (target) value is determined for each sample. For each sample a *target range* of 15% around its median is calculated.

This is a retrospective form of EQA. Target ranges cannot be calculated until after the testing is performed and all the results have been returned. INR results on an EQA survey sample within the target (acceptable) range for that sample, is deemed to be "w*ithin consensus*".
Results falling above or below the target (acceptable) range, are deemed "*outwith consensus*".
For example: Survey 1, sample XS01:01. Your INR result on this sample 2.6. Target (acceptable) range for this sample 2.3 – 2.9. Your result is "within consensus".

The total number of participants currently registered in the POCT INR programme is: 4534

Who can take part in the EQA programme?

- Participation in the programme is available to all centres performing point of care INR testing, both within and outside the UK.
- We are able to offer POC INR EQA programmes for Roche CoaguChek XS, XS plus, XS Pro, ProII and INRange devices, Hemochron, ISTAT and Xprecia Stride devices. For any other POC INR device, please contact us for information.

FREQUENTLY ASKED QUESTIONS

These are the questions which are regularly asked by our participants.

How should I store the sample package?

The samples have been stability tested and will be stable for several weeks at room temperature. They might be affected if they have been exposed to strong direct sunlight or to increased temperatures (for example, storage on top of a radiator).

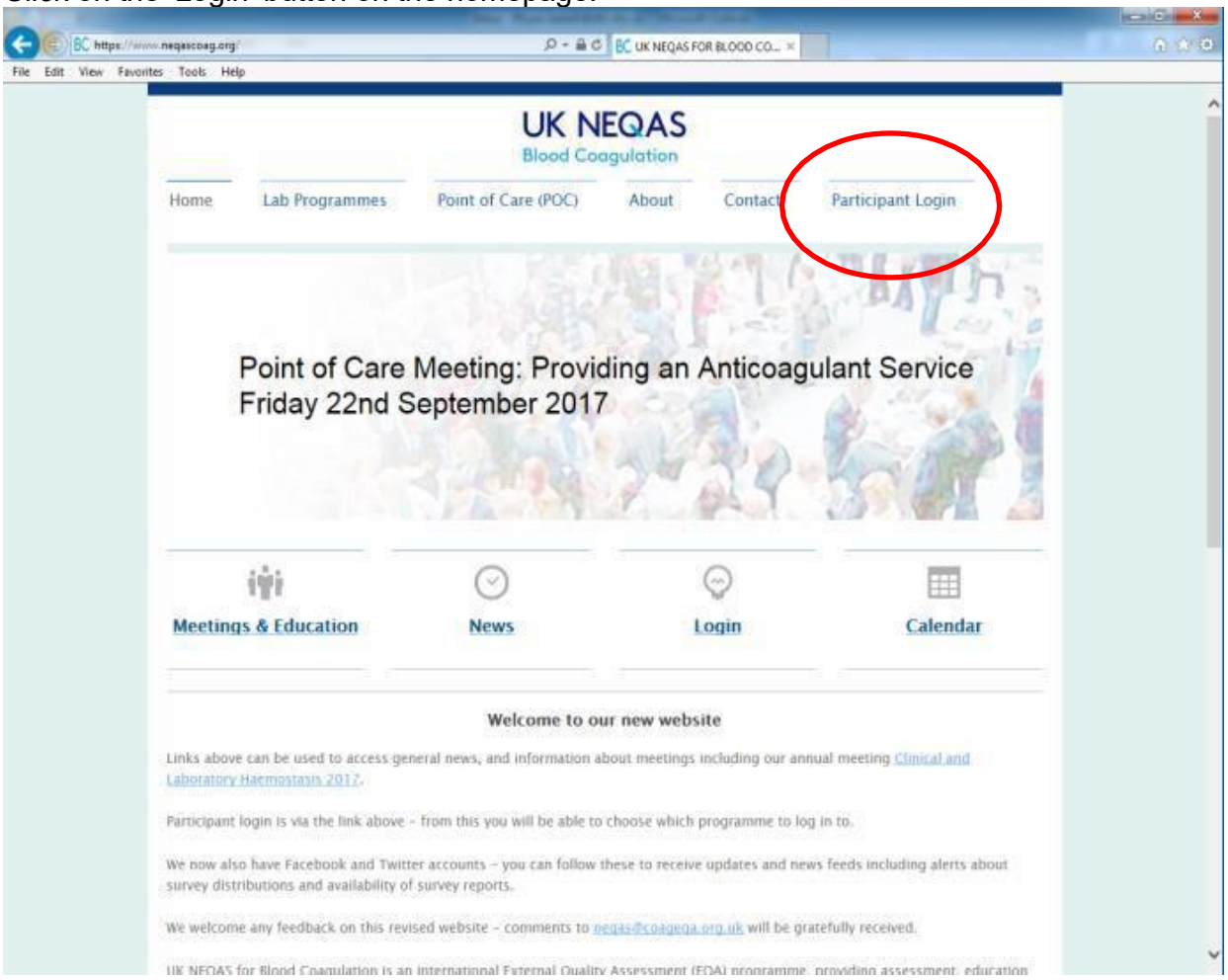
What is my participant number and where can I find it?

Your participant number is issued when you register in the programme along with your password. These are detailed in the letter confirming your registration in the UK NEQAS BC EQA Programme which is sent via email. It will also be on the address label of the survey packs and on any correspondence we may send to you. Your participant number is your unique identifier and must be quoted in all communications with us.

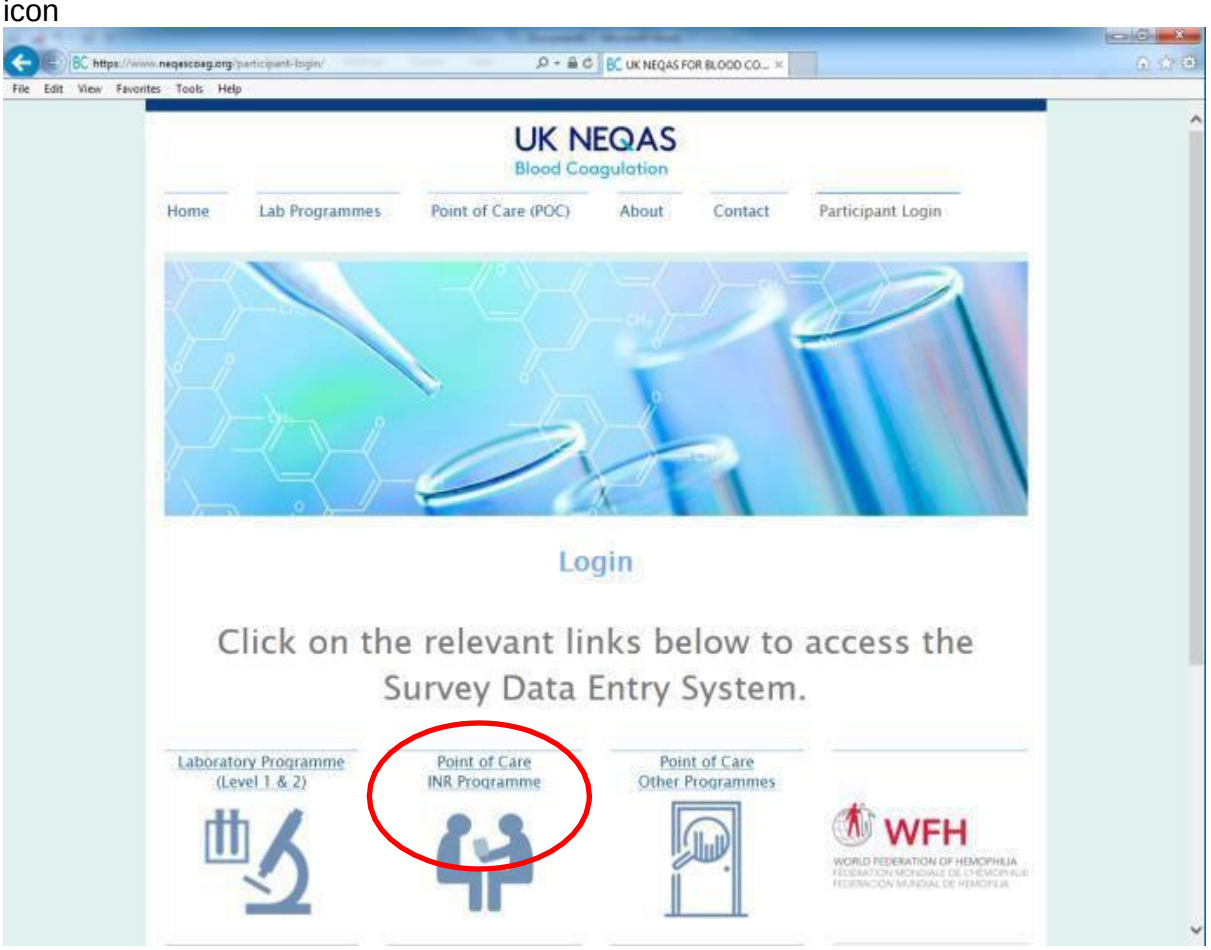
How do I submit my results?

Go to our website www.uknegasbc.org

Click on the 'Login' button on the homepage.

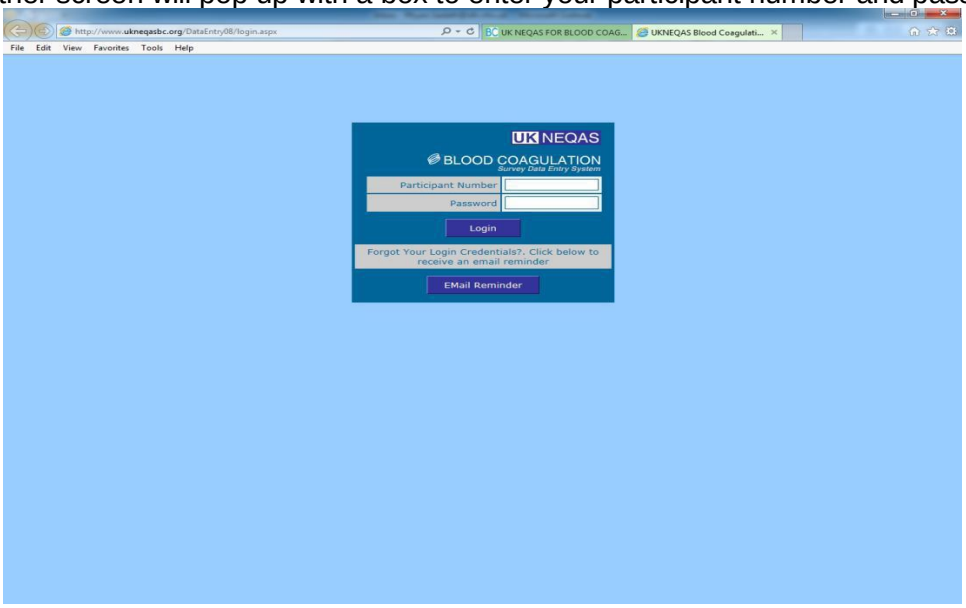


This will then take you to the following page. Choose the Point of care INR programme icon



The current login page will then open. Your login details (participant number and password) will remain unchanged.

Another screen will pop up with a box to enter your participant number and password to log in.



- Your participant number and password are provided in the letter co registration in the programme and must be kept in a safe place as required for each survey.

- Once you have entered this information, click 'Login'

- This will take you through to a screen listing the surveys. The current survey will be at the top of this list and say ‘Active’ at the end of the row. Click on this row.

- This will take you through to the screen to enter your results. You will see two boxes, each with a different sample number written inside. Enter your results into the relevant box, and the relevant lot number of the test strips.

- Once you are happy with all the information you have entered, click ‘Submit’ in the top right hand corner.

- Click the ‘Print’ button in the top right hand corner to print a copy to keep for your own records.

- Logout

How will I know if my results are within the acceptable range or not?*

When the results have been analysed, a report is produced which shows the target (acceptable) range for each sample and the results which you submitted. Participants will access this report via the website in the same way as they entered results. A pdf icon will be present on the right hand side of the survey line, the report is opened by clicking on this icon.
*(often referred to as ‘within consensus’. If your results are outside the acceptable range, this is referred to as outwith consensus.)

What do I do if my results are not within the acceptable range?

If one, or both, of your results fall outwith consensus, contact us by phone on 0114 2673300 or by email at neqas@coageqa.org.uk to request further samples so that you can repeat the test(s). If only one of your results is outwith consensus, you only need to request that sample. If, following the re test, your result falls within consensus, you don’t need to do anything, just keep the information for your own records. However, if your result falls outwith consensus again, please contact us for advice.
If your results are “outwith consensus” in 3 consecutive surveys you will receive a letter from the Scheme Director bringing this to your attention and offering assistance.

What happens if I don’t return my survey results?

If a participant does not return results for a survey this will be treated in the same manner as an outwith consensus performance. Participants not returning results in 3 consecutive surveys will receive a letter from the Scheme Director indicating performance ‘persistently outwith consensus’. UK NEQAS BC acknowledges that issues may arise which may impact on the testing of survey samples. If you are unable to return results for a survey e.g. if your machine is broken, please contact us and let us know. Dates for subsequent surveys are stated on the preceding survey report, allowing forward planning. Survey dates are also displayed on the website. Choose the Point of Care tab and then select Survey Schedules from the list on the left hand side of the page.

What information is shown in the report?

After analysis, each centre will receive a report showing their results and comparisons with the median (target) values obtained. UK NEQAS BC will indicate whether your results are within limits and also show previous survey performance in the form of a graph enabling each centre to check ongoing performance in the programme. It is important to store these documents, but should these be misplaced, copies of the report may be reprinted from each centre’s password secure page accessed through the UK NEQAS BC website.

What do I do if I want to register more than one device?

It is recommended that each device is registered in an EQA programme to individually test and check that reliable results are produced. Each device, when registered, will have its own unique participant number and password. If registering more than one device, it is advisable to assign the individual participant numbers (issued to you when we confirm your registration in the scheme) to the serial number which can be found on each device so that the testing history of each device is consistent.

Do I have to register each year?

Registered centres who require a purchase order to ensure payment of their invoices, will receive a re registration form (which will be printed on blue paper) with the January survey. This document shows the existing details which we hold for your registration(s) and must be returned to us along with a purchase order. Centres who do not require a purchase order for payment of their invoices will be asked to complete an online renewal form before entering their results. If there are any changes which have not previously been notified to us, we need to be aware of these so that we can update our records and ensure that we have accurate information.

If you no longer wish to participate in the scheme, you must also let us know, in writing, so that we can ensure that we do not send future surveys out to you or raise an invoice for your centre. Please keep a copy of the document for your own records. **If we do not hear from you, we will continue to provide this service for the following financial year, and you will receive an invoice as indicated below.**

What will you do with my information?

Participation and performance details are strictly confidential – UK NEQAS BC protects participant information and we do not share this with other participants or any third party, with the exceptions detailed below. Use of the participant number can assist in maintaining confidentiality in survey correspondence.

As part of registration, participants in the UK are requested to formally agree to adhere to the Joint Working Group's (JWG) Conditions of Participation in UK EQA Schemes https://www.rcpath.org/resourceLibrary/joint-working-group-on-quality-assurance-conditions-of-eqa-scheme-participation.html Under these conditions, the Scheme Director is obliged to share unresolved performance issues including the identity of the participant. with the appropriate National Quality Assurance Advisory Panel (NQAAP) and the Chairman and members of the JWG, who may require communication with further regulatory bodies.

What should I do if my machine is replaced by the manufacturer due to breakage, faults etc.?

If your existing machine is replaced, all you need to do is contact us to let us know the new serial number. Your existing registration details (participant number and password) will not be affected.

UK NEQAS for Blood Coagulation website

www.uknegasbc.org

On the website you can find information on our programmes, survey distribution dates, and downloadable files for information and registration documents together with information about educational meetings. There are also photo instructions that show you how to test survey samples.

Complaints and Appeals

If you wish to complain about any aspect of the UK NEQAS BC programme please contact us – details given below. Any complaint about UK NEQAS BC will be treated as serious and will be dealt with as soon as possible by the Director or Manager. If you think that your results have been scored inappropriately you can **appeal** this outcome. Please contact UK NEQAS BC either by e-mail or telephone (details shown below) If the outcome of a complaint is not to the satisfaction of the participant, referral may be made initially to the Chairman of the UK NEQAS BC Steering Committee.

Address for complaints and appeals: UK NEQAS for Blood Coagulation
3rd Floor, Pegasus House, 463A Glossop Road, Sheffield S10 2QD, UK Tel: +44 (0)114 267 3300
E-mail: negas@coagega.org.uk

OTHER PROGRAMMES

UK NEQAS BC also offers EQA for the following programmes:

- POCT D Dimer
- POCT ACT +
- POCT ACT LR
- POCT Rotem / TEG

For further information on any of our programmes, and details of annual fees, please contact us as follows:
Tel: +44 (0)114 267 3300
UK E-mail: negas@coagega.org.uk
Countries outside the UK E.mail: equals@sth.nhs.uk

Appendix 7: Training and Development Application Form

Community & Primary Care Division

TRAINING AND DEVELOPMENT APPLICATION FORM

PERSONAL DETAILS (please PRINT your name, job title and work address)

Surname:		**Forename**:	
Job title:		**Assignment Nº** *(from your payslip)*:	
Work base address (including postcode):			
Tel No:		**Mobile No:**	

Training provider (full name of company) & name of course	Level/Area *(if applicable)*	Date	Time
Duration of course / time commitment:			
Cost of training (if not on ESR):			
How will the course be funded?			
☐ **HEE** ☐ **Training budget** ☐ **Don't know**			
Please tell us why you are making an application for training below:			
How will this training support your own personal / professional development, and improve patient care / service delivery?			

Date discussed at appraisal/mid-point review and managers comments:

AUTHORISATION

Applicant's signature:		**Date:**	
Manager's signature:		**Managers name:**	
Manager's email:		**Date:**	

TO BE COMPLETED BY THE CLINICAL NETWORK GROUP

Date request considered by the Clinical Network Group:	

The above application has been considered by the appropriate Clinical Network Group. The application has been **Approved/ Declined*** **(* delete as appropriate)**
Reason application declined (if applicable):
Next steps: Applicant to work with admin in the team to book a place on the training and add a non-catalogue request to Oracle (Oracle order and invoice are not required if the course HEE funded).