Service Specification No.	11X-34 – v4
Service	Anti-Coagulation Initiation, Stabilisation and Monitoring
Commissioner Lead	As per the Particulars of the NHS Standard Contract
Provider Lead	As per the Particulars of the NHS Standard Contract
Period	01 April 2021 – 31 March 2024
Date of Review	October 2021

1. Population Needs

National/local context and evidence base

1.1 Anticoagulation therapy is required for people with a range of conditions, who are diagnosed in a range of settings. Atrial Fibrillation is the most common condition requiring anticoagulation and affects up to 2% of population. Other conditions in which patients require anticoagulation therapy include Venous Thromboembolism (VTE), Deep Vein Thrombosis (DVT) and other disorders requiring cardioversion.

1.2 There are currently around 4500 patients in Somerset on Warfarin representing a prevalence of 1.5% of the adult population. Anticoagulation aims to reduce the potential adverse haematological effects of the underlying condition requiring treatment.

1.3 Vitamin K antagonists are the most commonly prescribed medications used for anticoagulation of which warfarin is the most prescribed. Other drugs in this group include Acenocoumarol and Phenindione. While these are very effective drugs for this purpose, they can also have serious unwanted effects, e.g. severe haemorrhage, if given in excess, so careful monitoring is required.

1.4 The effectiveness of anticoagulation is measured by the International Normalised Ratio (INR) level. This measures the delay in the clotting of the blood caused by warfarin. While the "normal" INR is 1, the specific target range of INR to be achieved depends on the underlying clinical condition requiring anticoagulation. Warfarin monitoring aims to safely achieve and maintain anticoagulation within a defined target INR range and for a set period of time depending on the underlying clinical condition. Novel Oral Anticoagulants (NOACs) are increasingly being prescribed but do not require INR monitoring. However, despite the increasing number of patients on the new drugs, they are not appropriate for all patients needing anticoagulation and there will always be a need to have some patients requiring warfarin for this purpose.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	✓
Domain 2	**Enhancing quality of life for people with long-term conditions**	✓
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	✓
Domain 4	**Ensuring people have a positive experience of care**	✓
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	✓

2.2 Local defined outcomes CCG Outcomes Indicator Set

Domain 1	**Under 75 mortality from cardiovascular disease; under 75 mortality from cancer**	✓
Domain 2	**Ensuring people feel supported to manage their condition**	✓
Domain 3	**Emergency re-admissions within 30 days of discharge from hospital**	✓

Domain 4	**Patient experience of GP out-of-hours services and patient experience of hospital care**	✓
Domain 5	**Patient safety incidents reported**	✓

3. Scope

AIMS AND OBJECTIVES OF SERVICE

3.1 This service specification provides for the safe monitoring of patients prescribed vitamin K antagonist oral anticoagulants such as Warfarin.

3.2 It also provides for the initiation and stabilisation of patients for Atrial Fibrillation and Venous Thromboembolism:

Initiation, Stabilisation	**Monitoring**
Atrial Fibrillation (AF)	Atrial Fibrillation (AF)
Venous Thromboembolism (VTE)	Venous Thromboembolism (VTE)
	Prosthetic Heart Valves
	Cardiomyopathy
	Recurrent Transient Ischaemic attack
	Chronic Rheumatic Heart Disease
	Antiphospholipid Syndrome

3.3 This specification also supports additional monitoring requirements for patients prescribed a vitamin K antagonist pre and post operatively and pre and post cardioversion.

3.4 Patients from out of area may be managed within this service. It is recommended that patients requiring more than one Point of Care Test (POCT) should be monitored using the Provider's Clinical Decision Support Software (CDSS).

3.5 The service shall be provided in normal surgery hours.

3.6 The Provider shall ensure that the Anti-Coagulation Initiation, Stabilisation and Monitoring Service (referred to as 'the Service' hereafter), includes:

- the initiation, stabilisation and monitoring of patients, by the Provider, undertaken in accordance with the latest guidance including that produced by the British Committee for Standards in Haematology (refer to 4.1) and a practice Standard Operating Procedure (SOP)
- blood sampling (Capillary and Venous – as appropriate), testing and determining the INR
- anticoagulant dosing with prescribing in accordance with the latest guidance issued by the British Committee for Standards in Haematology (refer to 4.1) and relevant AF National Institute for Clinical Excellence (NICE) guidance (refer to 4.2)
- the minimisation of potential side effects of warfarin by utilising regular monitoring to stabilise the International Normalised Ratio (INR) levels of patients while continuing to maximise the effective benefits of such treatment
- the maintenance of monitoring of patients within agreed levels, including Time in Therapeutic Range (TTR) – see 'Monitoring Requirements'
- regular review of the requirement for continuation of therapy
- discontinuation of therapy when appropriate, e.g. when changed to an alternative treatment such as Novel Oral Anticoagulants

3.7 Domiciliary visits to housebound patients who require anti-coagulation monitoring may be undertaken by others, on behalf of the Provider, for the purpose of blood sampling, testing and determining the INR. The Provider will be responsible for the subsequent dosing and prescribing. This also applies to patients in nursing and residential care homes.

SERVICE DESCRIPTION / CARE PATHWAY

Accountability

3.8 The Provider shall nominate a GP as the clinical lead who will ensure that the service within the Practice is established in accordance with this specification and national guidance and recommendations. The name of the GP lead will be advised to the Commissioner.

3.9 Lines of accountability shall be clearly written into practice Standard Operating Procedures which shall cover but may not be limited to the following areas:

- Initiation and Stabilisation
- Training / Education for POCT and use of CDSS
- Use of POCT equipment (in accordance with the manufacturer's instructions)
- Health & safety
- Quality Assurance
- Maintenance
- Accreditation
- Record keeping
- Audit
- Adverse incident reporting

3.10 The Provider is clinically responsible for all patients, where accepted under their care, for anticoagulation initiation, stabilisation and monitoring. The Provider must ensure that explicit contingency plans are in place to cover absence for annual leave and sickness leave for both the running of clinics, supervision of staff and for advice to patients who have queries or problems.

Service Requirements

3.11 The Provider shall deliver the service in accordance with the following criteria:

a. Anticoagulation clinics will be held at least weekly or, have available appointments and domiciliary visits each week for a period sufficient to accommodate the number of patients requiring anticoagulation monitoring, in a timely manner.

b. The management of clinics and appointments adheres to current and future guidance and recommendations.

c. The Provider may agree not to provide a POCT service to housebound patients and opt into an alternative provision as arranged by the CCG. This alternative service does not include provision to patients in Nursing Homes.

d. If a Nursing Home carries out a PoCT for anti-coagulation monitoring and reports the result to the General Practice responsible for the patients' dosage, the Provider of this

service will:

- retain the clinical and medico-legal responsibilities for PoCT
- receive assurance that the Nursing Home regime for PoCT meets the required clinical standards, especially in relation to staff competencies, internal and external quality control

e. If an alternative provider undertakes INR testing on behalf of the commissioned Provider, the commissioned Provider must agree a protocol for the transfer of information using a standard template. An example of this is shown at Appendix A.

f. A person with AF identified as requiring anticoagulation therapy shall be initiated as clinically appropriate and as soon as possible.

g. At initial diagnosis and at least annually, an appropriate review of the registered patient's health is carried out including checks for potential complications and, as necessary, a review of the registered patient's own monitoring records. This should include assessment of the patient's risk of major bleeding. The HAS-BLED score is recommended for the assessment of the risk of bleeding in people who are starting or who have started anticoagulation therapy (refer to 4.3).

h. The use of Clinical Decision Support System (CDSS) software and any in-house POCT testing equipment must meet the standards set by the Medicines and Healthcare products Regulatory Agency (MHRA). (refer to 4.4)

i. For the purpose of this service, 'stable' is defined as three consecutive INR results in target range.

j. Offer and provide education to all patients in understanding their treatment in terms of their condition requiring warfarin, target range for INR, the effects of under/over anticoagulation, diet, lifestyle and drug interactions. Where a patient has been initiated on a Vitamin K antagonist by secondary care and discharged for ongoing monitoring within the Service, it is the hospital's responsibility to provide the patient with relevant information and education before discharge. The Provider should be assured this has been undertaken.

k. All patients (and/or their carers and support staff when appropriate) should receive advice on the appropriate management and prevention of complications for their condition; including the provision of patient held booklets.

l. The Provider will prepare individual management plans with patients, which give the diagnosis, planned duration and target range to be maintained during therapy. This shall be recorded in the patient held record (yellow book)

m. Where a patient is under the care of a hospital then the Provider must ensure it adheres to any agreed local protocol that exists between the Provider and the hospital.

n. Ensure that systematic call and recall of registered patients on the Register takes place as detailed in the guidance issued by British Committee for Standards in Haematology (refer to 4.1).

o. Practices should take reasonable steps to contact patients who fail to attend a clinic or appointment. The Provider should monitor regular non-attendance of patients and take reasonable steps to ensure that regular testing takes place and to assess any risk of over anti-coagulation. Where, in such circumstances, the Provider is considering discontinuation of treatment, it may be beneficial to seek advice.

p. If a patient requires Vitamin K for over anti-coagulation this should be arranged by discussion with a suitable clinician in the appropriate haematology department. The

practice should also complete a report via the Medications Incident Reporting System, (see paragraph 3.48 below).

q. In the event of failure of the blood testing equipment for a period longer than 24 hours, please refer to paragraph 3.28.

r. In the event of failure of CDSS software for a period of longer than 48 hours, please refer to paragraph 3.29.

s. All patients receiving anticoagulation therapy should be reviewed at least once a year, including but not necessarily limited to the following:

- Reassessment of stroke or VTE risk
- Reassessment of bleeding risk (the HAS-BLED score is recommended by NICE, refer to 4.3)
- Assessment of renal function with U&Es and FBC tests to ensure there is a record of measurement of renal failure (egfr) and any signs of anaemia
- Incidence of adverse events relating to anticoagulation therapy since last review
- Assessment of compliance against the patients TTR

Pre and post-operative monitoring including cardioversion

3.12 It is recognised that patients requiring cardioversion or other similar future interventions and those requiring elective surgery may require additional monitoring as advised by secondary care, pre and post operatively. Patients undergoing cardioversion may require more intensive monitoring before and after a procedure and in accordance with a protocol agreed with the patient's Cardiologist.

Consent

3.13 The patient should be fully informed of the treatment options, risk and the treatment being proposed, consented and willing to participate.

PATIENT INVOLVEMENT

3.14 People prescribed anticoagulation therapy should be involved in the decisions about their ongoing medication and given high-quality information about anticoagulants to enable them to make fully informed decisions regarding their ongoing care.

3.15 Practices should encourage, consider and report any patient feedback (positive and negative) on the service that they provide and use it to improve the care provided to patients, particularly if there are plans to alter the way a service is delivered or accessed.

TRAINING AND ACCREDITATION

3.16 The Provider shall ensure that each member of staff undertaking Point of Care Testing has received appropriate training approved by the CCG. It is an expectation that all staff undertaking POCT should review their training competency every 2 years (24 months) to ensure they remain compliant.

3.17 At the end of every 24 month period following initial accreditation all staff providing the POCT service should undertake the following questionnaire; https://www.surveymonkey.co.uk/r/N83JPCC

It is the responsibility of the provider to ensure this self-assessment questionnaire is undertaken and an appropriate process should be implemented in all providers to monitor

clinician training accreditation and expiry.

This questionnaire will determine whether or not that at the end of every 24 month period each person delivering the POCT service needs to attend the appropriate training course provided by SPS on behalf of Somerset CCG. The process for undertaking the questionnaire is as follows:

1. The provider contacts Somerset CCG to advise a clinician(s) is no longer compliant with training requirement and either requests details on training available or advises the questionnaire will be undertaken. Somerset CCG will be made aware via reports received from South West Pathology Services (SPS) that a clinicians training accreditation has expired but it is the providers responsibility to instigate this process
2. Provider completes self-assessment questionnaire which is in the form of a Survey Monkey (link above) which will determine whether or not it is appropriate for the clinician to undertake the training again (in line with the caveats listed in 3.18)
3. Provider to inform Somerset CCG of the outcome which will either be to book onto a training course through SPS or to submit a declaration in writing to the CCG stating that the self-assessment has been undertaken and the training has been deemed not required. If training is deemed not required, this certifies the clinician for a further 24 months. In order for it to be deemed the training is not necessary the clinician must answer 'yes' to each question on the self-assessment. This declaration should be sent to somccg.generalpractice@nhs.net.
4. A declaration has also been included on the Survey Monkey questionnaire asking the provider asking the provider to specify which option has been chosen and any subsequent action required
5. If the self-assessment questionnaire results in the clinician being required to attend the SPS training course and the provider fails to register that clinician onto a course within one month, Somerset CCG will issue the provider with a letter
6. Somerset CCG will liaise with SPS to ensure records are updated appropriately and remain consistent across both organisations

3.18 There are a number of important caveats to the self-assessment training questionnaire that overrule it being deemed not necessary for a clinician to attend the training course, these are as follows;

- Any new starters at a provider organisation MUST undertake the training provided by SPS and cannot be trained by an existing member of staff to ensure compliance
- If there are any significant changes to the training course provided by SPS (clinical processes/governance) will waiver the right for clinicians to complete the self-assessment questionnaire and will automatically require them to undertake the training at their next expiry interval. SPS are required to inform Somerset CCG of any significant changes to this effect

3.19 The Lead GP shall ensure that all staff involved in providing this service shall have their role and competencies reviewed as part of the annual appraisal process to identify any further training needs. If, by exception, staff have not attended the approved training the GP Lead shall be able to evidence that the individual is suitably qualified to conduct POCT.

3.20 Appropriate training is summarised below:

- By providing this service the Lead GP confirms he/she has the knowledge and experience or mentoring support in place to undertake this Service.

- Nurses and other non-prescribing clinical staff will attend the approved courses provided by or, on behalf of the CCG or, by exception, have demonstrated that they have the knowledge and experience to undertake this Service.

3.21 Training shall include but not necessarily be limited to:

- sample requirement and specimen collection

- sample preparation `
- stability of sample and reagents
- analyse measurement
- maintenance, calibration and cleaning of instrument
- appropriate use of equipment and consequences of inappropriate use
- reporting of results
- knowledge of normal and abnormal results and actions in the event of an abnormal result
- performance of quality control
- documentation of test and quality control results
- health and safety
- Determining the INR
- Patient education
- Drug interactions with Vit K antagonists

3.22 All members of the Provider team conducting POCT will have completed the appropriate training from the manufacturer or supplier of their chosen testing equipment and CDSS(this may take the form of an E-training module) or, receive training from a clinician who has previously undertaken training from the manufacturer or supplier.

3.23 The CCG will require evidence of the training completed including equipment and equipment cascade training to be available.

3.24 Providers should ensure that they are familiar with current national guidance on workforce competencies (refer to 4.5).

QUALITY REQUIREMENTS

3.25 The Provider will be familiar with the MHRA Patient Safety Alert 'Improving medical device incident reporting and learning (refer to 4.6)

3.26 The Provider will ensure that when undertaking point of care testing in the surgery or clinic, it uses appropriate Clinical Decision Support Software (CDSS) in order to maintain the INR levels within the therapeutic range, extend the time between INR tests and effectively manage anticoagulation records facilitating service audit. Each patient will receive printed information from the clinical decision support system software or, written information confirming their INR reading and dosage before leaving the surgery or clinic

3.27 The Provider will ensure that when undertaking point of care testing during a domiciliary visit or, if an alternative provider undertakes the testing on behalf of the commissioned provider, the results should be recorded in the patient's hand held record at the time of testing. This should subsequently be recorded using the clinical decision support system software within (24) hours of the test in order, to verify the dosage and maintain up to date patient records. If the clinical decision support system software recommends any changes in dosing this should be notified to the patient before the next dose of oral treatment is due.

3.28 The Provider will ensure that in the event of the failure of the blood testing equipment for

more than 24 hours, the Provider will liaise with the equipment provider to determine whether replacement equipment can be obtained. Should this not be feasible, then the Provider will:

- utilise the services of an alternative Somerset provider of this service or
- take a venous blood sample and send it for INR analysis inform the CCG within 48 hours of the action and the date when normal service will resume.

3.29 The Provider will ensure that in the event of failure of the clinical decision support system software the Provider will, within 48 hours either rectify the fault, or

- utilise the services of an alternative Somerset provider of this service or
- take a venous blood sample and send it for INR analysis
- inform their Commissioner at CCG within 48 hours of the action and the date when the Service will resume. The provider may continue to use the blood testing equipment during the initial 48 hour period where in the opinion of the practitioner patient safety may be compromised by the complete withdrawal of the service.

3.30 Patient information received at the Practice following discharge from hospital, concerning vitamin K antagonist dosing, should be reviewed and acted upon in a timely manner.

3.31 In the event of a patient requiring vitamin K for over anticoagulation, this should be reported as an incident as detailed in paragraph 3.48.

3.32 Quality assurance must be carried out in accordance with recommendations of the British Committee for Standards in Haematology (refer to 4.1).

3.33 Internal quality assurance checks and the cleaning of equipment must be carried in accordance with the manufacturers' instructions on each day that the equipment is used prior to their use on that day.

3.34 Strips and reagents must be stored in accordance with manufacturer's guidance. If refrigeration is required the reagents or strips stored must have temperature checks recorded on each working day.

3.35 External quality assurance checks must be conducted every two months to verify the accuracy of blood testing machinery and dosing. The Provider will need to be registered with an approved External Quality Assurance organisation that provides testing samples for the blood testing of equipment used.

3.36 Any External Quality Assurance organisation used to test blood as part of the Anti-Coagulation Monitoring Service has established quality assurance schemes in place and is accredited by Clinical Pathology Accreditation (UK) Ltd

3.37 A Standard Operating Procedure is in in place which meets the requirements of the MHRA guidance document Management and Use of IVD Point of Care Test Devices (refer to 4.4).

Infection Control

3.38 Providers must have infection control policies that are compliant with national guidelines and current handling protocols, including but not limited to The Health and Social Care Act 2008 Hygiene Code (refer to 4.8) and which takes into account:

- disposal of clinical waste
- needle stick incidents

- environmental cleanliness
- standard precautions, including hand washing
- Reference to lone worker policy especially for Domiciliary visits

3.39 Providers must ensure that all staff undertaking point of care testing have an up to date Hepatitis B vaccination.

REVIEW, MONITORING, AUDIT AND REPORTING

Review

3.40 The Provider shall carry out continuous monitoring of patients against the safety indicators for anticoagulation services developed by the National Patient Safety Agency (NPSA) (refer to 4.9 and below table) and the British Committee for Standards in Haematology (refer to 4.1) and have processes in place to respond to any trends/issues identified.

Monitoring

3.41 Overall patient results against the selected NPSA indicators (refer to 4.9) in Table 1, will be reported to the Support Service commissioned by the CCG* at the end of each quarter. The months for submission are therefore July; October; January; and April (Note: Data collection will be undertaken remotely by the Support Service and shared with the Commissioner as soon as possible)

*Presently provided by Somerset Pathology Services which currently also manages the External Quality Control process provided by WEQAS (Wales External Quality Assessment Scheme) and provides regular training workshops.

3.42 Practices shall aim to achieve the key performance indicators as set out in Table 1 below. Where there is a trend or significant variance from a KPI, the commissioner may require the Provider to share its remedial action plan.

Table 1: Safety Indicators for patients Prescribed Oral Vit K Antagonists for anticoagulation treatment.

	Reporting Requirements	KPI Standard
	New Patients	
1	Patients must follow an agreed initiation loading protocol.	95%
2	All incidences of patients suffering major bleeds in the first month of therapy are reported by the SEA reporting system.	95%
3	Percentage of patients issued with patient-held information and written dosage instructions at start of therapy	95%
	Established Patients	
4	Percentage of patients developing INR ≥ 5.0.	<5%
5	Percentage of patients developing INRs ≥ 8.0.	<0.5%
6	Percentage of patient time in therapeutic range (if this is not measurable because of inadequate decision/support software then secondary measure of percentage of INRs in range should be used).	≥65%
7	Percentage of INRs > 1.0 INR unit below target (e.g. percentage of INRs < 1.5 for patients with target INR of 2.5).	<5%

8	Percentage of patients with unknown stop date, where relevant.	<5%

Annual Service Audit

3.43 The Provider shall conduct an annual review of the Service in order to inform best practice and assist in the identification of training requirements. The review shall include:

- The name of the GP Lead
- Annual performance against the safety indicators as detailed at Table 1, together with any action taken where there a trend or significant variance from a KPI has been idendified.
- Information on the number of patients being monitored, the indications of anticoagulation, e.g. DVT etc., and the duration of treatment
- Information on the number/percentage of patients with appropriate clinical information e.g. diagnosis, target INR and last dosing record
- Details of any computer-assisted decision-making equipment used and arrangements for internal and external quality assurance
- Details of training and education relevant to (including undertaking the self-assessment questionnaire) the Service received by practitioners and staff, to provide assurance that all healthcare professionals undertaking Point of Care Testing, have the appropriate competencies; and
- Confirmation that the Practice Standard Operating Procedures are valid, and up to date.
- Percentage of patients suffering adverse outcomes categorised by type, such as a major bleed.
- A review of significant events and practice reporting

REPORTING

Activity Reporting

3.44 Activity data shall be submitted to the Commissioner using the enhanced services monitoring return which should be submitted by the 10th working day of the following month after the end of a quarter. The months for submission are therefore July; October; January; and April.

Reporting of Significant / Adverse Events

3.45 The Department of Health emphasises the importance of collected incidents nationally to ensure that lessons are learned across the NHS. A proactive approach to the prevention of recurrence is fundamental to making improvements in patient safety.

3.46 The Provider should be aware of (and use as appropriate) the various reporting systems such as:

- The National Reporting and Learning System (NRLS). Reports to NRLS can be submitted electronically via the General Practice Patient Safely Incident report Form, or the national GP e-form. If using the GP e-form please check the box to share your report with Somerset CCG.

- the Medicines and Healthcare products Regulatory Agency reporting systems for adverse reactions to medication (yellow card system), and accidents involving medical devices; and

- the legal obligation to report certain incidents to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)

3.47 In addition to their statutory obligations, the Provider will notify the Commissioner within 72 hours of being aware of the hospital admission or death of a patient being treated by the Provider under this enhanced service where the Provider believes that the anticoagulation treatment was a significant contributor to the cause of admission or death via the email address below.

3.48 In addition to any regulatory requirements the CCG wishes the Provider to use a Significant Event Audit system (agreed with the Clinical Commissioning Group) to facilitate the dissemination of learning, minimising risk and improving patient care and safety. Providers shall:

- Report all significant events (including incidences of INR results of 8 or above) to the CCG within 2 working days of being brought to the attention of the Provider via somccg.significantevents@nhs.net

- Undertake a significant event audit (SEA) incorporating root cause analysis using a tool approved by the CCG and forward the completed SEA report to the CCG within one month of the event via https://www.somersetccg.nhs.uk/for-clinicians/general-practice-significant-event-sea-and-serious-incident-support/

RECORD KEEPING

3.49 The Provider will ensure that the following data is collected and recorded for all patients for the Service:

- An up-to-date register of all registered patients using the Service, indicating patient name, date of birth, and the indication and length of treatment, including the target International Normalised Ratio: blood test result (INR) as recommended by the British Committee for Standards in Haematology (refer to 4.1) and National Patient Safety Agency;

- Adequate records of Vitamin K administration, including relevant known information, as appropriate, including for example, the number of bleeding episodes requiring hospital admission and deaths related to the prescribing of anti-coagulants;

- Maintaining records of and acting upon the outcomes of the quality assurance tests completed, for internal quality control each day POCT equipment is used and for external quality control, 2 monthly.

3.50 All clinical information is recorded in the registered patient's own GP held lifelong record, including the completion of the record that the registered patient is on anticoagulation treatment, the drugs used and the level and duration of dosage. Where a patient ceases to be on anticoagulation treatment then the patient record should be duly updated and in the event of an adverse incident all relevant information must be recorded.

PRICING

3.51 This service is subject to a local price per patient, which is set out in Schedule 3 Part A of the NHS Standard Contract.

3.52 Anticoagulation training, based on clinical competencies, is provided for Practice staff free of charge by the Support Service, on behalf of the Commissioner.

3.53 This Service has been funded to cover the cost of the purchase of testing strips and reagents, as a result of this there are no circumstances where testing strips and reagents may be obtained by the provider via the prescription route without prior consent from the commissioner. Software costs are met by the Commissioner.

PAYMENT

3.54 Payments will be made on a monthly basis using a budget based on the previous years out turn position.

3.55 Reconciliations will be completed after the end of the financial year by the commissioner.

3.56 Backfill to attend a CCG approved training course will be funded on receipt of a copy of the invoice, confirming the backfill costs to be reimbursed.

3.57 The CCG reserves the right to claim back the Annual Clinical Audit fee in the event that an audit report is not submitted.

Population covered

3.58 Patients must be prescribed a vitamin K antagonist oral anticoagulant, be aged 18 and over and be:

- a registered patient with the Provider
- a registered patient of any Somerset GP practice which has sub-contracted the service by the Provider
- a patient from out of area, by exception

Any acceptance and exclusion criteria and thresholds

3.59 The following patient groups are excluded from this service:

- people who are self-testing and self-monitoring their INR.
- people who are under 18 years of age

Interdependence with other services/providers

3.60 This service will be provided as part of an integrated model of care with community care, Out of Hours, Ambulatory Care Clinics and secondary care to ensure patients receive joined up care.

3.61 In particular, where other Providers undertake POCT on behalf of the Service Provider, it is essential that a robust form of communication is used between the 2 parties. The example template at Appendix A was developed by Somerset Partnership NHS Foundation Trust for the transfer of information between District Nurses and GPs.

4. Applicable Service Standards

Applicable National Standards (e.g. NICE)

References linked in the specification

4.1 British Committee for Standards in Haematology - Guidelines on oral anticoagulation with Warfarin – Fourth Edition 2011

https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2141.2011.08753.x

4.2 NICE Clinical Guideline 180 The management of atrial fibrillation http://pathways.nice.org.uk/pathways/atrial-fibrillation

4.3 HAS-BLED tool http://www.mdcalc.com/has-bled-score-for-major-bleeding-risk/

4.4 MHRA – Management and use of IVD point of care test devices January 2021 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/371800/In_vitro_diagnostic_point-of-care_test_devices.pdf

4.5 Training & accreditation current national guidance on workforce competencies http://www.nrls.npsa.nhs.uk/resources/?EntryId45=61790

4.6 MHRA Patient Safety Alert 'Improving Medical Device Incident Reporting and Learning' http://www.england.nhs.uk/wp-content/uploads/2014/03/psa-med-device-inci.pdf

4.7 NHS Improvement - Learning from Patient Safety Incidents https://www.england.nhs.uk/patient-safety/national-patient-safety-incident-reports/

4.8 The Health and Social care Act 2008: Code of practice on the prevention and control of infection and related guidance. https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance

4.9 NHS Improvements – Learning from Patient Safety Incidents – table 1

	Reporting Requirements	**KPI Standard**
	New Patients	
1	Patients must follow an agreed initiation loading protocol.	95%
2	All incidences of patients suffering major bleeds in the first month of therapy are reported by the SEA reporting system.	95%
3	Percentage of patients issued with patient-held information and written dosage instructions at start of therapy	95%
	Established Patients	
4	Percentage of patients developing INR ≥ 5.0.	<5%
5	Percentage of patients developing INRs ≥ 8.0.	<0.5%
6	Percentage of patient time in therapeutic range (if this is not measurable because of inadequate decision/support software then secondary measure of percentage of INRs in range should be used).	≥65%
7	Percentage of INRs > 1.0 INR unit below target (e.g. percentage of INRs < 1.5 for patients with target INR of 2.5).	<5%
8	Percentage of patients with unknown stop date, where relevant.	<5%

General references

4.10 NICE Clinical Guideline 144 Venous Thromboembolic diseases Published June 2014 http://pathways.nice.org.uk/pathways/venous-thromboembolism

4.11 NICE Quality Standard for diagnosis and management of Venous Thromboembolic diseases

https://www.nice.org.uk/guidance/qs29

4.12 MHRA Patient Safety Alert – Improving medical device incident reporting and learning 20 March 2014.
http://www.england.nhs.uk/wp-content/uploads/2014/03/psa-med-error.pdf

4.13 NICE Quality Standard for patient experience in adult NHS services
https://www.nice.org.uk/guidance/qs15

4.14 NHS Improvements – Learning from Patient Safety Incidents.
https://www.england.nhs.uk/patient-safety/national-patient-safety-incident-reports/

4.15 The NHS England National Reporting and Learning System
https://report.nrls.nhs.uk/nrlsreporting/Default.aspx

Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

4.16 British Committee for Standards in Haematology - Guidelines on oral anticoagulation with Warfarin – Fourth Edition 2011
https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2141.2011.08753.x

Applicable Local Standards

5. Applicable quality requirements

5.1 Applicable quality requirements (See Schedule 4 Parts A&C)

As Applicable

6. Location of Provider Premises

As per the Particulars of the NHS Standard Contract

NHS
Somerset
Clinical Commissioning Group

APPENDIX A

SOMERSET CCG POINT OF CARE TESTING POLICY (POCT)

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SOMERSET CCG POINT OF CARE TESTING POLICY

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SOMERSET CCG POINT OF CARE TESTING POLICY

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Sponsoring Director:	Lucy Watson, Director Quality, Safety & Governance
Author(s):	Karen Taylor, Head of Patient Safety & Governance, Somerset CCG
Document Reference:	Somerset CCG Point of Care Testing Policy v0.2

SOMERSET CLINICAL COMMISSIONING GROUP POINT OF CARE TESTING (PoCT) POLICY

1 INTRODUCTION

1.1 Laboratory tests can now be performed more frequently at the point of care (wards, theatres, General Practice, community hospitals, Minor Injury Units) for example using blood glucose meters, urine dipsticks, INR meters, haemoglobin meters, pregnancy testing kits and blood gas analysers.

1.2 PoCT is capable of delivering results in a timely manner that allows clinical decisions to occur quickly, potentially allowing better clinical (and/or) economic) outcome.

1.3 PoCT are subject to the same levels of governance that are applied within the traditional laboratory setting, with safety and quality needing to be ensured.

1.4 Management of a PoCT service should take due account of several important areas, including clinical governance, the Consumer Protection Act (1987) and public health considerations. Poor use of PoCT leading to the production of wrong results can lead to harm to patients and may have medicolegal implications, while under the terms of the Consumer Protection Act (1987) the use of instruments for purposes for which they are not intended will lead to liability transfer from manufacturer to user. Whilst there is a need for managerial responsibility of PoCT devices and a designated individual who will take formal charge of any PoCT programme, individual users trained and approved for PoCT will have responsibility and accountability for the results that they produce.

2 SUMMARY

2.1 Before any PoCT service is considered, the clinical need to improve outcomes for patients should be clearly identified and, where appropriate, a business case made, as set out in Section 5.

2.2 The selection of PoCT equipment should take due account of independent evaluation and have been shown to have the analytical performance required for the intended clinical use.

2.3 To meet the needs of clinical governance, Somerset CCG Patient Safety and Quality Assurance Committee will review and approve any new PoCT in any service it commissions.

2.4 Somerset CCG will involve appropriate pathology expert advice to implement new services which include PoCT.

2.5 Lines of accountability for POCT must be clear and managers of the service and the end-users must take due notice of their responsibilities through clinical governance.

2.6 Providers must ensure they have suitable governance arrangements in place to support any PoCT in use within their services.

2.6 Adherence for standard operating procedures must be followed, paying particular attention to training, management, quality assurance/control and health and safety policy, and must be reviewed at frequent specified intervals.

3 DEFINITIONS

3.1 PoCT is defined by the Medical Devices Agency in 'Management and Use of IVD Point of Care Test Devices', as 'any pathology test performed for a patient by a healthcare professional outside the traditional centralised laboratory'. Other terms commonly used to describe PoCT include:

- Near patient testing (NPT)
- Bedside testing
- Extra-laboratory testing
- Disseminated laboratory testing

3.2 For the purpose of this document, PoCT is a term that is applied to tests performed by non-laboratory staff outside an accredited diagnostic laboratory. These tests may be carried out in a wide range of non-laboratory sites.

4 SCOPE

4.1 This policy applies to Somerset CCG to support commissioning of enhanced services and the commissioned GP Primary Care service providers. Contracted providers are responsible for the clinical and quality governance in the services they provide. Where the Somerset CCG commissions new services which include the requirement of PoCT, as the commissioner Somerset CCG will support primary care providers, through the provision of model standard operating procedures. The provider remains responsible for assuring SOPs are adapted and suited to their local arrangements and appropriate clinical governance oversight.

5 MAKING A CASE FOR PoCT

5.1 The management and use of PoCT as an alternative to laboratory testing should be considered under the organisational clinical governance framework and subject to examination of clinical effectiveness. Such considerations will be achieved through all proposals for use of PoCT in new or updated commissioned services being reviewed and approved through Somerset CCG Patient Safety and Quality Assurance Committee.

5.2 Before deciding whether to implement PoCT it is essential to:

- establish a clinical need
- consider the benefit to patients of introducing PoCT
- establish PoCT performance, usability and cost

5.3 In many cases improving the patient pathway and experience could be major considerations when introducing PoCT. As regards clinical need, this should be based on establishing that the perceived need is valid. The diagnostic or care management value of doing the test with the patient present has to exceed the associated financial, organisational, training and regulatory cost. That means efficient testing is likely to be organised into clinics rather than ad-hoc.

5.4 In deciding whether PoCT is suitable the following issues should be considered:

- establish the clinical need for PoCT at the site
- obtain expert advice in the selection of appropriate equipment including whether the equipment is fit for purpose
- obtain expert advice on the need for IT and connectivity software
- discuss a suitable environment for placing the equipment
- perform comparisons of the point of care analytical method with the traditional laboratory method – simple correlation is insufficient
- review technical and clinical evidence
- examine the importance of a quality assurance programme required in relation to the PoCT. Best practice guidance is participation in an external quality assurance (EQA) programme, which reports issues of poor performance to an appropriate oversight panel
- the service must perform the test often enough to enable it to maintain effective internal quality control standards
- staff performing the test must do so often enough to maintain their competency

6 SELECTION

6.1 Once a service need is accurately identified, test systems should be reviewed. A suitable test system should meet the service need using equipment that is simple and reliable, but which has the necessary accuracy and precision to deliver results that alter patient management and that are similar to those produced by the routine laboratory. The system must be able to be used by individuals within that healthcare setting who are using it on a regular basis and who are performing appropriate quality checks on their work.

6.2 Somerset CCG will convene a specialist group of advisors through The Patient Safety and Quality Assurance Committee to review and approve the inclusion of PoCT in any new or revised service it commissions. This will include a representative for the intended users of the PoCT and pathology expertise.

7 TRAINING

7.1 All users of PoCT devices must be trained in the function and use of the devices as described in the standard operating procedure (SOP), and no user should be allowed to perform tests that will alter clinical management without the trainer being satisfied with the competence of the user. As PoC tests can never be 100% sensitive and specific, they work best in conjunction with assessment of clinical signs and symptoms. Staff should be aware of the potential for false positive and false negative results, and use their clinical expertise and experience to review test validity. If they have any reservations about the test result, staff should verify the result by re-testing with a different test source.

7.2 Upon completion of the training, all users must be registered and sign that they recognise the legal responsibilities of the test that they undertake. They must adhere to an SOP, including the use of internal and external quality assurance materials as detailed in a device specific SOP. A list of trained and authorised users should be maintained with each device and updated training arranged as appropriate.

7.3 Where PoCT is being used directly by patients or their carers, they must be provided with the necessary information to properly perform and interpret the test. The application of a test result to self-management by a patient must be taught by an individual who is judged competent by assessment within a teaching programme. Educational information must be specific to a patient's assessed needs, abilities and competence.

8 STANDARD OPERATING PROCEDURE

8.1 The service must ensure the use of each PoCT is controlled through the application of a Standard Operating Procedure (SOP), which is specific to use in their service.

8.2 The SOP should cover:

- clinical background
- analytical principle
- health and safety including:
  - information on COSSH (Control of Substances Hazardous to Health)
  - safe disposal of waste
  - control of infection
  - adverse incident reporting
- pre-analytical considerations
- equipment
- reagents, standards, controls and quality assurance
- test procedure
- sample analysis
- calculation of results

- assay performance
- maintenance
- record-keeping
- incident reporting

8.3 Internal quality assurance (IQA) must be used to ensure that operators of the device and/or the tests used are performing to an acceptable standard to utilise the results for patient management. External quality assurance (EQA) of devices must be mandatory but, although there are EQA schemes available, they are not at present comprehensive enough to provide universal cover for all the devices and tests available. There are processes that can be followed in such instances.

8.4 Two important and often neglected points are maintenance and record-keeping of PoCT devices. Many desktop devices now incorporate maintenance schedules into their software, preventing use until this is undertaken, and many now require valid user identification before they produce results. All analyses must be recorded in a record book or on laboratory IT and, where it is implemented directly, into an electronic patient record.

8.5 Where Somerset CCG commissions a new or revised service which requires the use of PoCT a model SOP will be drafted and approved through the CCG Patient Safety and Quality Assurance Committee.

9 CLINICAL GOVERNANCE

9.1 To ensure robust Clinical Governance of point of care testing providers must ensure there is an identified lead for point of care testing, and each test in use. The role of these individuals will be to ensure:

- Appropriate standard operating procedures are in place
- Point of care testing operators' training is undertaken and updated
- Routine audits and/or spot checks to ensure these procedures are being followed
- Routine internal quality assurance is carried out at frequent and specified intervals
- External quality assurance is carried out at specified intervals, as appropriate
- Testing results are recorded, and are monitored, and action taken where necessary.
- Patient involvement where appropriate
- Lead should be aware of their responsibilities as outlined in MHRA guidance

References:

1. The Royal College of Pathologists, Guidelines on point-of-care testing, 11 March 2004
2. MHRA, Management and use of IVD point-of-care-test devices, December 2013

Anticoagulation POCT Report Form

COMMUNITY NURSE/HEALTHCARE ASSISTANT TO COMPLETE

PATIENTS NAME:	
DATE OF BIRTH:	NHS No:
ADDRESS:	GP:
	NAME OF SURGERY:
TELEPHONE:	
ALTERNATIVE CONTACT:	
NAME:	TELEPHONE:
TELEPHONE:	

PLEASE COMPLETE BEFORE TEST

How have you been since last test e.g. abnormal bleeding, bruising (If yes please state)	
Have there been any changes in medication (stopping or starting) including over the counter medicines and alternative remedies? (if yes please state)	
What dose of warfarin have you been taking?	
Have you missed or forgotten your warfarin? (Please give details)	

TEST RESULTS

Name of person doing test:			
Date of Test:	Result of Test:	Result of Retest (if abnormal result)	Venous Test YES/NO (delete)
	Strip Code No.		
	Strip Date	**TEST RESULT ENTERED IN PT'S HAND HELD RECORD**	

DOCTOR/PRACTICE NURSE TO COMPLETE **FAX TO: **** ********

Date/Time Result Seen:	New Dose:	Date of Retest:
Date and Time pt contacted:	By Whom:	

COMMUNITY NURSE/HEALTHCARE ASSISTANT TO COMPLETE

District Nurse Federation / HUB:

Retest Date:	Entered on RiO[ ](tick to confirm)
Appointment Outcome [ ](tick to confirm)	
Signed (Name):	Signature:
Date:	

APPENDIX B

STANDARD OPERATING PROCEDURE FOR THE USE OF COAGUCHEK XS AND XS PLUS DEVICES WITHIN PRIMARY CARE

Table of Contents

INTRODUCTION

Warfarin is being used in the management of increasing numbers of patients and conditions including patient's post-myocardial infarction, atrial fibrillation, DVTs and other disorders. While it is a very effective drug in these conditions, it can also have serious side effects, e.g. severe haemorrhage if given in excess so careful monitoring is required.

These side effects are related to the International Normalised Ratio (INR) level, which measures the delay in the clotting of the blood caused by the warfarin. While the 'normal' INR is 1, the specific range of INR values depends on the disease and the clinical conditions. Warfarin monitoring aims to stabilise the INR within set limits to help prevent serious side-effects while maximising effective treatment.

Successful and safe anticoagulation depends on patient education, good compliance and clear communication with both patient and those various individuals responsible for their clinical and social care.

SCOPE AND PURPOSE

The Roche CoaguChek XS/XS plus device is intended for in vitro diagnostic (IVD) use by registered, trained clinicians/health care professionals/members of the Provider team for point of care usage in the management of patients on warfarin, using whole blood.

This standard operating procedure (SOP) details the routine use of the Roche CoaguChek XS/XS Plus device using whole blood.

The scope and purpose of this standard operating procedure is to articulate the process of safe, reliable and effective point of care INR testing using the Coaguchek devices.

Safe, reliable and effective use of point of care testing can contribute to improved patient outcomes by optimising therapeutic anticoagulation which may include: minimising the time to therapeutic anticoagulation; improving patient compliance and reduce the risks associated with INRs that fall outside of the recommended therapeutic range, including reduction of adverse events and hospital admissions.

It can be ineffective and potentially hazardous if not done correctly.

PROCEDURAL RESTRICTIONS

All members of the Provider team conducting POCT will have completed the appropriate training from the manufacturer or supplier of their chosen testing equipment and Clinical Decision Support Software (CDSS) (this may take the form of an E-learning module) or, receive training from a clinician who has previously undertaken training from the manufacturer or supplier.

ROLES AND RESPONSIBILITIES

It is the responsibility of the Provider 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, correct governance procedures and health and safety.

The Provider shall ensure that in the event of the failure of the blood testing equipment for more than 24 hours, the Provider will liaise with the equipment provider to determine whether replacement equipment can be obtained.
Should this not be feasible, then the Provider will:

- utilise the services of an alternative Somerset provider of this service or
- take a venous blood sample and send it for INR analysis, inform the CCG within 48 hours of the action and the date when normal service will resume.

The Provider shall ensure that each member of staff undertaking point of care testing has received appropriate training.

Training shall include but not necessarily be limited to:

- Sample requirement and specimen collection
- Sample preparation
- Stability of sample and reagents
- Analyse measurement
- Maintenance, calibration and cleaning of instrument
- Appropriate use of equipment and consequences of inappropriate use
- Reporting of results
- Knowledge of normal and abnormal results and action in the event of an abnormal result
- Performance of quality control
- Documentation of test and quality control results
- Health and Safety
- Determining the INR
- Patient education
- Drug interactions with Vit K antagonists

It is an expectation that all staff performing POC INR testing should receive appropriate training approved by the CCG on a 2 yearly basis.

All suitably trained staff are responsible for complying with the guidance set out in this document.

The Operator of the point of care device is required to do the following:

- Ensure he/she is suitably trained before using the Roche CoaguChek XS/XS plus device.
- Ensure an internal quality control (IQC) check is carried out in accordance with the manufacturers' instructions on each day that the equipment is used prior to their use on that day, ensuring the IQC result is within the stated reference range.
- Ensure external quality assurance (EQA) checks are conducted every two months to verify the accuracy of blood testing machinery and dosing, returning the results to the Point of Care team at South West Pathology Services for result submission and performance report generation prior to the distribution closing date.
- Ensure any patient tests performed using the Roche CoaguChek XS/XS plus meter are documented appropriately.
- Ensure cleaning/maintenance of the point of care device is carried out in accordance with the manufacturer's instructions on each day that the equipment is used prior to its use on that day.
- Ensure strips and reagents are stored in accordance with manufacturer's guidance. If refrigeration of the strips/reagents is required then temperature checks must be recorded on each working day.

INDICATIONS FOR USE

The provision of safe and effective INR point of care testing using the Coaguchek device will offer equitable, safe, local, standardised and clinically effective management for patients receiving warfarin therapy.

PRINCIPLE OF PROCEDURE AND REFERENCES

Anticoagulants, such as warfarin are used to control the coagulation of blood in patients with thrombotic disorders such as atrial fibrillation. By blocking the Vitamin K Epoxide Reductase, warfarin can disrupt the coagulation cycle and reduce the availability of active Vitamin K needed for blood coagulation.

Anticoagulants can have severe side effects on patients if left unmonitored, from bruising to haemorrhaging. Using the Roche CoaguChek XS/XS plus system clinicians can use the results obtained, reported in INR (International Normalised Ratio) units to monitor and adjust patient dosage if required.

The Coaguchek test strips contain the reagents thromboplastin and peptide substrate. When a capillary blood sample is added to the test strip it combines with the reagents. The time taken from sample addition to the formation of a clot is detected electromagnetically and produces the INR result.

The test is intended for capillary whole blood samples or non-anticoagulated venous whole blood only.

INCIDENT REPORTING

Any incidents involving the use of the Coaguchek testing devices should be reported using the practice's own internal incident reporting procedures. This requirement is in addition to the reporting of significant/adverse events process which is outlined in the current CCG anticoagulation specification.

INFECTION CONTROL

Providers must have infection control policies that are compliant with national guidelines and current handling protocols, including but not limited to The Health and Social Care Act 2008 Hygiene code and which takes into account:

- Disposal of clinical waste
- Needle stick incidents
- Environmental cleanliness
- Standard precautions, including hand washing
- Reference to lone worker policy especially for Domiciliary visits

SAFETY INFORMATION AND RISK ASSESSMENTS

Substance/Kit

List of Substances /Kits	Risk Score (Risk Rating from COSHH assessment 0 (No hazards identified) Low (1-6), Medium (8-12), High (15-25))	Notes
Biological Samples	Low	When handled according to local policy
Roche CoaguChek XS plus system PT strips	Low	When used according to manufacturer's instructions
Roche CoaguChek XS/XS plus system	Low	When used according to manufacturer's instructions
Roche CoaguChek XS PT Controls	Low	When used according to manufacturer's instructions
WEQAS POCT INR Control	Low	When used according to manufacturer's instructions
External Quality Assurance (EQA) samples	Low	When used according to manufacturer's instructions
Lancet (s)	Low	When used according to manufacturer's instructions

Personal Protective Equipment (PPE)/Control Measures

Control Measures	Comments (When and how are these used?)
Laboratory Coats/Uniform	At all times
Gloves	At all times
Hand Hygiene	Refer to local policy

Risk Assessments

Assessments	Maximum risk score (providing SOP and any control measures followed) Risk Score - Low (1 to 6), Medium (8 – 12), High (15 – 25)
Equipment	Low
Sharps	Low
Handling and Disposal of Clinical/Infected Material	Low
Transport of Clinical Material	Low
Premises and Working Environment	Low
Fire	Low
Lifting and Handling	Low

STANDARDISED COAGUCHEK XS/XS PLUS DEVICE SETTINGS

- Ensure the language is set to English and the correct date and time is set using the 24 hour clock option.
- Ensure units of measurement are set to INR. This is the machines default setting.
- Ensure the beep function is set to 'on'.

PERFORMANCE SPECIFICATIONS

Roche CoaguChek XS/XS plus system operating conditions

- Ensure the meter is on a flat, stable, vibration free surface when performing a test, or hold the device in your hand so that it is horizontal.
- Apply the blood drop to the test strip within 15 seconds of lancing the fingertip.
- Check the operating temperature is between **15 – 32 °C** (displayed on the main LCD screen)
- Use the meter at humidity of less than **85%**
- Maximum altitude of use is **4300** meters (**15,000 feet**)
- If the meter is to be stored for long periods of time, remove the batteries to avoid battery leakage.

Roche CoaguChek XS/XS plus system PT strips conditions

- Storage temperature: **+2°C to +30°C**
- Stable until the expiry date on the box if unopened
- Stable for **6 months** once opened

Whole Blood	Test Range	Unit
International Normalised Ratio (INR)	0.8 – 8.0	INR

Roche CoaguChek XS PT Controls (IQC)

- Storage temperature: +2 to +8°C
- Stable until the expiry date stated on the box/control samples
- Reconstituted material is stable for 30 minutes

WEQAS POCT INR Control Internal Quality Assurance Sample (IQC)

- Storage temperature: +2 to +8°C
- Stable for two (2) weeks when stored un-opened at +2 to +8°C
- Stable for five (5) days when stored opened at +2 to +8°C

WEQAS POCT INR External Quality Assurance Sample (EQA)

- Storage temperature: +2 to +8°C
- Stable for two (2) weeks when stored un-opened at +2 to +8°C
- Stable for five (5) days when stored opened at +2 to +8°C
- Samples stored at +2 to +8°C prior to analysis must be brought to room temperature and assayed within 30 minutes

PRIMARY SAMPLE TYPE

The Roche CoaguChek XS/XS plus system is only approved for use with capillary whole blood or non-anticoagulated venous whole blood.

Minimum sample volume

- 8 µl

EQUIPMENT AND REAGENTS

Equipment:

- Roche CoaguChek XS/XS Plus System
- Test code chip
- Roche CoaguChek XS PT strips
- Lancet (s)
- Cotton wool and gauze for cleaning puncture site
- Gloves
- Biohazard waste container
- Plasters

Reagents:

- Roche Coaguchek XS PT Controls
- WEQAS POCT INR Control

All reagents/controls should be refrigerated (2 - 8°C) upon arrival and used when required.

CALIBRATION PROCEDURES

- Calibration is not required by the user.

INTERNAL QUALITY CONTROL (IQC)

Internal Quality Control (IQC) is a means of checking that patient results are reliable before they are issued, providing reassurance that the analyser is working correctly and giving the correct results.

IQC Procedure for the Roche Coaguchek XS Plus meter

A QUALITY CONTROL MUST BE RUN BEFORE THE FIRST PATIENT TEST OF THE DAY TO ENSURE THE RESULTS GIVEN BY THE COAGUCHEK XS PLUS METER ARE RELIABLE

CoaguChek XS PT Control - IQC Sample

- Please store the CoaguChek XS PT Control samples (IQC) in the refrigerator (2 – 8 °C) as soon as possible on receipt.
- A control sample needs to be tested by a trained member of staff on a daily basis if the Roche CoaguChek XS Plus meter is used daily or before the first patient of the day.
- The control sample is stable for 30 minutes once reconstituted.
- The results should be within the stated range for that lot of control material displayed on the screen of the meter.

Daily or Prior To First Patient Test

- Check the control material is in date.
- Control samples are stable for 30 minutes once reconstituted.

Preparation of Internal Quality Control material

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 test strip code chip that came with these test strips is at hand.

3. Make sure the bottle of freeze-dried 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, and 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 in contact with the dried control plasma.

8. Close the container 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.

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

12. The control solutions may be reconstituted (mixed) after removal from the refrigerator. The resulting solution may be used up to 30 minutes after reconstitution.

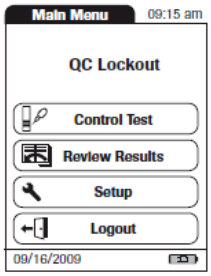
Performing a liquid quality control test

1. Place the meter on a level, vibration free surface. Turn the meter on by pressing the ON/OFF button. Alternatively, you can insert a test strip.

2. Wait until the menu is displayed.

3. Check the date and time are correct.

4. Touch **Control Test**.



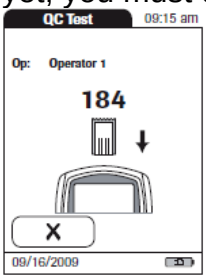
5. The test strip symbol prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

6. Hold the test strip so the lettering ‘Coaguchek XS PT’ is facing upwards.

7. Slide the test strip into the test strip guide in the direction indicated by the arrows.

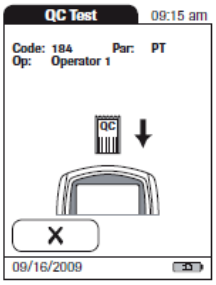
8. Slide the test strip in as far as it will go. A beep tone indicates that the meter has detected the test strip.

9. If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now.



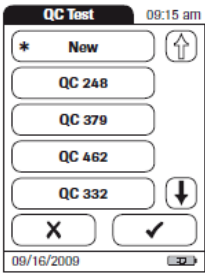
10. As with the test strips, a quality control code chip is also provided with the liquid quality controls. This chip tells the meter the acceptable ranges of results for that lot of controls. The information on the code chip is retained in the memory so you can use the same control solutions at any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

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



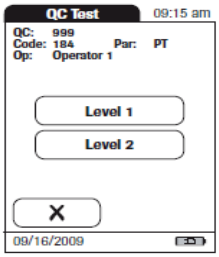
12. Select the code already stored for your current control solution, or touch **New** to use new control solution.

    Please note: When you first run your control, the QC TEST screen will not display. This screen will display the next time you use the control.



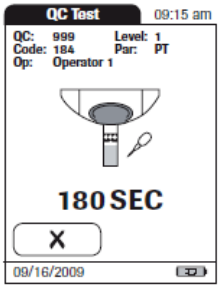
    If the code chips get mixed up the way to differentiate between the 2 is;
    The code chip that came with the test strips starts with the letter S, and the name of the code chip that came with the control solution starts with the letter C.

13. Select the level for this measurement



14. The hourglass symbol shows that the test strip is warming up. When the warming up process is complete, a further beep tone indicates that you can now apply control solution.
15. The dropper symbol flashes to indicate that the meter is ready to perform the test and is waiting for the sample to be applied.

16. At the same time, a 180 second countdown begins. You must apply the sample within this time otherwise you will receive an error message.



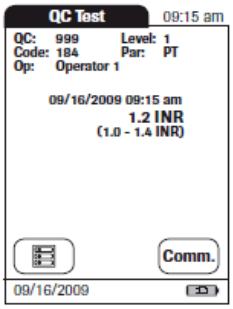
17. Using the dropper, draw up the dissolved contents of the vial

18. Apply a single drop of control solution directly from the dropper to the semicircular, transparent sample application area of the test strip. **DO NOT ADD MORE CONTROL**

19. You hear a beep tone when you have applied enough control solution. The dropper symbol disappears and the test starts.

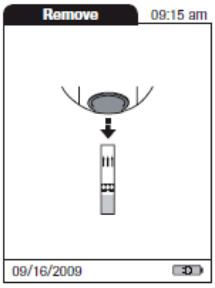
20. The result of the liquid quality control test is displayed. It is automatically saved to memory.

21. The acceptable range of results for the liquid control is displayed below the current result.



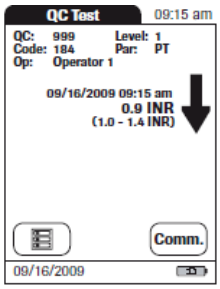
22. **RECORD THE IQC RESULT**

23. Remove the test strip from the measurement chamber



24. Dispose of the used test strip according to local policy

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



Repeat steps 1-19 above if the quality control test fails.

25. When the test is complete, remove the quality control code chip from the meter and store it with the controls.

YOU MAY ONLY START PATIENT TESTING WHEN YOU HAVE RUN A SUCCESSFUL INTERNAL QUALITY CONTROL TEST

IQC Procedure for the Roche Coaguchek XS meter

A QUALITY CONTROL MUST BE RUN BEFORE THE FIRST PATIENT TEST OF THE DAY TO ENSURE THE RESULTS GIVEN BY THE COAGUCHEK XS METER ARE RELIABLE

WEQAS POCT INR Control - IQC Sample

- Please store the WEQAS POCT INR Control (IQC) in the refrigerator (2 – 8 °C) as soon as possible on receipt.
- A control sample needs to be tested by a trained member of staff on a daily basis if the Roche CoaguChek XS meter is used daily or before the first patient of the day.
- **The control sample is stable for 5 days once opened when stored at 2-8°C.**
- The results should be within the stated expected range for the specific lot number of POCT INR control material displayed on the intended use sheet.

Daily or Prior To First Patient Test

- Check the control material is in date.
- Control samples are stable for **5 days** once **opened** when stored at 2-8°C.
- Control samples are stable for **two (2) weeks unopened** when stored at 2-8°C.

Preparation of Internal Quality Control material

1. Allow the dropper bottle to stand for **at least 15 minutes at room temperature (15-30°C)**
2. Gently mix the contents of each vial before sampling to ensure homogeneity.

Performing a liquid quality control test

1. Have the test strip container at hand.

2. Make sure that the test strip code chip that came with the test strips is at hand.

3. Before switching on the meter, insert the **Test Code Chip** supplied with the CoaguChek XS PT strips as shown below.

4. Take **one** test strip from the container; ensure you close the container tightly. You will have **10 minutes** to use the test strip once removed from the container.

5. Insert the test strip facing upward as shown below. The meter will power on and the code number of the inserted chip code will flash on the display

6. Confirm that the number displayed matches the number on the test strip container and then press

7. An hourglass  appears as the meter warms up which takes about 30 seconds.

8. When the meter is warmed up a flashing test strip appears and the meter beings a countdown.

You will have 180 seconds to apply the POCT INR Control to the test strip

9. Always wear gloves to avoid contamination.

10. Position the INR Control sample bottle downward at a 45° angle and gently squeeze the bottle to form a hanging drop.

11. Apply a single drop of control solution directly from the dropper bottle to the semicircular, transparent sample application area of the test strip.
DO NOT ADD MORE CONTROL SOLUTION.

12. The meter will beep and the timer icon will replace the blood drop icon.
Do not add more control solution after the test has begun. Do not touch the test strip.

13. Wipe any excess material from the dropper bottle with a clean tissue.

14. Replace the cap of the dropper bottle and store at 2-8°C.

15. The Roche CoaguChek XS system will take approximately one minute to run the test, once complete, the results will be displayed on the main screen in INR units.

16. **RECORD THE IQC RESULT.**

17. Remove the test strip and dispose of any consumables used according to local policy.

Repeat steps 1-17 above if the quality control test fails.

YOU MAY ONLY START PATIENT TESTING WHEN YOU HAVE RUN A SUCCESSFUL INTERNAL QUALITY CONTROL TEST

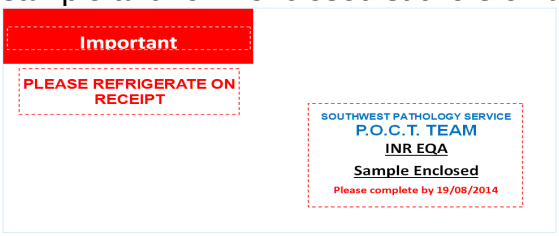
18. Power the meter off if no further tests are to be run. 

19. If the meter is dirty, wipe clean according to manufacturer's instructions.

20. Perform hand decontamination.

External Quality Assurance (EQA)

- A distribution letter and EQA sample will be sent to you in the post every 2 months from the Point of Care Team (P. O. C team) at Southwest Pathology Services.
- The envelope will have coloured **Southwest Pathology Service**, EQA sample and form enclosed stickers on them for ease of identification.



- You will be required to test the sample as soon as possible on receipt and return the results to the P.O.C team by the stated closing date.
- You will have approximately 10 working days to complete the test and return the results.
- Please refrigerate the sample if there is a delay in testing.

Running an EQA Test on both the Coaguchek XS and XS Plus Meter

Treat the EQA sample as a patient sample

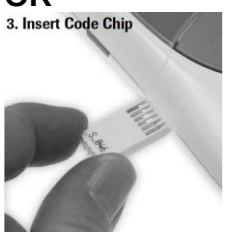
Preparation of External Quality Control material

- Ensure the correct Test Code Chip is used when using a new test strip.
- Before testing the EQA sample, leave at room temperature for 10-15 minutes.
- Ensure you have run a successful quality control test prior to EQA testing

Performing an EQA Test

1. Before switching on the meter, insert the **Test Code Chip** accompanying the CoaguChek XS/XS Plus system PT strips as shown below.

OR



Note: Ensure the Code Chip is inserted before the meter is switched on and the corresponding PT strips

For the Coaguchek XS Plus Device

1. Place the meter on a level surface free from any vibration or hold in a horizontal position.

2. Press the power button and select **Patient Test**, enter the required details using the touch screen.

3. A Test Strip Icon will appear on the screen, prompting you to insert a Test Strip.

4. Take **one** test strip from the container; ensure you close the container tightly. You will have **10 minutes** to use the test strip once removed from the container.

5. Insert the test strip facing upward as shown below, with the sound enabled you will hear the meter beep once the test strip is inserted.

For the Coaguchek XS Device

1. Take **one** test strip from the container; ensure you close the container tightly. You will have **10 minutes** to use the test strip once removed from the container.

2. Insert the test strip facing upward as shown below. The meter will power on and the code number of the inserted chip code will flash on the display

3. Confirm that the number displayed matches the number on the test strip container and then press

4. An hourglass  appears as the meter warms up which takes about 30 seconds.

5. When the meter is warmed up a flashing test strip appears and the meter beings a countdown.

Once the coaguchek XS/XS Plus meter beeps, you have 180 seconds to apply the <u>WEQAS INR EQA solution</u>.

6. Apply the WEQAS INR EQA material as shown below after **gently inverting the sample 6-8 times**.

Note: The meter will beep, once enough EQA material has been applied.

7. The Roche CoaguChek XS/XS plus system will run an additional control check: This does not equal a liquid quality control test.

8. Results will be displayed on the main screen. Record the results on the accompanying result sheet provided by the Point Of Care Team at Southwest Pathology Services and return the sheet by post/ e-mail/fax. All return details are on the result sheet.

9. Remove the test strip and dispose of any consumables used according to local policy.
10. Power the meter off if no further tests are to be run.

11. EQA performance reports will be distributed to practices once the distribution has closed. Monitoring information is sent on a monthly basis to the CCG by the POC team.

RESULTS

- Record results to ensure safe patient record management for example on the appropriate clinical software, GP record or patient handheld record e.g. yellow book and in addition to the local specification requirements.

- **Always** record the result to one decimal point, for example, record a results of 5 as 5.0.

- **If an unexpected result is obtained, repeat the test on the point of care device for confirmation.**

- All practices must report **INR results of 8 or above** to the CCG, via the Medications Incident Reporting System (via the icon situated on the GP desktop or the Pathway Navigator) within 2 working days of being brought to the attendtion of the provider. Also, undertake a significant event audit (SEA) incorporating root cause analysis using a tool approved by the CCG and forward the completed SEA report to the CCG within one month of the event.

INTERFERENCE AND LIMITATIONS

Results given by the Roche CoaguChek XS/XS Plus system can be affected by the following;

- Haematocrit ranges from 25% - 55%
- Patients with suspected APAs (Anti-phospholipid antibodies) will require an APA-insensitive laboratory method.

If in doubt send the sample to the laboratory for testing.

REFERENCE RANGES

Whole Blood -	**Test Range**	**Unit**
Patient: AF, DVT/PE*	2.0 – 3.0	INR
Patient: Most Valve Prosthesis*	3.0 – 4.0	INR

***These reference ranges are for guidelines only, please refer individual patient results to the GP to establish a safe INR range for said patient.**

Out of Range Values

- The Coaguchek XS PT strips provide test results if the INR value is 0.8 to 8.0.
- If the results fall outside of this range, the meter will display < (less than) 0.8 or > (greater than) 8.0.
- If the meter indicates an out-of-range value, repeat the test.
- In rare cases, an ‘error 7’ message can occur in patients with long coagulation times (>8.0). If this message appears again when the test is repeated, the result must be checked using an alternative method. (Send sample to the laboratory for confirmation).

METHOD FOR PERFORMING A PATIENT TEST

It is the responsibility of the Provider to ensure the equipment is demonstrably fit for purpose.

The following procedure should be followed when performing POC INR testing using the Coaguchek XS/XS plus device.

- Clean the device as recommended by the manufacturer (refer to maintenance section).
- The meter should only be operated on a level surface free from any vibration or whilst being held horizontally and at ambient temperature between 15-32°C.
- Prepare all equipment, check expiry date, lot number of strips and that correct code chip is in place.
- Explain procedure to patient and obtain consent.
- Perform hand hygiene and wear gloves as per the infection control protocol.
- Have the patient wash his or her hands with warm soapy water and ensure they are dried thoroughly.
- Observe clinical presentation of patient.

Performing a Patient Test – Coaguchek XS Plus Meter

YOU MAY ONLY START PATIENT TESTING WHEN YOU HAVE RUN A SUCCESSFUL QUALITY CONTROL TEST

1. Before switching on the meter, insert the **Test Code Chip** supplied with the CoaguChek XS PT strips as shown below.

Note: Ensure the Code Chip is inserted before the meter is switched on and the corresponding PT strips

2. Place the meter on a level surface free from any vibration or hold in a horizontal position.

3. Press the power button and select **Patient Test**, enter the required details using the touch screen.

4. A Test Strip Icon will appear on the screen, prompting you to insert a Test Strip.

5. Take **one** test strip from the container; ensure you close the container tightly. You will have **10 minutes** to use the test strip once removed from the container.

6. Insert the test strip facing upward as shown below, with the sound enabled you will hear the meter beep once the test strip is inserted.

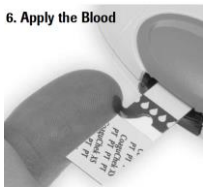
Once the meter beeps you will have 180 seconds to apply the blood to the test strip

Specimen Reception and Handling

- **Note:** Once the test strip is inserted into the Roche CoaguChek XS plus system , you will have 180 seconds to apply the sample
- Ensure the patient has washed his/her hands.
- Use a safety lancet (select the required depth) to puncture the chosen finger (the side of the middle finger is preferred between the Distal knuckle and the nail bed. Avoid using the area around the nail as this can cause nerve damage. If possible also avoid using the thumb and index finger).
- Gently milk finger to form a good hanging blood drop.
- Discard the lancet into a biohazard waste container.

7. Once a blood drop has formed, transfer it to the test strip as shown below (**within 15 seconds of sticking the fingertip**)

O R



The meter will beep and the timer icon will replace the blood drop icon. Ensure the finger maintains in contact with the test strip until the machine beeps indicating sufficient blood has been applied **N.B. Use only the first drop of blood and do not add more blood after the test has begun. Do not touch the test strip.**

8. Encourage the patient to apply pressure to the finger prick site with cotton wool until bleeding ceases.

9. Should the test fail for any reason repeat the process using a different finger and a new test strip.

10. After the blood sample has been transferred to the Roche CoaguChek XS plus system it will begin a **Quality Control self-test**: **This alone does not equal a quality control test, you are still required to run a liquid quality control test prior to the first patient of the day.**

11. The Roche CoaguChek XS plus system will take approximately one minute to run the test, once complete, the results will be displayed on the main screen in INR units.

12. Document the results to ensure safe patient record management for example on the appropriate clinical software, GP record or patient handheld record e.g. yellow book and in addition to the local specification requirements.

13. Remove the test strip and dispose of any consumables used according to local policy.

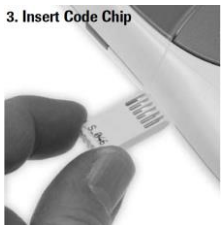
14. Place a plaster over the finger prick site if necessary.

15. If the meter is dirty, wipe clean according to manufacturers instructions.

16. Perform hand decontamination

Performing a Patient Test – Coaguchek XS Meter

1. Before switching on the meter, insert the **Test Code Chip** supplied with the CoaguChek XS PT strips as shown below.



2. Take **one** test strip from the container; ensure you close the container tightly. You will have **10 minutes** to use the test strip once removed from the container.

3. Insert the test strip facing upward as shown below. The meter will power on and the code number of the inserted chip code will flash on the display

4. Confirm that the number displayed matches the number on the test strip container and then press

5. An hourglass  appears as the meter warms up which takes about 30 seconds.

6. When the meter is warmed up a flashing test strip appears and the meter beings a countdown.

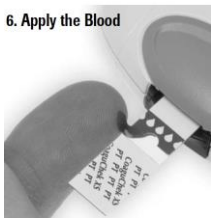
You will have 180 seconds to apply the blood to the test strip

Specimen Reception and Handling

- **Note:** Once the test strip is inserted into the Roche CoaguChek XS system , you will have 180 seconds to apply the sample.
- Ensure the patient has washed his/her hands.
- Use a safety lancet (select the required depth) to puncture the chosen finger (the side of the middle finger is preferred between the Distal knuckle and the nail bed. Avoid using the area around the nail as this can cause nerve damage. If possible also avoid using the thumb and index finger).
- Gently milk finger to form a good hanging blood drop.
- Discard the lancet into a biohazard waste container.

7. Once a blood drop has formed, transfer it to the test strip as shown below (**within 15 seconds of sticking the fingertip**)

O
R



The meter will beep and the timer icon will replace the blood drop icon. Ensure the finger maintains in contact with the test strip until the machine beeps indicating sufficient blood has been applied **N.B. Use only the first drop of blood and do not add more blood after the test has begun. Do not touch the test strip.**

8. Encourage the patient to apply pressure to the finger prick site with cotton wool until bleeding ceases.

9. Should the test fail for any reason repeat the process using a different finger and a new test strip.

10. After the blood sample has been transferred to the Roche CoaguChek XS system it will begin a **Quality Control self-test**: **This alone does not equal a quality control test, you are still required to run a liquid quality control test prior to the first patient of the day.**

11. The Roche CoaguChek XS system will take approximately one minute to run the test, once complete, the results will be displayed on the main screen in INR units.

12. Document the results to ensure safe patient record management for example on the appropriate clinical software, GP record or patient handheld record e.g. yellow book and in addition to the local specification requirements.

13. Remove the test strip and dispose of any consumables used according to local policy.
14. Power the meter off if no further tests are to be run.

15. Place a plaster over the finger prick site if necessary.

16. If the meter is dirty, wipe clean according to manufacturer’s instructions.

17. Perform hand decontamination.

MAINTENANCE

Cleaning

- **Ensure the meter has been switched off before any cleaning procedure is undertaken.**
- **Do not use sprays of any sort.**
- **Ensure the swab or cloth is only damp, not wet.**

Cleaning/Disinfecting the Exterior

Use only the following items for cleaning/disinfecting the Coaguchek XS/XS Plus meter housing for a contact time of >1 minute:

- 70% isopropyl alcohol
- 10% Sodium hypochlorite solution (1 part bleach to 9 parts deionised water, made fresh every 24 hours)
- **DO NOT SURE ANY OTHER DISINFECTANTS/CLEANING SOLUTIONS ON THE METER HOUSING**
- With the meter powered off, wipe the meter's exterior clean
- Do not let liquid accumulate near any opening.
- Make sure no liquid enters the meter.

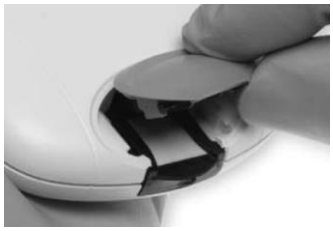
Dry the Exterior

- With a lint free tissue, dry the meter.
- Wipe away residual moisture and fluids after cleaning the housing.
- Allow wiped areas to dry for at least 10 minutes before performing a test.

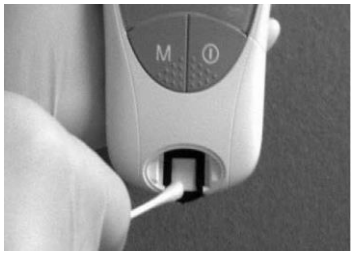
Cleaning/Disinfecting the Test Strip Guide

Interior

- Use only 70% isopropyl alcohol or 10% bleach solution to clean the Coaguchek XS/XS Plus test strip guide
- **Do not use any other cleaning/disinfecting solutions on the test strip guide. Use of other cleaning/disinfecting solutions could results in damage to the meter**.
- With the meter powered off, use your thumbnail to open the cover of the test strip guide by pressing it's front edge upward. Move the cover safely away from the meter. Then rinse the cover with water or wipe it clean



- Hold the mter upright with the test strip guide facing down.
- Clean the easily accessible areas with a cotton swab
- Ensure the swab is only damp not wet.
- Apply cleaning agent for a contact time of >1 minute.
- Wipe away residual moisture and fluids.



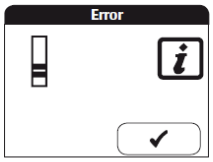
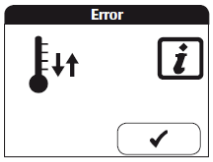
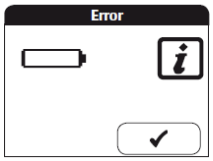
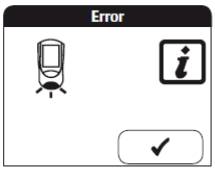
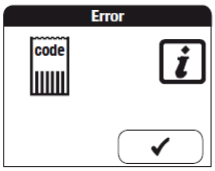
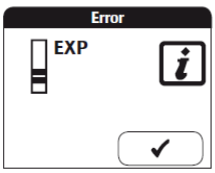
- **Do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide.**
- With the cover off, allow the test strip guide to dry for at least 10 minutes before re-attaching the test strip guide cover and testing again.
- Close the cover and make sure it snaps in place.

TROUBLESHOOTING

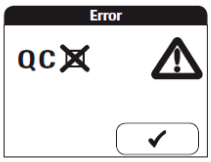
The images below may vary depending on software version on analyser.

Error messages

Error messages overview

Error message (always prefaced by **Error**)	Brief description
	Test strip in meter or Test strip unusable or the test strip is not a CoaguChek XS PT test strip
	Meter too warm or too cold
	Battery level too low
	Test strip guide cover open
	Code chip error
	Test strip beyond expiration date

Error messages continued (2)



Quality control: Test strip unusable or quality control for new lot missing

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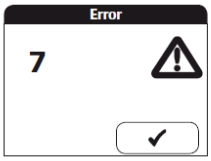
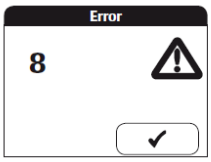
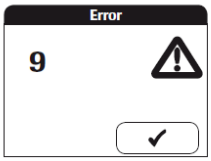


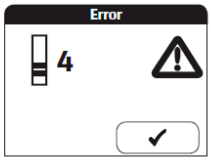
Measurement error



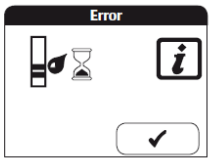
Diagnostic testing error



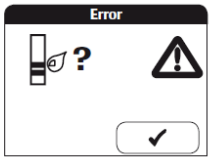
Diagnostic testing error



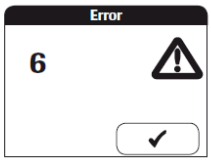
Test strip unusable



Allowed time for blood application exceeded

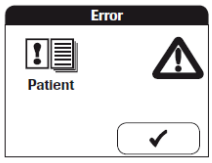


Blood application error

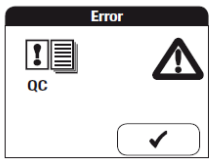


Measurement error

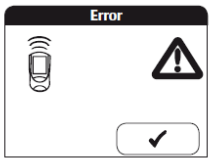
Error messages continued (3)



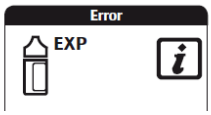
Internal memory error (patient)



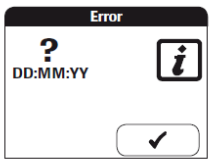
Internal memory error (QC)



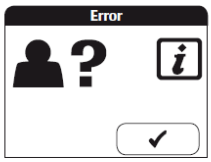
Data transfer error



Control solution beyond expiration date



Date/time inconsistent



ID error