Standard Operating Procedure CN.09	
Title: CoaguChek XS and XS Plus - use of the devices by community staff for anticoagulation therapy	
Prepared by: Liz Salter, Lorraine Webber	
Presented to: Care and Clinical Policies Group	Date:09 /09/15
Ratified by: Care and Clinical Policies Group	Date: 09/092015
	Review date: September 2018
Links to policies:	Production and Control of Clinical Policies, Guidelines, Protocols and Standard Operating Procedures Medical Devices Policy Medicines Policy for Registered Professionals

Purpose of this document

To ensure that Patient Safety, Governance and Quality Assurance issues are considered when Community Staff conduct Near Patient Testing (NPT) using the Coagu Chek XS and XS Plus INR monitoring device within a patient's own home.

Scope of this SOP

Applicable to all Torbay & Southern Devon Health and Care Trust (TSDHCT) community staff who perform near patient testing INR monitoring procedure.

Competencies required

All staff undertaking this procedure must have completed relevant training to include practical and theoretical use of the Coagu Chek XS and XS Plus devices (to include quality assurance measures), finger lancet (Softclix lancet or Unistik® 3), infection control measures, documentation and record keeping.

All staff undertaking this procedure must hold a completed competency checklist signed by a suitable trained person and be using the skill at least once every 12 weeks to maintain competency. Competency checks should be reassessed every 3 years.

All staff must keep a record of training in their personal portfolio.

Patients covered

All patients receiving anticoagulant therapy who require monitoring using an NPT procedure and performed by community staff who are employed by TSDHCT

Risk Assessment

All patients referred to the community nursing service for anticoagulation monitoring using a NPT procedure require **risk assessment (Appendix 1)** to ensure the individual can understand the reason for the procedure, can take their anticoagulation medication safely and can receive, understand, retain and act on information that will be passed to them in relation to their medication dose.

Where a patient is deemed unsuitable for NPT procedure for anticoagulation monitoring the staff member completing the risk assessment should liaise with the patient, GP and carer/family to plan a suitable management plan. A copy of the risk assessment should be provided for the GP patient records.

Community Staff will complete Form B **Medication Check List for Patients on Anticoagulation form (Appendix 2)**at each visit for NPT. Any relevant changes eg regular missed doses or new medication must be communicated to the patient's GP during the same day.

Infection Control

There is a potential risk of infection. Healthcare professionals using the Coagu Chek XS and XS Plus system must be aware that any object coming into contact with human blood is a potential source of infection. Healthcare professionals must also be aware that any cross-contamination is a potential source of infection for patients. The following measures should be taken to reduce risks:

- Wash and dry hands thoroughly before and after the procedure
- Wear protective gloves
- Use of disposable single use lancet device
- Dispose of all waste products in accordance with local health and safety and waste management policies

The Coagu Chek XS and XS Plus system

The Coagu Chek XS and XS Plus system measures the International Normalised Ratio (INR) using capillary blood. The INR should be used to monitor oral anticoagulant therapy and should not be used as the sole test for investigating bleeding disorders.

Before using the meter for the first time (i.e. after you have first inserted the batteries), you must set the date and time correctly to allow you to carry out measurements properly. Each time you replace the batteries you need to check (and, if necessary adjust) the date and time.

The CoaguChek XS and XS Plus monitor can be used with batteries only.

The memory facility should not be used when using a single device across multiple patients.

All blood samples must be regarded as potentially infectious and handled with appropriate care.

All used lancets and reagent strips must be disposed into an appropriate sharps waste container.

Equipment Required

CoaguChek XS and XS Plus device (including batteries), Lancet device, Sharps bin, INR test strips

Operating Conditions

To ensure that your CoaguChek XS and XS Plus System functions properly, please observe the following guidelines:

- Only use the meter at a room temperature between 15°C and 32°C. Only use the meter at a relative humidity between 10% and 85%.
- When testing, place the meter on a level, vibration-free surface or hold it so it is roughly
- horizontal.
- If the meter is to remain unused for a longer period of time, keep it in the carry-case supplied

Using a new batch of test strips

Each new batch of test strips comes with a Code chip. The code chip provides all the information required for the monitor to perform the INR test ie test method, lot number and expiry date. Each code chip is specific to one lot of test strips and cannot be interchanged.

Installing the code chip

- Remove the old code chip, if one is inserted in the meter. Discard the old code chip with household waste.
- Always make sure that the number on the code chip matches the number on the label of the test strip container
- Slide the new code chip into the slot on the side of the meter as shown until you feel it snap into place.
- Every time you insert a test strip in the meter, the display shows the number of the code chip that is presently inserted. Always compare the code number you see on the display with the number that is printed on the test strip container. If the two numbers are identical, confirm by pressing the **M** button.

If the code numbers are not identical, turn the meter off and insert the correct code chip. Discard the old code chip. If the code chip is missing or incorrectly inserted, **Error** and **Code** appear in the display

CoaguChek XS and XS Plus Test strips can be stored at room temperature 15oc -32oc and have a shelf life of 12 months.

Once opened test strips should be used within 6 months.

Consent: All staff must ensure their practice is in line with Consent Policy.

Patients / clients consent should be obtained prior to taking any blood sample.
A clear explanation of the procedure, reasons for the procedure should be made.
Where the patient's consent is not given, the health care professional should attempt to gain an understanding for this decision. The refusal and reason should be documented in the patients / clients nursing notes and their G.P / Consultant informed.

PROCEDURE: Using the CoaguChek XS and XS Plus device within the patients home environment

Getting a good capillary blood sample – assist the patient to wash hands in warm water and dry thoroughly. Residues of water on the skin can dilute the drop of blood and so produce false results.

a) Let the hand hang down to the side before lancing the finger - Immediately after lancing, massage gently along the side of the finger to obtain a sufficiently large blood drop without pressing or squeezing too hard.
b) Have the test strip container to hand. Make sure that the code chip belonging to these test strips is inserted in the meter.
c) Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal. Turn the meter on by pressing the On/Off button. Alternatively, you can insert a test strip to turn it on.
d) Check that all of the display symbols are displayed properly. Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests. Check that the date and time are correct

The flashing test strip symbol prompts you to insert a test strip. Remove a test strip from its container. Immediately after removing a test strip, close the container again with the stopper.

f) Hold the test strip facing upwards, Slide the test strip into the test strip guide in the direction indicated by the arrows Slide the test strip in as far as it will go. A beep tone indicates that the meter has detected the test strip (provided the beep tone is turned on in the settings).
g) The code number of the code chip inserted in the meter flashes in the display. Make sure that this number is identical with the code number printed on the test strip container. The hourglass symbol shows that the test strip is warming up. A further beep indicates that the blood should be applied.
h) Apply the blood to the test strip within 15 seconds of lancing the finger. Applying blood after this period of time would falsify the result, as the coagulation process would already have begun. A further beep tone is given to indicate that sufficient blood has been applied.
i) The meter now performs an automatic quality control check on the test strip. “QC” appears in the display. The result is then displayed.

Results

All INR results below 1.2 or above 4.5 must be repeated. If the second result remains within 0.5 of the previous result this indicates that the device reading is accurate and that the high reading is therefore accurate. The GP should be informed and a venous sample forwarded.

Results from monitor’s internal memory – where the monitor is used across multiple patients results must not be recalled or recorded from the memory function to reduce the risk of incorrect patient results being applied.

Error Codes

Error Message	Description
Error number 000	Allowed time for blood application exceeded
Error number 3	Beyond expiry date
Error number 4	Test strip unusable
Error number 5	Blood application error
Error number 6 or 7	Measurement error
Error number 8 or 9	Internal error
Error numbers 1 & 2	Reserved for internal purposes by manufacturer

Further technical support can be obtained from Roche Helpline

Roche Technical Support Tel 0808 100 9998

Record Keeping

Document the result of the NPT on Form C **Anticoagulation recording sheet** (Appendix 3) and in the patient's **Yellow Book**. One copy of this form per patient. Documentation for Near Patient Testing is in accordance with TSDHCT record keeping policy/guidance.

Community Staff will telephone the result to a NOMINATED NAMED member of staff at the GP practice to advise of the NPT result. It is also recommended that with prior agreement with the GP Practice, results are also sent to the GP Practice via a secure email account and within an agreed time frame after near patient testing. Process and templates for use are provided (Appendix 6 & 7).

Communication of INR results to GP practice using facsimile should only be undertaken in exceptional circumstances and should always be in accordance with the Trusts policy: Safe Haven procedure for transferring personal information, section 5.

Ensure the NOMINATED NAMED member of staff at GP practice repeats the NPT result back to community staff member to confirm correct result heard and documented.

A copy of Form C Anticoagulation **recording sheet** (Appendix 3) may be left for NOMINATED NAMED person at the GP practice if required.

It is the responsibility of the prescriber and not TSDHCT community staff to communicate any changes in anticoagulation medication regime to the patient or an agreed nominated 3rd party/carer/family member.

Quality Assurance

Standard QA systems for community teams using the CoaguCheck monitor are:

- Device calibrated with each new strip insertion
- Venepuncture sample sent with minimum of every 50th NPT undertaken
- Venepuncture sample sent if NPT test result **>4.5**
- For any result **>4.5** a second NPT should be undertaken with a new strip - if the reading is within 0.5 of the first reading, this can be assured as an accurate reading –Inform the GP and venepuncture sample should be sent
- All quality control checks should be recorded using Form E , **Quality Control Log (Appendix 4)**

Variance: An external quality assurance (EQA) process is also recommended. Where community teams are invited by a GP practice to participate in the EQA used within the GP practice, this should be undertaken.

Monitoring

Service calibration record of equipment	100%	nil
INR results documented in writing	100%	nil
Incident monitoring	100%	Annually
Risk assessment completed for each patient commencing NPT	100%	Audit of records
How will monitoring be carried out?	Internal audit of records	
When will monitoring be carried out?	Annually (or sooner if dictated)	

Who will monitor compliance with the guideline?	Community nursing zone leads managerially responsible for ensuring compliance with SOP.

References

NPSA Patient safety alert: Actions that can make anticoagulant therapy safer available at http://www.npsa.nhs.uk/nrls/alerts-and-directives/alerts/anticoagulant/ accessed 12.05.09

SDHCT Point of Care Testing (POCT) Policy available at http://nww.sdhs.nhs.uk/dept/Laboratory_Medicine/csshandbook/pointofcare/pointofcare-policy.htm accessed 18.08.09

CoaguChek XS and XS Plus user manual.
http://coaguchek-usa.com/documents/coaguchek-xs-plus-user-manual.pdf

Appendices

Appendix 1 - Form A Risk Assessment Form for Near Patient Testing

Appendix 2 - Form B Medication Checklist for patients on anticoagulation therapy

Appendix 3 - Form C Anticoagulation Recording Sheet

Appendix 4 – Form D Quality Control Log

Appendix 5 – Form E CoaguChek XS and XS Plus System Competency Checklist

Appendix 1 Form A – Patient risk assessment for NPT monitoring

RISK ASSESSMENT FOR INDIVIDUALS NEEDING NEAR PATIENT TESTING		
NAME	D.O.B	
ADDRESS	GP	
	NHS NO	
	PARIS NO	
	YES (PLEASE TICK)	NO (PLEASE TICK)
VISION		
Has this person good sight ?		
If not are glasses worn to correct this?		
Do they help?		
If NO is answered to any of the above state measures put in place to help with medication management		
HEARING		
Is this person's hearing good?		
Do they wear hearing aids to correct this?		
Do they help?		
Can they hear a conversation adequately over the phone?		
If NO to any of the 4 questions above state measures put in place to help with medication management		
COGNITION		
Does this person understand what their anticoagulation medication is		
Is this person able to differentiate between different anticoagulation doses i.e. warfarin		
Can this person determine the correct time of day, and correctly identify when		
If NO is answered to any of the 3 questions above indicate what measures have been put in place to help with medication management		
Signature of Nurse	Date of assessment	

Appendix 2 – Form B Medication Checklist for patients on anticoagulation therapy

MEDICATION CHECK LIST FOR PATIENTS ON ANTICOAGULATION THERAPY To be retained in patient care plan	
NAME	D.O.B
ADDRESS	GP
	NHS NO

	YES (Please tick)	**NO** (Please tick)	FURTHER DETAILS
Patient reports dose taken since last test as:			
Have you taken your anticoagulant at the same time each day?			
Can you confirm there has been NO change in any of your medication since your last INR			
Please sign and date			
Patient reports dose taken since last test as:			
Have you taken your anticoagulants at the same time each day?			
Can you confirm there has been NO change in any of your medication			
Please sign and date			
Patient reports dose taken since last test as:			
Have you taken your anticoagulants at the same time each day?			
Can you confirm there has been NO change in any of your medication			
Please sign and date			

Appendix 3 Form C Anticoagulation Recording Sheet

Retain at office base to be collected by nurse conducting patient visit

1/ Name of patient	
NHS number	
Date of today's INR	
INR result	
Comments and signature	
2/ Name of patient	
NHS number	
Date of today's INR	
INR result	
Comments and signature	
3/ Name of patient	
NHS number	
Date of today's INR	
INR result	
Comments and signature	
4/ Name of patient	
NHS number	
Date of today's INR	
INR result	
Comments and signature	
5/ Name of patient	
NHS number	
Date of today's INR	
INR result	
Comments and signature	
6/ Name of patient	
NHS number	
Date of today's INR	
INR result	
Comments and signature	

Appendix 4 Form D – Quality Control Log

Date of Testing	Patient Name & NHS No.	Coaguchek Result	Laboratory Result	% Difference	Comments / Action

Appendix 5 – Form E CoaguChek XS and XS Plus System Competency Checklist

Name:.....

Work Location.....

Date.....

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

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

Additional Comment

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

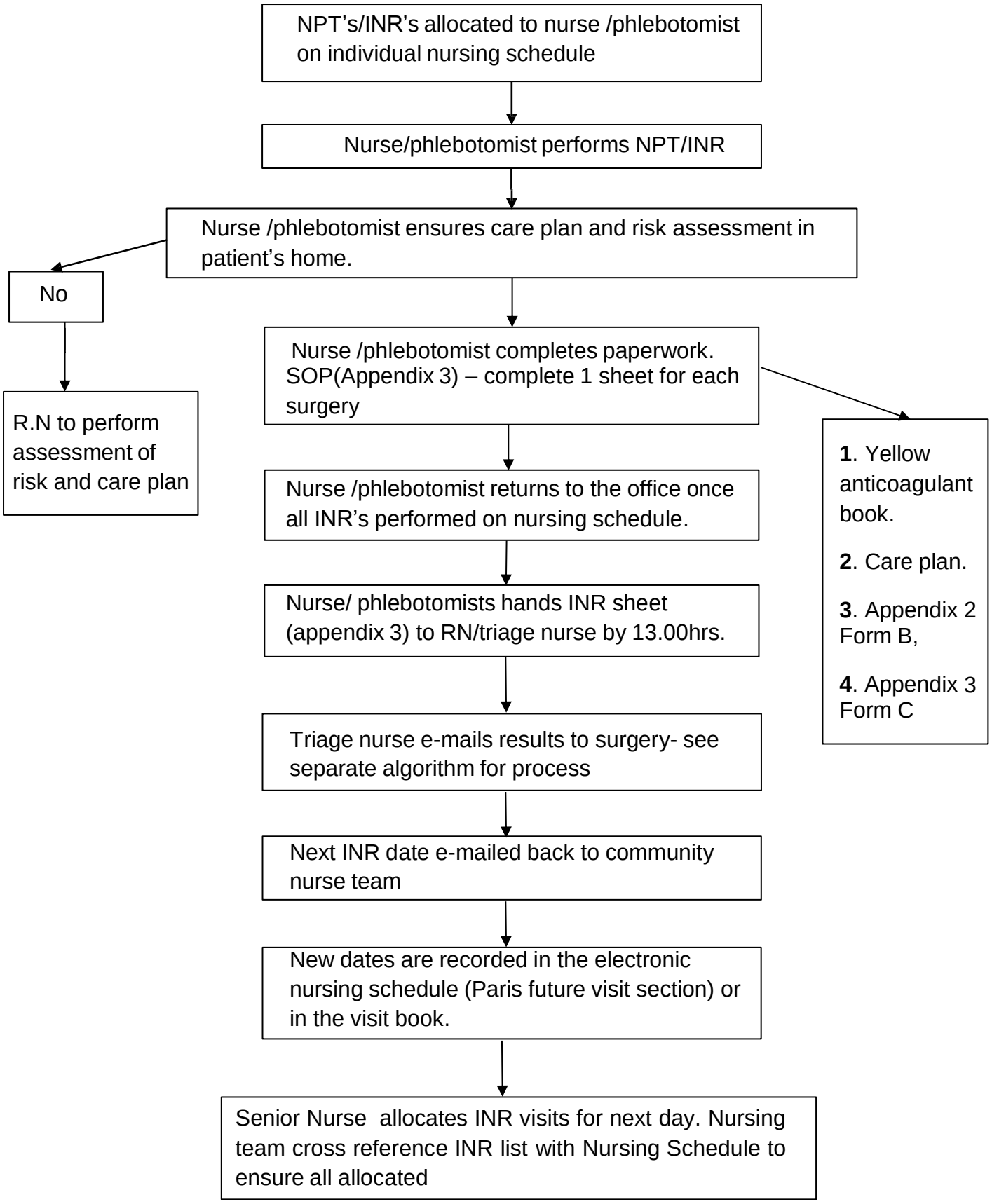
Role/Work location.....

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

Role/Work location.....

Appendix 6

ALGORYTHM FOR NPT/ INR PROCESS



Appendix 7 - Email Template

ANTI COAGULATION THERAPY (INR* RESULT)

Results should be submitted to GP Practice no later than 2pm

STAFF NAME		**DATE**	

PATIENT DETAILS			
NAME			
DATE OF BIRTH		**NHS NUMBER**	

PATIENT INFORMATION	
Current Health Status	
Any new medication? (Prescription or over the counter)	
Lifestyle advice/changes (eg green vegetables, alcohol, cranberry) given?	
Patient reports dosage since last test as?	
Any missed doses?	**YES** ☐ **NO** ☐
Has patient recently been discharged from hospital?	**YES** ☐ **NO** ☐
If 'Yes' what warfarin dose has the patient been on?	
If 'Yes' what was the patient's last INR* result?	

RESULT	
VENOUS SAMPLE TAKEN (if INR outside range <1.2 or >4.5)	**YES** ☐ **NO** ☐

GP Practice ADMIN USE ONLY

Appendix 8 – Coaguchek S and Coaguchek XS plus analyser Internal Quality Control Log Sheet

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

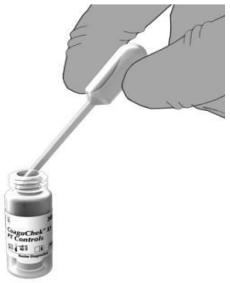
Torbay and Southern Devon Health and Care NHS Trust

CoaguChek XS Plus

Quality Control Testing

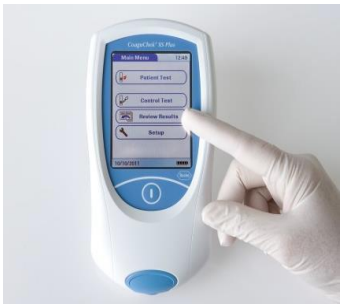
1) Remove plastic cap and rubber bung

2) Ensure no liquid is in the end of pipette and carefully cut end off and empty all contents into glass vial, ensuring not to touch the powder.



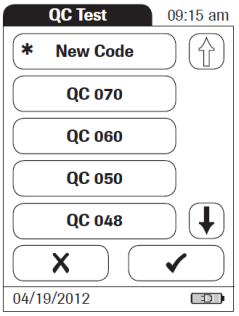
3) Replace the black cap and swirl on desktop (do not shake), until all the powder has dissolved. Solution now stable for 30 minutes.

4) Touch 'Control Test'

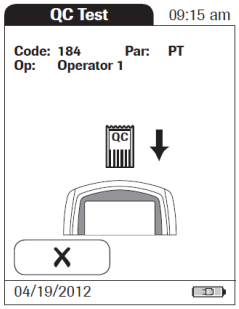


5) Insert test strip when prompted and test strip code chip (if prompted)

6) Check lot number on side of QC bottle then select from list, or select 'New'

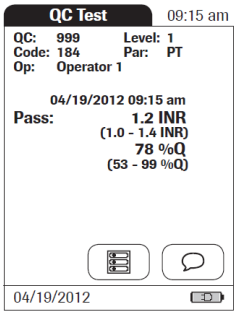


7) If 'New' option selected, insert code chip when prompted



8) Once the 180 Second countdown starts, apply the solution to the test strip using the pipette

9) The sample will be analysed and the result and acceptable range displayed on the



For a full protocol refer to the operators manual for your CoaguChek XS Plu