Use of the CoaguChek Pro II

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Review Interval	2 years

Changes from last version of this document

General review & tidy

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1 Purpose and Principle

The Roche CoaguChek Pro II monitor is intended for use in the determination of blood INR at the Point of Care.

The CoaguChek test strip contains human recombinant tissue factor. When a blood sample is applied to the test strip, the reagent dissolves, generating an electrochemical signal. The signal is then converted via an algorithm to INR units and the result is displayed.

2 Patient Preparation & Sample Requirements

- 8µL fresh capillary whole blood
- Non-anticoagulated venous whole blood. If this is from a syringe please discard the first 4 drops of blood.
- Non-anticoagulated arterial whole blood. If this is from a syringe please discard the first 4 drops of blood.

3 Tasks, Responsibilities and Authorisations

Tasks	Responsible	Authorised By
Patient testing	Clinical staff who have received POCT training as above	Trained member of POCT staff or certified POCT link trainer
Maintenance tasks	Clinical staff who have received POCT training as above	Trained member of POCT staff or certified POCT link trainer

4 Equipment

CoaguChek Pro II –meter

CoaguChek Pro II- Base station

Equipment is supplied by Roche

Roche Diagnostics Limited

Charles Avenue

Burgess Hill

West Sussex

RH15 9RY

Tel 0808 100 1920

In the event of a breakdown please contact the POCT team on 01904 725890

CoaguChek PT test strips 06688721- These can be stored at 2-30C

CoaguChek PT control solutions 06679684- These should be stored at 2-8 C

5 Chemicals and Reagents

The manufacturer indicates no particular hazard involved with use of the reagents.

Attention is, however, drawn to the fact that the reagents have not been fully examined and may be irritant. Serum/ blood samples may constitute a biohazard. Please take usual precautions; i.e. wear gloves and employ routine hygiene techniques. All sharps must be disposed of in a sharps bin.

GENERAL FIRST AID

The following first aid guidelines may be applied to all the substances detailed in this SOP.

Eyes: Irrigate thoroughly with water. At least 10 minutes is the recommended duration. Sterile saline is also available at the eye wash stations.

Lungs: Remove from exposure, rest and keep warm.

Skin: Wash substance off skin thoroughly with water. Remove contaminated clothing and wash before re-use.

Mouth: Wash out mouth thoroughly with water and give plenty of water to drink.

Remember – If at all concerned about the nature or severity of the problem, SEEK MEDICAL ADVICE.

6 Risk Assessment (Environmental and Safety Controls)

Full risk assessment can be found in PC/RA/YS-5 on Q-pulse

Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be always followed during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.
- Include reference to table in ‘chemicals and reagents’ section for specific COSHH assessment.
- Include reference to the process risk assessment which shall identify potential risks to patient care as well as staff safety. Ensure this document is up to date and has considered any non-conformities raised against the process.

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk is mitigated as far as possible and or monitored with health surveillance to ensure health and safety for all those affected by this procedure.

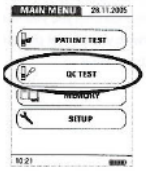
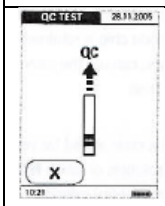
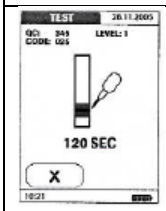
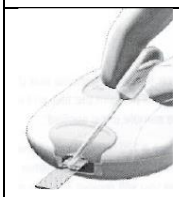
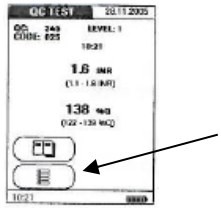
7 Calibration

- Calibration of the meter must be carried out each time a new container of test strips is opened, using the code chip provided in the test strip box.
- Remove the ID chip from the meter and dispose of immediately to avoid confusion.

	• 1. Check the number on the code chip matches the number on the test strip container
	• 2. Slide the new code chip into the slot on the top of the monitor until you feel it snap into place. The monitor is now ready to run the QC sample.

8 Quality Control

One CoaguChek plasma control solution should be run every day the monitor is in use. If the quality control fails, the meter must not be used. Please contact the POCT team for further information Tel. York 772 5890

	1. Remove the control vial and pipette from fridge and allow 5 minutes for the vial to come up to room temperature
	2. Open the lid of the vial and remove the rubber cap. Hold the pipette with the sealed neck pointing upwards and flick the top to ensure there is no liquid stuck in the top of the pipette. Cut off the sealed end of the pipette and transfer the entire contents into the vial (keep the pipette for later). Replace lid and swirl the vial gently to dissolve the contents. Allow to stand for 5 minutes to reconstitute. Use the reconstituted solution within 30 minutes
	3. Place monitor on a level surface and switch on the meter. Switch on the meter using the on/off button Log on using your operator ID this may be scanned from your barcode. Enter your password when prompted. Check date and time are correct. Touch the Control Test button and then press the Control Test button again.
	4. When the test strip icon prompts. Hold the test strip so the lettering “CoaguChek PT” is facing up and insert the strip into the monitor until it stops. An hourglass icon shows the test strip is warming up. Select the correct QC lot number from the ones shown. If it is a new lot number touch the new code. Remove the code chip from the meter and insert the code chip that came with the control solution. Pick the correct level of control for the sample you are running.
	5. The pipette icon flashes to indicate that the monitor is ready and a 120 second countdown begins. The sample must be applied within this time otherwise you will receive an error message.
	6. Using the pipette draw up the dissolved contents of the vial and apply a drop of control solution on to the semi-circular, transparent sample application area in the centre of the test strip. The test will start, indicated by an hourglass icon.
	7. If the QC fails an arrow will indicate if the INR is too high or too low. If this occurs return to the main menu and repeat steps 3 to 7. The results will be saved to Cobas IT.

9 External Quality Assurance (EQA)

Coaguchek meters are enrolled in the quarterly UKNEQAS Coagulation scheme.

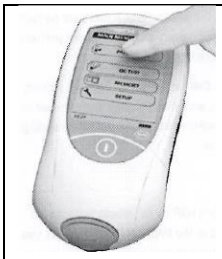
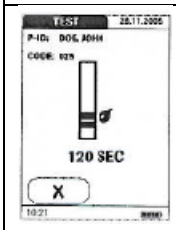
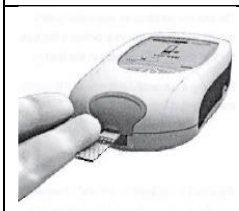
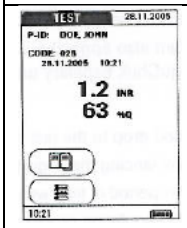
Samples are distributed in a bright yellow envelope every 2 months with instructions of how to process and reports are reviewed by a BMS from POCT.

10 Procedural Steps

10.1 Obtaining a patient sample

- Protective gloves **must** always be worn.
- Check the patients' details i.e. name and date of birth.
- Explain the procedure and obtain consent.
- Ask patient which finger they would like the sample taken from.
- Clean the patients' hands or finger prior to testing.
- Puncture finger with lancet and draw a small drop of blood for use on the test strip.
- Give the patient a clean swab when test is complete.

10.2 Analysis of the sample

	1. Switch meter on using the on/off button. Log on to the meter using your operator ID which is scanned from scanned from your barcode enter your password manually. Touch the patient test button and you will be prompted to enter the patient ID or pick from the ward list. You may scan the patients NHS number from the patients wrist band or press new change the screen from alpha to numeric using the [123] key at bottom of the screen and enter the patient's NHS number.
	2. Insert test strip when the icon flashes, the sample must then be applied within 2 minutes. Using a lancet, puncture finger and gently massage to develop a hanging drop of blood.
	3. Touch the blood drop against the side of the sample application area in the centre of the test strip; the test strip draws up the blood by capillary action. The blood should cover the entire application area. When enough blood has been applied the blood drop icon disappears and the test starts.
	4. The INR result is displayed after approx. 1 minute. Write the INR result in the patient's notes along with the operators name date and time of the analysis. Alternatively give the result to a member of the nursing team to document. The results will automatically be uploaded to Cobas IT 5. Remove strip and place in clinical waste. Log out and turn the monitor off. Please clean the meter after every use. The strip guard can be removed to ensure adequate cleaning, please do NOT use Clinell wipes as this leave deposits on the instrument that can cause interference. Do not use Quaternary Ammonium compounds on the black area with the connection ports. **The device should be cleaned with an alcohol wipe such as 70% isopropanol Sanicloth.**

11 Reporting of Results

If INR result is >4.5 a venous sample must be sent to the laboratory for urgent confirmation.

Nursing staff are responsible for documenting the result, informing the patient of the result (if appropriate) and informing the clinician looking after the patient

The CoaguChek Pro II has a measuring range of INR: 0.8-8.0. Results outside this range are indicated by **<** (smaller than) or **>** (greater than) symbols and should be rechecked.

- Critical/Alert values must be included here, or, where critical/alert limits are consolidated in one document, a reference to the Q-Pulse filename of this document must be given here, along with its physical location if available in hardcopy.

- Procedure & criteria for notifying requesters if there is likely to be a clinically significant delay in providing results (e.g., analyser failure).

12 Reference Intervals

Patients have an individual therapeutic range, which varies depending on the patient's diagnosis.

13 Performance Characteristics

Calibration Information; Each lot of strips is calibrated to reference lot that is traceable to the WHO International Reference Preparations. See product insert for more information.

The lowest value displayed is INR 0.8. The measurement range is INR 0.8-8.0

14 Known Limitations

Many prescription and non-prescription drugs including antibiotics and alcohol affect the action of warfarin and hence affect the INR result. Any changes in medication or missed doses should be noted by the patient so these can be taken into consideration when a clinician is interpreting the result.

There is no significant effect on the test results in blood samples with

- Bilirubin up to 513umol/L
- Haemolysis up to 0.62mmol/L
- Triglycerides up to 11.4 mmol/L
- Haematocrit ranges between 15%-55%
- Ascorbic Acid up to 50mg/L

The Coagu Chek PT test is insensitive to unfractionated and fractionated heparin concentrations up to 3 IU/ml Blood

Patients being treated with Protamine sulfate should not be tested on the meter.

Precision data quoted by Roche-Due to the cost a full evaluation was not carried out.

Repeatability

Range (INR)	Number of tests	SD (INR)	CV%
<1.2	42	0.04	3.6
1.3-1.9	19	0.05	3.0
>2.0	7	0.10	2.0

Reproducibility

PT control level	Mean INR	SD (INR)	CV%
1	1.28	0.04	3.2
2	2.94	0.09	3.1

15 Related Forms/Templates and Documents

- CoaguChek Pro II operators manual (PC/ED/YS-3)
- CoaguChek PT test strip insert

16 References

- CoaguChek Pro II operators manual (PC/ED/YS-3)