Key Trainer Handbook

Roche CoaguChek Pro II - INR Meter

Contents

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Introduction to Point of Care

This handbook has been compiled by the Point of Care Testing Department (POCT) for LTHT to help you, the healthcare professional, achieve consistently reliable and accurate results. It also hopes to explain the importance of good practice when producing laboratory results outside of the Pathology environment.

The different sections of the booklet cover aspects of working with the Roche CoaguChek including routine use and quality control.

On completing this training all users should be able to analyse samples obtaining an accurate result whilst minimising risk to themselves and patients.

Ensuring Quality

Leeds Teaching Hospitals Trust Pathology service is required to meet the nationally agreed standards set by UKAS, the national accreditation body recognised by the UK Government. A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. Pathology is currently using ISO standards to assess their performance. Following the Clinical Area Standard Operating Procedure (SOP) and using the training material provided is essential to us meeting these standards.

The use of analysers by untrained staff, without adequate management supervision of the equipment and without the use of quality control procedures, can lead to misleading results and adversely affecting the treatment of patients.

Definitions

Calibration - A set of known standards are run at different concentrations and used to assess and adjust the accuracy of the analyser.

Internal Quality Control (IQC) - The role of IQC is to monitor the day-to-day precision and accuracy of a given assay by comparing it to known values. Best practice dictates both a high and low are run, ensuring accuracy at both ends of the result range.

External Quality Assurance (EQA) - The role of EQA is to provide a broader comparison. Enrolling in an EQA scheme allows one analyser's results to be compared to many others, both of similar and different methods. It is also performed by a member of staff and so can be used to monitor user proficiency.

Key Trainer Role

The role of the Key Trainer is to cascade training from the POCT department to all members of ward staff who are required to use the Roche CoaguChek. They are also responsible for keeping a copy of training documentation for all trained members of staff.

Their main duties consist of the following:

- Ensuring members of staff who wish to undergo training read the Form 1: Knowledge and Assessment and complete the Form 2: Competency Questions.

- Witness the member of staff run a standard test and then complete the Competency Assessment Form 3.

- Maintain ward records, this involves retaining a copy of Competency Assessment Form 3 as part of the Key Trainer records on the ward. These can be used as proof of training and also as a reminder for 2 yearly retraining.

- Complete and return the Registry Form to POCT department so that passwords can be updated and access granted. This also allows the POCT to update MELVIS.

- Key Trainers will be expected to attend training session updates and relay any changes in practice.

Training Documents

Form 1: Knowledge and Skills. To be read by the member of staff being assessed to ensure knowledge and understanding of the standards required. This form should be retained by the Trainee for future reference.

Form 2: Competency Questions. Contains questions which are based on the information in Form 1. This form should be retained by the member of staff as a reminder for reassessment.

Form 3: Competency Assessment. Is to be filled in by the Key Trainer and member of staff when the assessment has been undertaken and is to ensure standards are being met. This form is held as a paper copy by the Key Trainer. It may form part of the Personal Development Record (PDR).

Registry Form. Please complete thoroughly and clearly, providing all contact details requested to allow POCT staff to update training records. Please return to the POCT department by email as soon as training has been completed. Leedsth-tr.pointofcare@nhs.net

Training for the Roche CoaguChek.

Objective

This competency covers the INR analysis of patients using the Roche CoaguChek in a Point of Care (POCT) setting.

Assessment

This assessment is relevant to anyone required to carry out INR analysis on the Roche CoaguChek. This includes having an understanding of how to collect an appropriate sample, how to use the analyser to perform a patient test, all relevant health and safety issues, who to contact for machine failure and the importance of password protection.

Other Helpful Documents

Found on the Pathology Website - http://www.pathology.leedsth.nhs.uk/Pathology/

This document is for use within the Leeds Teaching Hospitals NHS Trust ONLY. It should not be printed, but accessed electronically so that only the most up to date instructions are available.

PLEASE NOTE: The sharing of passwords is against Trust policy, both the Data protection policy and the use of computers policy. Every member of staff is required to undertake mandatory Information Governance (IG) training and should be aware of this. Sharing passwords breaks principle 7 of the Data Protection Act (1998), which could be interpreted as unauthorised processing. This is unlawful under section 55 of the Act. It is also an offence under the Computer Misuse Act (1990).

Form 1– Knowledge & Assessment Worksheet - Roche CoaguChek Pro II

Topics covered	Training detail
Medico-Legal	• Passwords (Trust ID badge barcodes**) MUST NEVER** be shared to prevent device misuse and to protect both patients and staff. Passwords are unique to every user. • It is against Information Governance and Trust IT Policies to share passwords. It is a disciplinary offence. • Training will last for two years. All users must have an update every two years. Your training expiry date can be found on the MELVIS database. • Patient ID must be checked before bleeding the patient using at least 3 points of ID e.g. Name, DOB and address and the sample labelled with a barcoded sticker where appropriate. • Acceptable forms of Patient ID are: 1. The NHS, PAS or A&E number. 2. If the above are not to hand, the patient's FULL name. 3. In an emergency ONLY the reason why the blood gas is being carried out e.g. CRASH, COLLAPSE, RTC, etc.
Analyser overview (Hardware)	• Touch screen (pressure release not pressure sensitive) and Power button. • Strip insert/insert cover. • Barcode scanner. • Battery compartment and Code Chip slot. • Dock (charging terminals/infrared interface/power supply). • Strips - stable at room temperature, expiry date displayed on vial. • QC - single use, check expiry date on box, **keep refrigerated.**
Analyser overview (Screen)	• Log in, scan ID badge to enter main menu **Options** - Patient test - Control test - Review results - Setup - Log out
Calibration	• Calibration data contained in the code chip; provides the specific performance characteristics of the corresponding QC solution or test strips • Self-check performed by meter prior to sample analysis
Quality Control (QC)	• **Liquid QC to be analysed by the user on a weekly basis** • Meter will lock weekly, cannot be used until the QC has been analysed • QC to be stored at 2-8°C, must be used within 15-20 minutes once at room temperature. • Two levels to analyse, results to be recorded in ward folder **Preparing/running QC solution** • Remove plastic cap/rubber bung from vial. • Cut off end of pipette provided (ensure there is no liquid in the end) and empty contents into vial. • Replace cap and swirl on desk to mix, **DO NOT SHAKE** and ensure all the white powder has mixed with the liquid. • Allow to stand for 5 minutes to reconstitute and use within 30 minutes. • Log in by scanning Trust ID badge and select "Control Test" from main menu • Insert strip when prompted (MUST ONLY be handled on the lettered end of the strip and check blue strip on the back of the strip, if it's purple, the strip has been stored incorrectly and you must discard it). • Select QC lot number (present on side of QC vial) from list on screen, or select New if not on the list. • If New is selected, insert code chip (supplied with QC in box) when prompted. • 180 sec countdown will begin, apply QC to test strip using pipette provided. • Results and range will be displayed on screen, document in ward folder and indicate pass/fail. • Run second control • If QC fails, repeat test and if QC fails for a second time then contact Point of Care.
Pre-Analytical	• Wash patient's hands prior to testing and to help increase blood flow, have patient hold their hand in a downward position whilst preparing the meter. • Applying gentle pressure, massage patients hand from the palm/base of finger up to the tip of the finger you are going to puncture (choose middle, ring or little finger) • Disinfect puncture site using skin prep pad (or equivalent) and make sure it is dry before testing (alcohol/other skin prep solutions may interfere with testing mechanisms causing inaccurate results)
Sample Analysis	• Log in by scanning trust ID badge and select "Patient Test" from main menu • Scan patient ID when prompted (can input manually via touch screen)

	• Insert test strip when prompted only touching the indicated end of the strip. • An egg timer is now displayed as the meter warms reagent and detects strip lot information from the code chip • If using a new lot number of strips insert the new code chip when prompted • Only AFTER 180 sec countdown has begun, lance the prepared finger **Note** – Holding the puncture site downward, gently "milk" patients hand from wrist to puncture site. **Avoid** squeezing/strong pressure at puncture site as this may contaminate sample with tissue fluid • WITHIN 15 SECONDS of lancing, apply drop of blood to the test strip using either top or side dosing (minimum of 8µl is required ≈ the size of a ladybird) • Meter MUST be in a horizontal position when in use • DO NOT remove finger from the strip until the meter has beeped (beeping is a filling indicator: 1 beep = good, 2 beeps = bad) • An egg timer will now be displayed whilst the meter performs the on board QC • The result will now be displayed on screen, document all the required information in your ward folder **EQA** • Samples are sent out bimonthly. All users must run an EQA sample at some point. Samples are to be run as if they were a patient sample, using the barcode provided for ID and the results recorded in the ward folder. The results **MUST** then be emailed to point of care so they can be submitted to WEQAS.
Results	• Analytical range of the meter 0.8-8.0 INR • **A sample should be sent to the Haematology Laboratory for confirmation (venous whole blood in a trisodium citrate blood tube) with a requesting form if:** ○ **Results >3.0** ○ **Results that are outside the analytical range, or do not fit with the patients clinical picture.**
Recall results	• Log in and select review results from the main menu • Results will be displayed chronologically starting with the most recent • Can search via patient ID • Stores up to 2000 test results • Results should be recorded in your ward folder
Error messages / troubleshooting	• Most common error is a blood application error when sampling from a patient. In this case there is insufficient sample volume for analysis (often caused when the patient's finger has been removed from the strip before the meter has beeped when sampling). If this occurs then repeat analysis with a new strip and puncture site • If any other error message is displayed then please contact Point of Care for further advice/assistance • When reporting clinical incidents on DATIX, tick the tick box for incidents involving Trust equipment and select 'in-vitro Medical Devices' from the drop down list.
Maintenance	• Clean and disinfect the exterior of the meter and the test strip guide between patient tests. • Clean and disinfect the meter with alcohol wipes, allow to air dry for at least 10 minutes before use. • Power off the meter and remove the test strip guide cover and clean with an alcohol wipe, clean the white area with a moistened cotton swab/bud, allow to air dry for 10 minutes before re-attaching the cover.
Conclusion	Refresh: • **Medico-Legal** • **Contact details** • **Importance of pre-analytics**

Name of member of staff (Please Print):	Name of assessor (Please Print):
Member of staff signature:	Assessor Signature:
Date of Training:	Date Recertification Due:

Form 2 Questions - Roche CoaguChek Pro II

1. When you start a new lot number of strips/QC, what must you do to load the new lot number data onto the CoaguChek?

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2. How often should you run a QC test?

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3. According to Trust Policy, who can use the CoaguChek? How often do you need to be trained?

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4. Who is responsible for ensuring you are trained?

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5. What mandatory patient ID is required?

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6. Who do you contact if the machine is not working and cannot be resolved by your link nurse/advanced user?

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7. How do you contact POCT?

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8. What is the correct way to hold the test strip?

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Form 2 Questions - Answers for Key Trainers - Roche CoaguChek Pro II

1. When you start a new lot number of strips/QC, what must you do to load the new lot number data onto the Coaguchek?

   The Code chip inside the new box of strips/QC must be inserted so the machine can read the new details.

2. How often should you run a QC test?

   Two levels, once a week

3. According to Trust Policy, who can use the CoaguChek? How often do you need to be trained?

   All staff who have been trained and competency assessed will be activated for two years.

4. Who is responsible for ensuring you are trained?
   Personal responsibility

5. What mandatory patient ID is required?

   The NHS, PAS or A&E number

6. Who do you contact if the machine is not working and cannot be resolved by your link nurse/advanced user?
   Contact the Point of Care Department

7. How do you contact POCT

   Contact details are found in the Key Trainer handbook email - leedsth-tr.pointofcare@nhs.net Ext 22338/64791

8. What is the correct way to hold the test strip?

   By the lettered end of the strip to avoid damage to the strip and possible erroneous results.

FORM 3 Observational Assessment: Performing an INR test on the Roche CoaguChek Pro II
TO BE RETAINED BY THE KEY TRAINER

Core competency	Please record whether or not the member of staff completed the task.
1 Has the member of staff read the knowledge and understanding worksheet (Form 1)?	
2 Has the member of staff completed the questions?	
3 Did the member of staff correctly use the relevant ID • Did the member of staff scan the correct patient bar code as ID? • Did the member of staff check the patients ID on screen matched that of the patient who the sample came from? • ***Did the member of staff enter their own bar code password?***	
4 Sampling-can be done with either patient or QC sample • Was the sample applied to the strip correctly? • Did the member of staff handle the strip correctly?	
5 Coaguchek analyser use • Does the member of staff know how to load on a new lot number of strips/QC using the code chip? • Does the member of staff know how to contact Point of Care in the event of machine breakdown?	
6 Did the member of staff demonstrate effective health and safety measures? • Were gloves worn? • Was the used syringe/capillary/lancet disposed of in a clinical waste or sharps bin? • Was the machine left clean for the next user?	
7 Result Reporting • Were the results reported according to ward/departmental procedures ensuring the correct patient ID? • Were the results acted on accordingly?	

Staff Member
I the undersigned declare that I have read Form 1 and completed the questions and the practical assessment
Assessor
I the undersigned declare that the staff member has completed the competency tests to a satisfactory standard.

Name of member of staff (Please Print)	Name of assessor (Please Print)
Operator Number:	Date of assessment
Department:	Signature:
Signature:	Staff member's E-mail:

Roche CoaguChek Pro II Training Register

Hospital and Ward No: | **Date of Training:**

Name of Trainer:

Forename	Surname	Analyser Training	Site(s) access required for	Operator ID (7/8 DIGIT NO.)	E-mail address	Key Trainer
e.g. JOE	*BLOGGS*	*CoaguChek*	*CROSS SITE*	*1234567*	*Joe.bloggs1234@nhs.net*	