NHS
North East London

Expected Standards on Quality Assurance of Point-of-Care Testing from Community Anticoagulation Service providers in NHS North East London (NEL)

This paper makes recommendations regarding actions required now to mitigate any concerns and inconsistencies with QA of devices in the current commissioned services.

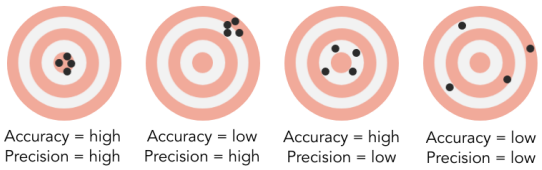
Contents

1. Background

A recent review of community based anticoagulation services across the NEL ICB has shown that the standard of quality assurance around point of care testing (POCT) devices varies across NHS NEL. This guidance serves as a reminder and provides clarity to providers on the requirements around quality assurance of POCT devices and makes recommendations on actions required to mitigate concerns and inconsistencies in current commissioned services.

2. Introduction

NHS North East London have created this document to ensure that there is a consistent approach to Quality Assurance (QA) with respect to anticoagulation POCT medical devices. This document makes clear the expectations and requirements of services utilising anticoagulation POCT devices in order to ensure that services are safe and effective for patients. QA is the overall term used to describe all measures that are taken to ensure the reliability of results from anticoagulation POCT testing and reporting. Internal Quality Control (IQC) and External Quality Assessment (EQA) are two distinct, yet complementary components of Quality Assurance. Both components, IQC and EQA, are required for QA. IQC is performed to ensure that INR test results are precise. Precision can be defined as how close measurements of the same item are to each other. EQA is performed to ensure that INR test results are accurate. Accuracy can be defined as how close a measurement is to the true value. POCT devices need to be both highly precise and highly accurate.



3. Professional Regulatory Requirements on the Maintenance of Medical Devices

Provision, maintenance and repair of medical devices is part of risk assessment activity. This comes under the Health and Safety at Work Regulations 1999 (management regulations). The Health and Safety Executive publish comprehensive guidance on risk assessment.

3.1 For service providers operating from Pharmacies regulated by the General Pharmaceutical Council (GPhC)

Principle 5 In the standards for registered pharmacies stipulates that *"The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public"*. Standard 5.2 under Principle 5 stipulates that equipment is *"safe to use and fit for purpose"* and *"appropriately maintained".*

The Royal Pharmaceutical Society (RPS), GPhC and NHS England (NHSE) have jointly published guidance on POCT in community pharmacies, including extensive section on clinical governance and quality assurance. – click here for more information

3.2 For service providers operating from GP Practices regulated by the Care Quality Commission (CQC)

With respect to devices such as anticoagulation POCT devices, The CQC stipulates that these are covered by Regulation 12 (Safe care and treatment) and Regulation 15 (Premises and Equipment) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, as part of their Key Lines of Enquiry (KLOE), particularly when assessing KLOE S1 Safeguarding and protection from abuse.

- **Regulation 12(e)** stipulates that providers must ensure that *"the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way"* – read full guidance here
- **Regulation 15(c)** stipulates that that providers must ensure that premises and equipment are *"suitable for the purpose for which they are being used"* - read full guidance here
- **Regulation 15(d)** stipulates that providers must ensure that premises and equipment are *"properly maintained"* – read full guidance here

The CQC have also published a GP myth buster concerning the maintenance of medical equipment. The myth buster specifically notes that "Equipment must be maintained in line with manufacturer's instructions. Records should be kept of internal and external quality assurance" – read the full myth buster here

4. Internal Quality Control

Internal Quality Control is used to maintain precision. Precision refers to how close measurements are to one another. There are three types of IQC: Electronic IQC, On-Board/Integral IQC and Liquid IQC. The Roche Diagnostics CoaguChek® POCT devices all utilise On-Board/Integral Internal Quality Control, this means that quality control functions are integrated into the device and the test strips. In Roche CoaguChek® devices, the On-Board/Integral Internal Quality Control will perform:

- A check of the electronic components and functions every time the meter is powered on.
- A check of the test strip temperature while a test is in progress.
- A check of the expiration date and lot information on the test strip carried out by the code chip.
- A two-level, onboard quality control test and patient result determination within a single test chamber

However, national and international guidelines, recommend that the manufacturer's Liquid Internal Quality Control materials should be used whenever the manufacturer makes Liquid IQC materials available. Liquid IQC provides verification of test performance independent of the On-Board/Integral IQC.
Whenever a manufacturer makes Liquid IQC materials available, NHS North East London requires a Liquid IQC assay to be performed for each active POCT device at least every 31 days. Service providers should therefore check with their device manufacturers to determine availability of Liquid IQC materials. See below for further details.

4.1 Internal Quality Control for service providers using of Roche Diagnostics' CoaguChek® systems

Roche Diagnostics have made Liquid IQC materials available for customers of their CoaguChek® systems. Therefore, Community Anticoagulation Providers who use CoaguChek® devices at their service are required to perform a Liquid IQC assay for each active POCT device every 31 days, it is recommended that the "QC lockout" function is enabled for at least every month. The QC lockout function prevents end users performing further tests unless a Liquid IQC has been performed successfully, with the results in-range.

The control solution required to perform the test varies depending on the type of CoaguChek® device, please see table below to determine which control solution is compatible with your CoaguChek® device.

Machine	Control Solution for Liquid IQC
CoaguChek® XS Plus	CoaguChek® XS PT Controls
CoaguChek® XS Pro	CoaguChek® XS PT Controls
CoaguChek® Pro II	CoaguChek® PT Controls

The results of Liquid IQC & POCT batch testing should be recorded in the anticoagulated computerised decision support software, where this functionality exists. This may be used as evidence of Liquid IQC. When built in functionality does not exist in the computerised decision support software, providers should maintain appropriate records.

Useful Resources
Adding and activating POCT batch details in INR Star
Adding Internal Quality Control results in INR Star

5. External Quality Assessment

EQA is used to maintain accuracy. Accuracy refers to how close a measurement is to the true value. EQA complements, but does not replace, IQC. EQA involves an accredited assessor providing all service providers a sample of a known but undisclosed analyte concentration at both clinical decision levels and levels that reflect the linearity of a device, at varying frequencies. The service provider tests the test samples on their device and returns the results to the assessor via a web-based platform to allow the assessor to compare with the results of other centres using the same device. International Council for Standardisation in Haematology (ICSH) guidance for INR and D-dimer testing using point of care testing in primary care stipulates EQA should be performed at a minimum, every 3 months using an EQA provider accredited by the UKAS against ISO 17043. It is advised that the following not-for-profit EQA providers are used to perform EQA on each of your anticoagulation POCT devices.

EQA Provider	**Website**
UK NEQAS	UK NEQAS Blood Coagulation
WEQAS	WEQAS POCT Services

Where the functionality exists, the results of EQA should be recorded in the anticoagulated computerised decision support software. Evidence of EQA should be maintained by the service provider in the form of a certificate of test compliance of EQA issued by UK NEQAS or WEQAS. Where a service provider relies on an intermediary to arrange EQA, it is the service providers responsibility to ensure that EQA is performed for each active device, evidence of EQA is maintained and readily accessible, and that devices are safe to use in a clinic setting.

Useful Resources
Adding an External Quality Assessment provider into INR Star

6. Medical Equipment Calibration and Portable Appliance Testing

Medical Equipment Calibration services do not replace IQC and EQA. Furthermore, Portable Appliance Testing (PAT) is the process of checking the safety of electrical appliances through visual inspections and electronic tests. PAT testing ensures that devices are compliant with electrical safety standards. **PAT tests and Medical Equipment Calibration are inadequate for QA purposes and PAT labels, or Medical Equipment Calibration certificates are not acceptable evidence for any component of QA.**

7. Training and Education on Device Maintenance

Service providers should refer to the operator manual for the POCT device. Some device manufacturers also provide training and customer support.

For users of the CoaguChek® device range from Roche Diagnostics, information on training can be found here. Alternatively, you can email Roche Diagnostics for more information, training and education on their CoaguChek® POCT devices via burgess_hill.pocetraining@roche.com

The content of the training programme and the knowledge/skills level assessment process should all be documented. Knowledge/skills requirements include the ability to demonstrate an understanding of the appropriate use of the device, the theory of the measurement system, and appreciation of the pre-analytical aspects of the analysis, including:

- Sample collection
- Clinical utility and limitations
- Expertise in the analytical procedure
- Reagent storage and stability
- Quality control and quality assurance
- Technical limitations of the device and reflex testing
- Response to results that fall outside pre-defined limits,
- Correct documentation and maintenance of devices/results

Providers must ensure that there are retraining intervals, a programme of continuing education and that training records for staff are maintained. Training & education of operators should be assessed at a minimum, annually.

8. Useful Resources

- Medicines and Healthcare products Regulatory Agency – Managing Medical Devices Guidance for health and social care
- Medicines and Healthcare products Regulatory Agency – Devices in Practice – Checklists for using medical devices
- British Society for Haematology Guidelines on Point of care testing in general haematology
- International Council for Standardisation in Haematology guidance for INR and D-dimer testing using point of care testing in primary care
- Roche Diagnostics - CoaguChek®
- Point of Care Testing in Community Pharmacies Guide

9. Contact NHS North East London

If you are a service provider in NHS North East London and have questions about Quality Assurance of anticoagulation POCT devices, please contact the Pharmacy & Medicines Optimisation team via nelondonicb.medicinesoptimisationenquiries@nhs.net. The Pharmacy & Medicines Optimisation team will forward your query to the relevant team and commissioner within NHS North East London, to assist with this, please include the borough where you provide your anticoagulation service in the email.

10. Actions for Service Providers in NHS North East London

- Must ensure that annual registration to an External Quality Assessment (EQA) service provider accredited by United Kingdom Accreditation Service (UKAS), is maintained & performed for every anticoagulation point-of-care testing (POCT) device.

- Must ensure that for every active anticoagulation POCT device, intervals between EQA conducted by a UKAS accredited EQA service provider, do not exceed more than 3 months.

- Must ensure that for every active anticoagulation POCT device, whenever a manufacturer has made Liquid Internal Quality Control (IQC) materials available, intervals between IQC using Liquid IQC materials, do not exceed more than 31 days.

- Must maintain an internal audit record and schedule to ensure that both IQC and EQA are recorded and routinely performed & monitored.

- Must be able to readily demonstrate to NHS North East London, on request, evidence of up-to-date records of both IQC and EQA for all active anticoagulation POCT devices. An up-to-date certificate issued by a UK Accreditation Service accredited EQA provider is expected to be held for each active device.

- Must ensure that only operators who are trained and fully competent should perform anticoagulation POCT testing. Providers must ensure that healthcare professionals demonstrate appropriate competencies through an accredited POCT training scheme, and that training and proficiency assessments are routinely assessed on an on-going basis. Records of POCT training and proficiency assessments must be maintained and evidence of POCT training & education must be readily demonstrated to NHS North East London upon request.

- Must ensure that operators of POCT devices operate and maintain the device in accordance with the operator's manual as provided by the device manufacturer. Operators must be knowledgeable on the contents of the operator's manual.

- Must ensure that they have due regard to national and international guidance particularly, British Society for Haematology Guidelines on POCT testing in general haematology and the International Council for Standardisation in Haematology guidance for INR and D-dimer testing using POCT testing in primary care

- Must take steps to ensure that they adhere to professional and regulatory standards and requirements which reference medical equipment and POCT, including, but not limited to materials produced by
    - Medicines and Healthcare products Regulatory Agency (MHRA)
    - Care Quality Commission (CQC)
    - General Pharmaceutical Council (GPhC)
    - Royal Pharmaceutical Society (RPS)
    - NHS England (NHSE)

- Must nominate a named clinical lead to action the standards outlined in this document