University Hospitals of Derby and Burton
NHS Foundation Trust

TRUST POLICY FOR POINT OF CARE TESTING IN CLINICAL AREAS

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Version / Amendment History	Version	Date	Author	Reason
	1	2005	Operational Manager Pathology	Original version
	2	2009	Pam Twine	Reviewed and reformatted to NHSLA standard
	3	2014	Julia Forsyth	Review
	4	2018	Julia Forsyth	Review and identify specific sits where policy is applicable.
	5	2022	Julia Forsyth	Review
Intended Recipients: All clinical and medical staff.				
Training and Dissemination: An operator who has been trained and deemed competent shall be registered on the POCT system, and have their training certified and registered with the Trust.				
To be read in conjunction with: Risk Management Policy and Procedures				
In consultation with and Date: Pathology Point of Care Managers; Procedural Documentation Review Group, TDG (April 2018)				
EIRA stage One Completed Yes stage Two Completed No				
Approving Body and Date Approved	Trust Delivery Group – 28 November 2022			
Date of Issue	November 2023			
Review Date and Frequency	November 2025 then every 3 years			
Contact for Review	Assistant Clinical Director Pathology, Blood Sciences			
Executive Lead Signature	 Garry Marsh, Executive Chief Nurse			

Appendices

TRUST POLICY FOR POINT OF CARE TESTING IN CLINICAL AREAS

1. Introduction

Point of Care Testing (POCT) is defined as any Pathology test performed by a member of the healthcare team outside the conventional laboratory setting. Locations this policy is applicable to: University Hospitals of Derby and Burton All Sites including but not exclusive to Royal Derby Hospital (RDH), Florence Nightingale Community Hospital (FNCH), Queens Hospital Burton-upon-Trent (QHB).

Background

POCT encompasses a range of testing of different analytes across pathology. Most hospitals use POCT, as it is capable of producing results in a timely manner that allows clinical decisions to be made quickly, potentially allowing better clinical outcomes. However, effective governance procedures including training of staff and quality control procedures are crucial to the successful implementation and safe use POCT.

POCT includes various different types of systems and analysers, including:

Non-instrumental systems:	disposable devices such as urine reagent test strips
Small analysers:	hand held devices such as blood glucose meters
Desktop analysers	larger systems such as blood gas analysers

Current pathology POCT in the Trust includes:

- Blood glucose and ketone meters
- Urine Pregnancy testing
- Haemoglobinometers
- Blood gas analysers
- Electrolyte analysers
- Coagulometers (INR)
- HbA_1c analysers
- Full blood count (FBC)
- Activated clotting time (ACT)
- Influenza A/B
- SARS Cov-2
- Clotting analysers in theatres
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2. Purpose and Outcomes

This policy provides a framework for quality assurance of POCT within the Trust. This will be achieved by:

- Introduction of standard operating procedures (SOPs) for the appropriate use and maintenance of equipment.
- Training of all operators to an agreed level of competence in the performance of pathology POCT and quality control procedures.
- Providing a practical assessment of competence wherever possible for all operators of pathology POCT equipment within the Trust.
- Developing appropriate I connectivity of POCT equipment wherever possible in line with Trust IT procedures.

The policy will apply throughout UHDB at All locations and apply to all clinical staff carrying out point of care testing.

3. Definitions Used

POCT	Point of care testing
INR	International normalised ratio
Quality Control	The techniques and procedures that monitor performance characteristics
Internal Quality Control (IQC)	A means of validating results before they are issued
External Quality Assessment (EQA)	A means of validating results and assessing accuracy after they are issued and usually uses samples whose value is unknown to operators.
Operator	A member of clinical staff trained and deemed competent to carry out POCT.
HbA1c	Glycosylated haemoglobin (used for monitoring glucose control in patients with diabetes mellitus).
UKAS	United Kingdom Accreditation Service
MHRA	Medicines and Healthcare products Regulatory Agency
SOP	Standard operating procedure
Connectivity	The use of IT links to interface POCT equipment with laboratory and hospital IT systems. This should normally allow the transfer of patient and/or QC results and remote control of POCT equipment.

4. Key Responsibilities/Duties

Individual members of staff (users)

Individuals must be trained and assessed as competent by the Pathology Point of Care Department of RDH or QHB or an assessed cascade trainer, to perform POCT. They must register with the Pathology Point of Care Team, in order to become operators.

Ward Managers

Ward managers/matrons will agree the training requirements for their staff with the Point of Care Team and ensure that the staff are compliant with this policy.

They will nominate link staff to facilitate training and ensure all prescribed maintenance of pathology POCT equipment is carried out to the locally recommended standard.

Pathology Point of Care Team

The Team will report to the UHDB Trust POCT Group and will work to implement this policy and achieve the following:

- All significant changes in the service are reported to the Trust POCT group, email dhftpoctmanager@nhs.net
- The use of analytical equipment is in accordance with Trust policy.
- That documented quality policies and protocols for the performance of all POCT and associated quality control and quality assurance are established, in accordance with UKAS and MHRA standards.
- Monitoring of EQA and IQC values and procedures for POCT equipment
- An annual POCT audit programme is documented and carried out, and the findings discussed at the Pathology Department Quality and Improvement meeting.
- Provision of advice on POCT tests and services, repeat test frequency and type of sample required.
- Maintain awareness of current trends in POCT and work to identify and implement possible improvements in the service.

UHDB Pathology Point of Care Team

The Pathology Point of Care Team will provide Ward Managers/Matrons with information regarding the use and maintenance of equipment in their area.

Operators who are non-compliant with this policy will be re-trained by the Pathology POCT Department or the Link Trainer for the ward. The Ward Manager will be informed of any non-compliances in their area.

The Pathology POCT Department will inform managers of problems of a general nature and of items of wider interest as required.

UHDB Trust Point of Care Group

The UHDB Trust multidisciplinary Point of Care Group will have representation from the main users and providers of POCT and will:

- Ensure the provision of a quality management system for POCT.
- Accountability: to Divisional management team in first instance and overall accountability to 'Learning Review Group' Formal report twice per year.
- Ensure that responsibilities and authorities are defined and communicated within the Trust.
- Review all reported incidents related to POCT and agree actions to prevent recurrence.
- Review any EQA non-compliances. Suggested modifications arising from any of these reviews will be incorporated into the POCT policy, processes and procedures.
- Recommend that any POCT device or system be withdrawn from service if critical requirements are not met or safety becomes an issue.
- Produce an annual review of POCT for the Trust.
- Consider all proposals to introduce any product, device or system for POCT.
- Set up a Project Group when required, to assist in evaluating and selecting POCT devices and systems.

5. Implementation of the Policy for the Management of Point of Care Testing in Clinical Areas

5.1 Registration

The successful implementation of this policy will be dependent on a robust training and registration scheme for operators and participation in the POCT competency assessment plan.

5.2 Training

Individuals who have been trained to the agreed standard must register with the Point of Care Team in order to become operators. Training should include some aspects of sample collection/ preparation, demonstration of the proper use of equipment in accordance with the manufacturer's specification, the consequences of improper use, internal quality control, basic understanding of significance of results obtained and health and safety. An operator who has been trained and deemed competent shall be registered on the POCT system, and have their training certified and registered with the Trust.

5.3 Control Schemes

All operators will take part in the relevant competency assessment scheme, which will either be the analysis of IQC, EQA or undergoing an examination audit. These are the various methods used to monitor each operator's competence.

5.4 New Pathology POCT Equipment

Details of POCT equipment that members of staff wish to be considered for acquisition and implementation should be outlined on the proposal form found in Appendix 1, this includes equipment for clinical service and research and development purposes

6. Monitoring Compliance and Effectiveness

The Pathology Point of Care Team will periodically review the level of training for POCT equipment with the senior users and will act to address training quality where levels are below the Trust standard.

The Pathology Point of Care Team will inform Ward Managers of non-compliant operators in order to highlight this as a training need. Persistent non-compliance will result in the removal of the operator's POCT registration. Operators will not therefore be able to perform POCT.

The Risk Manager and appropriate Clinical Governance Lead will be informed of areas or individuals where the level of training is below that which is acceptable. Any examples of practices which could have a detrimental effect on a patient result will be reported through the normal risk reporting process.

Progress reports, activity, non-compliance issues, EQA, IQC, equipment performance and suggested improvements for staff will be discussed at the Trust POCT Group. Items that may have a direct impact on the Pathology Department are also discussed at the Pathology Quality and Improvement meeting.

7. References

MHRA	2021.	Management and use of in vitro diagnostic POCT devices.
ISO 22870	2016	Point-of-care testing (POCT) – Requirements for quality and competence
ISO 15189	2012	Medical laboratories –requirements for quality and competence.(ISO 15189: 2012)
Royal College of Pathologists	March 2020	Guidance for use of point of care testing equipment in positive patients and those with a suspected diagnosis of COVID-19
Royal College of Pathologists	March 2004	Guidelines on point of care testing
IBMS document reference PR/07	July 2004	Point of Care Testing (Near Patient Testing), Guidance on the Involvement of the Clinical Laboratory .04
Public Health England	2014	NHS Health Check programme standards: a framework for quality improvement

Appendix 1 Application for acquisition and implementation of POCT equipment

(Electronic template available from and to be returned to dhft.poctmanager@nhs.net)

.Requestor (Clinical unit/department):

Manufacturer(s)/suppliers for consideration:

Analytes for consideration:

Proposed location of device:

Grade/number of staff to use device:

Approximate cost of device:

Department manager NAME _____