

## Point of Care Testing Policy

**CONTROLLED DOCUMENT**

<b>CATEGORY:</b>	Policy
<b>CLASSIFICATION:</b>	Governance
<b>PURPOSE</b>	This aim of this policy is to ensure all Point of Care Testing systems used within the Trust and Partnerships are fit for purpose, properly maintained and are used safely.
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<b>Controlled Document Lead:</b>	Chair for Point of Care Testing Steering Group
<b>Will this Controlled Document impact upon any contracts held by the Trust?</b>	<input type="checkbox"/> Yes <sup>1</sup> <input checked="" type="checkbox"/> No
<b>Approved By:</b>	Chief Executive
<b>On:</b>	September 2018
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<b>Distribution:</b>	
<ul style="list-style-type: none"> <li>• <b>Essential Reading for:</b></li> </ul>	All users of Point of Care Testing Systems and Instrumentation
<ul style="list-style-type: none"> <li>• <b>Information for:</b></li> </ul>	All staff

<sup>1</sup> If this Controlled Document will have an impact on any contracts held by the Trust, once approved, this will need to be sent to the Procurement Team requesting that it be added to the Procurement Policy Portal

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## 1. Policy Statement

- 1.1 University Hospitals Birmingham NHS Foundation Trust (the 'Trust') is committed to providing the best in patient care within a safe environment. Point of Care Testing (PoCT) systems play a key role in patient care.
- 1.2 The aim of this policy is to protect both staff and patients through the correct use of PoCT systems, by ensuring that all such systems used within the Trust are fit for purpose, properly maintained and used safely.
- 1.3 PoCT is defined as any analytical test performed for a patient by a healthcare staff member outside of the conventional laboratory setting where the result has a direct effect on patient treatment. Other terms commonly used to describe PoCT include:
  - near patient testing (NPT).
  - bedside testing
  - extra-laboratory testing
  - disseminated/decentralised laboratory testing.
- 1.4 Only PoCT systems conforming to relevant specifications, current legislation and standards (including MHRA and UKAS) may be used within the Trust.

## 2. Scope

- 2.1 This policy applies to all users of any PoCT system or equipment and applies to the management, procurement and introduction of new in vitro diagnostic Medical Devices used for PoCT and the use of all PoCT on Trust sites and in Community settings and locations where the service is provided by the Trust or its Partnerships. This includes all services under Umbrella, Community based services, services based at Dialysis centres, and services managed at other Trusts whereby there is a formal agreement to provide the service.
- 2.2 This policy covers both existing and new procedures.
- 2.3 This policy applies to all areas and activities of the Trust and to all individuals employed by the Trust including contractors, volunteers, students, locum and agency staff and staff employed on honorary contracts.
- 2.4 Whilst the Trust supports patients in the continued safe and appropriate use of self-testing instruments, this policy does not apply to patients who use self-testing at home (other than those and in Community settings and locations where the service is provided by the Trust or its

Partnerships) or patients who bring self-testing PoCT systems or kits into the Trust. Patients, whilst under the care of the Trust, are encouraged to continue their self-monitoring but any changes to the management of a patient must be based on Trust approved instruments that have undergone a Quality Control test.

### **3. Framework**

- 3.1 This section describes the broad framework for the management of all PoCT systems and instruments throughout the Trust and those used in Community settings and locations where the service is provided by the Trust or its Partnerships. Detailed operational instructions for implementation of this policy are contained within the associated Point of Care Testing Procedure and specific system/instrument procedures.
- 3.2 The PoCT Steering Group shall approve all procedural documents associated with this policy and any amendments to such documents, and is responsible for ensuring that such documents are compliant with this policy.
- 3.3 The PoCT Steering Group shall provide a forum for the overseeing and co-ordination of PoCT system training.
- 3.4 This policy covers all aspects of the management of PoCT systems including patient and staff safety, procurement, specification, training, decontamination, maintenance, contracts, disposal, infection control, tracking and tracing, documentation and certification and quality control and assurance.
- 3.5 The PoCT team will be responsible for:
  - a) identification of the most appropriate piece of equipment;
  - b) full costing of the service to be approved by the requesting Division and Trust;
  - c) Evaluation of any equipment;
  - d) Ordering of equipment and contracts for equipment in conjunction with the Procurement team;
  - e) Delivery, installation and implementation including all necessary training of staff;
  - f) All documentation including procedures, COSHH, risk assessments, training documentation;
  - g) Maintenance and troubleshooting of all equipment;

- h) Monitoring of the use of the equipment in line with procedures (audits); and
- i) Alerting all necessary staff to any identified abuse of PoCT systems/equipment and preventing relevant staff from accessing such systems until they have undergone a refresher training session.

Please note: the PoCT team do not manage the staff who use the equipment on a day to day basis but are responsible for ensuring the equipment is used as expected and as demonstrated within the training. Where abuse is identified, the PoCT will raise a Datix incident and where appropriate or necessary disciplinary action may be taken in line with the Trust procedure.

### 3.6 Definitions

The Medicines and Healthcare Products Regulatory Agency (MHRA) provides the following definitions which apply to this policy.

<b>In Vitro Diagnostic Medical Device</b>	' <i>In vitro</i> ' Diagnostic Medical Device, is any device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used <i>in vitro</i> for the examination of specimens including blood and tissue donations, derived from the human body, solely or principally for the purposes of providing information.
<b>Quality Assurance</b>	Quality assurance is an essential component of PoCT and includes all the measures taken to ensure that investigations are reliable. These will include; <ul style="list-style-type: none"> <li>• correct identification of a patient</li> <li>• appropriate test selection,</li> <li>• obtaining a satisfactory specimen, analysing it and recording the results promptly and correctly,</li> <li>• interpreting the result accurately,</li> <li>• taking appropriate action,</li> <li>• Documenting all procedures for reference.</li> </ul>

### Inspections and Audits by External and Internal Bodies

- 3.7 All PoCT systems shall be audited in accordance with a programme agreed by the PoCT Steering Group. If appropriate this will be carried out by the supplier of the system/instrument. This schedule is approved by the PoCT Steering Group. All reports are reviewed and monitored by the PoCT Steering Group

- 3.8 Audits will also be carried out by PoCT team which will be scheduled, monitored and reviewed by the PoCT Steering Group.
- 3.9 Systems may be subject to inspections by external bodies such as UKAS. Any exceptions will be monitored and reviewed by the PoCT Steering Group.

#### Procurement of PoCT Systems and Instruments

- 3.10 All PoCT systems or equipment used for patient care must be procured through the Procurement Department, and approved by the PoCT Steering Group. This includes all instruments which are purchased through Trust funds, purchased by Endowment funds, leased or donated including Charity donations. No instrument or system may be brought into the Trust for a study or trial without approval being sought from the PoCT Steering Group. This includes the trialling of any PoCT system or equipment. If any equipment is identified within the Trust that has not been approved the PoCT team have the authority to remove this.
- 3.11 When procuring PoCT systems, a pre-purchase questionnaire must be completed, which shall include the following:
  - 3.11.1 CE Marking;
  - 3.11.2 Management System Standards;
  - 3.11.3 Safety Standards;
  - 3.11.4 Service/Spares/Installation;
  - 3.11.5 Ionising Radiation;
  - 3.11.6 Decontamination/Reprocessing; and
  - 3.11.7 Warranty.
- 3.12 Only IT connected systems shall be purchased that allow full traceability of testing and reporting. Any exceptions to this must be risk assessed and approved by the PoCT Steering Group beforehand.

#### Use of PoCT Systems

- 3.13 PoCT Systems must be used in accordance with all of the following measures so that patient and staff safety is ensured at all times by means of appropriate control measures which include:
  - 3.13.1 Traceability (para 3.13)

3.13.2 Risk Assessment (para 3.14)

3.13.3 User Instructions (para 3.15)

3.13.4 Notices affecting a medical device (para 3.16)

3.13.5 Training (para 3.17)

3.13.6 Maintenance and Cleaning (para 3.18)

### 3.14 Traceability

3.14.1 The Trust shall maintain systematic inventories of all PoCT systems used within the organisation.

3.14.2 There will be (where possible) full traceability of who performed what test on which patient.

3.14.3 Any member of staff identified as using the equipment outside of the approved procedures will have access removed and offered re-training. Any member of staff identified as having been sharing their individually issued password access or using someone else's access will have access removed and all staff involved will be dealt with under the associated Disciplinary Policy. Any inappropriate use will be treated as a potential disciplinary offence.

### 3.15 Risk Assessment

3.15.1 All new PoCT systems (i.e. of a type/model that is not in current use in the Trust) shall be assessed to identify any risks associated with their use by the PoCT laboratory staff.

### 3.16 User Instructions

All PoCT systems and instruments will have an operating procedure which will be made available for all staff to view and follow. This will be produced by the PoCT team.

### 3.17 Notices affecting a PoCT system

If the Trust is notified, or becomes aware of, a risk or safety alert associated with a PoCT system that is in use within the Trust, any staff likely to use such a device must be notified immediately of the risk. The PoCT team will assess the risk and take any necessary steps to deal with and reduce the risk. Details of such safety notices must be recorded by the Safety Alert Bulletin Liaison Officer (SLO). For further information please refer to the MHRA DB2010 (02) Reporting Adverse Incidents and Disseminating Medical Advice Alerts which are viewable

on the MHRA website and the associated Procedure for Dissemination and Implementation of Central Alert System.

### 3.18 Training

Please refer to the relevant procedures for training in the safe use of PoCT systems and the training procedures for specific PoCT systems.

3.18.1 No member of staff may use a PoCT system unless:

- a) They have been appropriately trained and assessed as competent in the use of the particular system;
- b) They are doing so under supervision as part of such training or assessment.

3.18.2 The training requirements must be met as set out in accordance with the procedures for training in the safe use of PoCT systems in place at QEHB and HGS Divisions.

3.18.3 Accurate and up to date records of all training must be maintained in accordance with the procedures for training in the safe use of PoCT systems. All data relating to PoCT training must be forwarded to the PoCT team and also kept in each area as a record.

3.18.4 The PoCT Steering Group shall provide a forum for the overseeing and co-ordination of PoCT system training.

### 3.19 Maintenance, Repair and Cleaning

3.19.1 The maintenance requirements for each PoCT system will be assessed and, where required, a scheduled maintenance programme will be assigned. If appropriate, a manufacturer service agreement will be provided. Checks will be carried out by the PoCT team and will be made to ensure maintenance is carried out in accordance with manufacturer and Trust schedules.

3.19.2 If any PoCT system is faulty and requires repair, this must be reported to the PoCT contacts within the relevant departments so that necessary action is carried out.

3.19.3 All re-usable PoCT systems must be cleaned/decontaminated between patients and prior to disposal in accordance with the Decontamination Policy and Procedures.



### 3.20 Advice

Liaison or advice on any of the above must be sought through the PoCT team. This information is available on the Trust Intranet and is provided at training sessions.

## **4. Duties**

### **4.1 Divisional Management Teams**

4.1.1 Divisional Management Teams (DMTs) have the responsibility for implementing and monitoring adherence to this policy and associated procedures throughout their Divisions.

4.1.2 DMTs will ensure that all PoCT systems used within their Division are procured appropriately.

### **4.2 Group Managers, Matrons, Ward Managers and Line Managers**

4.2.1 Group Managers, Matrons, Ward Managers and Line Managers have responsibility for the day to day implementation of this policy and associated procedures. They shall:

- a) Ensure that any PoCT system is appropriate and sufficient for its intended use and it complies with all regulatory requirements and guidance;
- b) Ensure that all PoCT incidents are reported in accordance with the Policy for Reporting and Management of Incidents including Serious Incidents Requiring Investigation and that these are immediately escalated to the appropriate personnel (including the PoCT Team); and
- c) Ensure that satisfactory arrangements for all appropriate tests, checks, validation, commissioning, verification and paperwork are carried out before installation and use of the PoCT system(s). This would normally be carried out via the PoCT team.

4.2.2 Group Managers, Matrons, Ward Managers and Line Managers will also be involved in identifying needs and requirements for all PoCT systems by developing specifications and providing these to the PoCT Steering Group for approval.

### **4.3 Director of IT**

The Director of IT shall ensure that:

- 4.3.1 Requirements for the connection of any PoCT systems to the Trust network have been approved and configured by the IT services Department;
- 4.3.2 In Vitro Diagnostic Medical Devices are approved for connection to the Trust network meet local procedures for interoperability and security management as part of the Trust-wide implementation; and
- 4.3.3 Any requests for equipment are from an approved list.

#### **4.4 Head of Procurement**

The Head of Procurement shall ensure that:

- 4.4.1 No Point-of-Care PoCT is purchased or leased without prior approval from the PoCT Steering Group; and
- 4.4.2 Requests for all PoCT systems are notified to the PoCT Steering Group, where necessary providing the specifications, manufacturer's instructions, decontamination instructions, training needs, location and division of use, funding for maintenance and compatibility.

#### **4.5 Point of Care Testing Steering Group**

- 4.5.1 The role of the PoCT Steering Group at QEHB is to manage, oversee and approve all current PoCT systems and any new or proposed systems that may be needed within the Trust. This group meets on a quarterly basis throughout the year. An annual report is produced by the PoCT team and presented at these meetings.
- 4.5.2 See Appendix B for Terms of Reference for the PoCT Steering Group.

#### **4.6 Clinical Laboratory Service (CLS) Lead for PoCT (Chair for PoCT)**

The Clinical Laboratory Service (CLS) Lead for PoCT will be supported by the PoCT Team and is responsible for:

- 4.6.1 Identifying risks in relation to PoCT and liaising with Directorates, Clinical Directors and Managers to agree appropriate management plans; and
- 4.6.2 Chairing the PoCT Steering Group. This duty may be delegated to a nominated representative.

## 4.7 Point of Care Testing Lead/Manager

4.7.1 The PoCT Lead/Manager will:

- a) Be a member of the CLS who will liaise closely with the CLS lead and the PoCT leads both within the Department and within the Trust; and
- b) Sit on the PoCT Steering Group.

4.7.2 The PoCT Lead/Manager may also be the nominated Laboratory Discipline Specific PoCT Lead.

4.7.3 The PoCT Lead/Manager is responsible for:

- a) Overseeing and managing all the PoCT services within the Trust (and outside the Trust where appropriate);
- b) Ensuring that all PoCT systems are run and managed in line with the requirements set down by the appropriate accreditation bodies;
- c) Ensuring any Safety Alerts are actioned and disseminated to relevant staff throughout the Trust; and
- d) Assisting and co-ordinating any investigations involving any PoCT systems.

## 4.8 Laboratory Discipline Specific Point-of-Care Testing Leads

4.8.1 Laboratory Discipline Specific PoCT Leads may be the PoCT Lead if appropriate. In most cases it is likely that advice and experts will be co-opted in as needed for specific devices.

4.8.2 The Laboratory Discipline Specific PoCT Leads will also be responsible for developing the relevant SOP.

## 4.9 All staff

All Staff are responsible for:

- 4.9.1 Making themselves aware of this policy and any associated procedural requirements;
- 4.9.2 Not sharing individually issued barcodes or passwords for access to the instruments with others;
- 4.9.3 Reporting any issues identified with equipment as soon as identified and escalating the same;

- 4.9.4 Ensuring they have reported to their line manager any deficiency in their training on any of the PoCT systems used by them in the workplace;
- 4.9.5 Ensuring they are competent to operate any piece of equipment as deemed necessary for their department and role;
- 4.9.6 Undertaking Local Inductions which will include the use of PoCT systems as required by a role and/or department; and
- 4.9.7 Not permitting any unauthorised party (e.g. a patient, supplier or contractor) to connect any PoCT system to the Trust network, without prior authorisation from the IT services Department.

## **5. Implementation and Monitoring**

### **5.1 Implementation**

This policy will be available on the Trust's Intranet and external internet site. The policy will also be disseminated through the management structure within the Trust;

### **5.2 Monitoring**

Appendix A provides full details on how the policy will be monitored by the Trust.

## **6. References**

ISO 15189:2012 Medical laboratories – Particular requirements for quality and competence

ISO 22870:2016 Point-of-care testing (PoCT) – Requirements for Quality and competence

MHRA Device Bulletin Management and Use of IVD Point of Care Test Devices DB2010 (02) February 2010

## **7. Associated Policy and Procedural Documentation**

Disciplinary Policy

Patient Identification Policy

Point of Care Testing Procedure

Procedure for Dissemination and Implementation of Central Alert System (including National Patient Safety Alerts)

Procedure in the Safe Use of Medical Devices

Procedure for the decontamination of reusable medical devices prior to patient use, inspection, servicing, repair or return to Departments or Organisations

Specific Procedures for Specific Point-of-Care Testing Systems

## Appendix A

## Monitoring Matrix

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Monitor system down times/engineer visits/supply/loan requests reported to the PoCT co-ordinator and ensure they are dealt with in the set timescales	Point of Care Testing Lead	Point of Care Testing Steering Group	Report provided to PoCT Steering Group	Quarterly
Monitor management of incidents and management of safety alerts	Point of Care Testing Lead	Point of Care Testing Steering Group	Report provided to PoCT Steering Group	Quarterly
		Patient Safety Group	Report provided to Patient Safety Group	Annual
Monitor correct use of PoCT systems throughout the Trust	Point of Care Testing Lead	Point of Care Testing Steering Group	Audits performed and reviewed by PoCT Steering Group	Annual
Audit of PoCT testing	Point of Care Testing Lead	Point of Care Testing Steering Group	Schedule of audits	Annual
Inspections of PoCT systems	External bodies, i.e. UKAS	Point of Care Testing Steering Group	Reports provided to PoCT Steering Group	Currently not under UKAS

Procurement of PoCT systems meet requirements	Point of Care Testing Lead	Point of Care Testing Steering Group	Pre-Purchase questionnaire completed which will include: a) CE Marking; b) Management System Standards; c) Safety Standards; d) Service/Spares/Installation; e) Ionising Radiation; f) Decontamination/Reprocessing; and g) Warranty.	Annual
Traceability: Systematic inventories of all PoCT systems	Point of Care Testing Lead	Point of Care Testing Steering Group	Full traceability of who performed what test on which patient (where possible)	Weekly
Training in safe use of PoCT systems	Point of Care Testing Lead	Point of Care Testing Steering Group	Training records	Annual review
Maintenance, repair and cleaning of PoCT systems	Point of Care Testing Lead	Point of Care Testing Steering Group	Scheduled maintenance programme	Quarterly review
PoCT systems perform in line with supplier specifications	Laboratory discipline Specific Point of Care Testing Leads reporting to Point of Care Testing Lead	Point of Care Testing Steering Group CQMG Medical Devices	Validation and Verification IQC review EQA review	Annual

## **Appendix B**

### Point of Care Testing Terms of Reference

#### **Membership:**

##### **Chair:**

CLS Consultant with interest/expertise in PoCT (this post may be rotational)

##### **Membership:**

PoCT Lead

Pharmacy

Divisional Head of Nursing (or delegate)

Representative(s) nominated by the Executive Medical Director

IT (co-opted in as necessary)

Procurement

CLS Quality Manager

Head of Clinical Governance and Patient Safety, or assigned deputy

**Frequency of meetings:** quarterly

#### **Objectives**

To improve patient care by applying Quality Assurance and Total Quality Management principles in utilisation of the Point of Care Testing systems which includes the continual education of users around Point of Care Testing Procedures.

#### **Duties**

This Group shall:

1. Ensure that the responsibilities and authorities necessary for quality management of Point of Care Testing are defined and communicated within the UHB organisation.
2. Assist the Point of Care Testing Lead in evaluating and selecting Point of Care Testing equipment and systems, using defined health care and patient outcomes consistent with the UHB PoCT Policy and Procedures, the MHRA Device Bulletin Management and Use of IVD Point of Care Test Devices DB2010(02) February 2010, the International Standard ISO 15189 and the associated Point of Care Testing Standard, ISO 22870.
3. Evaluate end-user Point of Care Testing proposals for the purchase and installation of Point of Care Testing equipment.
4. Designate staff responsible for Point of Care Testing in the various patient care areas.



5. Ensure that appropriate systems are in place for:
  - monitoring the training, certification and re-certification of Point of Care Testing system operators;
  - maintenance of machines and consumable supplies and reagents;
  - appropriate quality assurance and record keeping; and
  - security from unauthorised or inappropriate use of Point of Care Testing devices
6. Provide input for the identification of Point of Care Testing improvement opportunities including equipment upgrades and replacements, connectivity options, documentation requirements.
7. Advise changes to Point of Care Testing policies, processes and procedures when appropriate.
8. Participate in the review of External Quality Assessments.