# Point of Care Testing Policy

**CATEGORY:** Policy  
**CLASSIFICATION:** Governance  

**PURPOSE**  
This aim of this policy is to ensure all Point-of-care-Testing systems used within the Trust are fit for purpose, properly maintained and are used safely.

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**Distribution:**  
- **Essential Reading for:** All users of Point of Care Testing Systems and Instrumentation  
- **Information for:**
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1. **Policy Statement**

1.1 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 ensure that all PoCT systems used within the Trust are fit for purpose, properly maintained, and used safely to protect both, staff and patients in the correct use of the systems.

1.3 Only Point-of-Care systems conforming to relevant specifications, current legislation and standards (including MHRA and UKAS) may be used within the Trust.

1.4 This policy is approved and supported by the POCT Steering Group. See Annex 1 of this policy for Terms of Reference for the PoCT Steering Group.

2. **Scope**

2.1 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.

2.2 This policy applies to all users of any Point of Care Testing system and applies to the management, the procurement and introduction of new *in vitro* diagnostic Medical Devices used for PoCT and the management of existing PoCT on Trust sites. This covers both existing and new procedures.

2.3 This policy covers all patients whilst being treated by University Hospitals Birmingham NHS Foundation Trust or by patients being treated at another Trust where there is a service level agreement with UHB for Point of Care Testing Services. 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 or patients who bring self-testing PoCT systems or kits into the Trust.

3. **Framework**

3.1 This section describes the broad framework for the management of all PoCT systems and instruments throughout the Trust. 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 Point of Care Testing Steering Group, chaired by the Consultant Chemical Pathologist, 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 Point of Care Testing Co-ordinator is responsible for overseeing and managing all of the PoCT services and the PoCT team who are based within Clinical Laboratory Services. The PoCT team support practice, maintain equipment and are a resource for training.

3.4 Definitions

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

3.4.1 Point of Care Testing (PoCT)

PoCT is defined as any analytical test performed for a patient by a healthcare staff member outside of the conventional laboratory setting where a 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.

3.4.2 In Vitro Diagnostic Medical Device

‘In vitro’ 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 in vitro for the examination of specimens including blood and tissue donations, derived from the human body, solely or principally for the purposes of providing information.

3.4.3 Quality Assurance

Quality assurance is an essential component of PoCT and includes all the measures taken to ensure that investigations are reliable. These will include;

- correct identification of a patient
- appropriate test selection,
- obtaining a satisfactory specimen,
- analysing it and recording the results promptly and correctly,
- interpreting the result accurately,
• taking appropriate action,
• Documenting all procedures for reference.

3.4.4 Accreditation
Accreditation is an external audit of the ability to provide a service of high quality. By defining a standard of practice and having this independently confirmed, approved Laboratory Medicine departments are able to attain a hallmark of performance and offer reassurance to users of their service. In the UK, Clinical Pathology Accreditation (UK) Ltd (CPA) and UKAS provide a means by which this can be achieved.

3.2 Procurement of Point of Care Testing Systems and Instruments

3.2.1 It is the policy of the Trust that all PoCT systems purchased by, or on behalf of, the Trust must be procured through the Procurement Department, which must be involved in the procurement of POCT systems from the start of the process when a requirement is identified and approved by the POCT Steering Group. This includes all instruments that are purchased by Trust funds, purchased by Endowment funds, leased or donated, including Charity donations. No instrument or system can be brought into the Trust for a study or trial without approval being sought from the POCT Steering Group.

3.2.2 When procuring PoCT systems, a pre-purchase questionnaire must be completed, which shall include the following:

• CE Marking
• Management System Standards
• Safety Standards
• Service/Spares/Installation
• Ionising Radiation
• Decontamination/Reprocessing
• Warranty

3.3 Traceability
The PoCT Co-ordinator shall maintain systematic inventories of all PoCT systems used within the organisation.

3.4 Risk Assessment
All new medical devices (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.

3.5 Training

Please refer to the Procedure for Training in the Safe Use of PoCT Systems and the Training Procedures for specific PoCT systems.

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

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

3.5.2 All training requirements must be met in accordance with the Procedure for Training in the Safe Use of PoCT Systems.

3.5.3 Accurate and up to date records of all training must be maintained in accordance with the Procedure for Training in the Safe Use of PoCT Systems. All data relating to PoCT training should be forwarded to the PoCT co-ordinator.

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

3.6 User Instructions

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

3.7 Use of Point of Care Testing Systems

PoCT Systems must be used so that patient and staff safety is ensured at all times by means of appropriate control measures which include:

- Traceability (3.5)
- Risk Assessment (3.6)
- User Instructions (3.8)
- Notices affecting a medical device (3.10)
- Training (3.7)
- Maintenance and Cleaning (3.11)

3.8 Notices affecting a PoCT system
3.8.1 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 by the Datix Safety Alert System which is managed by the Risk management Department.

3.8.2 All staff involved in the PoCT system must be made aware of the alert by their line manager. The line manager and the PoCT co-ordinator must also put in place appropriate controls to deal with 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 Trust Procedure for Dissemination and Implementation of Central Alert System (including National Patient Safety Alerts)

3.9 Maintenance, Repair and Cleaning

3.9.1 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 made to ensure maintenance is carried out in accordance with manufacturer and Trust schedules.

3.9.2 If any PoCT system is faulty and requires repair, this should be reported to the PoCT team so that necessary action is carried out.

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

3.10 Advice

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

3.11 Inspections and Audits by External and Internal Bodies

3.11.1 Where appropriate, audit of PoCT testing will be carried out by the supplier of the system/instrument. An audit schedule will be approved by the POCT Steering Group and all reports are reviewed and monitored by the Steering Group.
3.11.2 Audits will also be carried out by the POCT team which will be scheduled, monitored and reviewed by the Point of Care Testing Steering Group.

3.11.3 All PoCT systems must be inspected in accordance with external regulatory bodies such as MHRA, UKAS. These will be monitored and reviewed by the POCT Steering Group.

4 Duties

4.2 Ward and Departmental Managers

Ward and Departmental Managers have responsibility for the day to day implementation of this policy and associated procedures.

4.2.1 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 Point of Care Testing Co-ordinator)

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 co-ordinator.

4.2.2 They 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 Medical Equipment approved for connection to the Trust network meet local procedures for interoperability and security management as part of the Trust-wide implementation.

4.3.3 Users do not permit any unauthorised party (e.g. a patient, supplier or contractor) to connect any PoCT system to the Trust network, without prior authorisation form the IT services Department.

4.4 Head of Procurement

The head of Procurement shall ensure that:

4.4.1 No PoCT system is purchased without prior approval from the PoCT Steering Group.

4.4.2 Requirements 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 PoCT Steering Group

The role of the PoCT Steering Group is to manage and to 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.

See Annex 1 for Terms of Reference for the PoCT Steering Group.

4.6 Clinical Laboratory Service (CLS) Lead on PoCT

4.6.1 The CLS lead (who will be of Consultant grade) is the Trust expert lead on PoCT management and will chair the PoCT Steering group.

4.6.2 He/she is responsible for identifying risks in relation to PoCT and liaising with Directorates, Clinical Directors and Managers to agree appropriate management plans.

4.6.3 He/she is supported in this role by the PoCT Co-ordinator and the PoCT Steering Group.

4.7 POCT Co-ordinator
4.7.1 The POCT Co-ordinator will 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.

4.7.2 The POCT Co-ordinator will sit on the PoCT Steering Group within the Trust.

4.7.3 The PoCT Co-ordinator will sit on the Medical Devices Group.

4.7.4 He/she will be responsible for overseeing and managing all the PoCT services within the Trust (and outside the Trust where appropriate) and will ensure that all PoCT systems are run and managed in line with the requirements set down by the appropriate accreditation bodies.

4.7.5 He/she will ensure any Safety Alerts are actioned and disseminated to relevant staff throughout the Trust.

4.7.6 He/she will assist and co-ordinate any investigations involving any PoCT systems.

4.7.7 Any new PoCT systems that require IT connectivity shall have a change control form created and sent to the IT department in order to identify an IT project number and a project lead. This will be the responsibility of the PoCT Co-ordinator.

### 4.8 PoCT Team within Clinical Laboratory Services

4.8.1 The Management of the Clinical Laboratory Services is responsible for ensuring that the appropriate number and grades of staff are appointed to these posts.

4.8.2 This may be the PoCT Co-ordinator, if appropriate.

4.8.3 It is the responsibility of PoCT Leads to ensure that all PoCT systems for which they are responsible are performed in line with the information supplied to the PoCT Steering Group and relevant Standard Operating Procedure. They will also be responsible for developing the relevant SOP.

4.8.4 This person will also act as a point of contact for the PoCT Steering Group and will be responsible for notifying the Steering Group via the PoCT Co-ordinator of any changes made to the scheme and to submit an annual report to the group. A template agreed by the Steering Group will be issued to relevant parties.
4.9 All staff

4.9.1 It is the responsibility of all employees to make themselves aware of this policy and any associated procedural requirements.

4.9.2 They must also ensure that they have reported to their line manager any deficiency in their training on any of the PoCT systems used by them in the workplace.

4.9.3 All staff must ensure that they are competent to operate any piece of equipment as deemed necessary for their department and role.

4.9.4 The use of PoCT systems as required by a role and/or department must also form part of the Local Induction process for all new starters/transfers/secondments/temporary staff to UHB.
### 5. Implementation and Monitoring

#### Monitoring Matrix

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<thead>
<tr>
<th>MONITORING OF IMPLEMENTATION</th>
<th>MONITORING LEAD</th>
<th>REPORTED TO PERSON/GROUP</th>
<th>MONITORING PROCESS</th>
<th>MONITORING FREQUENCY</th>
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<tbody>
<tr>
<td>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</td>
<td>Point of Care Testing Co-ordinator</td>
<td>Point of Care Testing Steering Group</td>
<td>Report provided to PoCT Steering Group</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Monitor management of incidents and management of safety alerts</td>
<td>Point of Care Testing Co-ordinator</td>
<td>Point of Care Testing Steering Group</td>
<td>Report provided to PoCT Steering Group</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Ensure compliance with the PoCT Policy and Procedures.</td>
<td>Point of Care Testing Co-ordinator</td>
<td>Point of Care Testing Steering Group</td>
<td>Audits performed and reviewed by POCT Steering Group</td>
<td>Quarterly</td>
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6. **References**

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

Clinical Pathology Accreditation (UK) Ltd - Additional Standards for Point-of-Care Testing (POCT) facilities v1 April 2010

ISO 15189:2007 Medical laboratories – Particular requirements for quality and competence

ISO 22870:2006 Point-of-care testing (PoCT) – Requirements for Quality and competence.

7. **Associated Policy and Procedural Documentation**

Point-of-Care Testing Procedure

Procedure in the Safe Use of Medical Devices

Specific Procedures for Specific PoCT Systems
Annex 1

Point of Care Testing Steering Group

Terms of Reference

**Membership:**

**Chair:**
Consultant Chemical Pathologist

**Membership:**
PoCT co-ordinator
Pharmacy
Nurse Managers and nursing representation
Medical representation
IT
Procurement
CLS Quality Manager
Clinical Governance

**Frequency of meetings:** quarterly

**Objectives**

- To advance knowledge about POCT practices within the Trust
- To improve patient care by applying Quality Assurance and Total Quality Management principles in utilisation of the POCT programs
- To promote communication and cooperation between professional groups directly and indirectly involved in the POCT systems and programs
- To assist in implementing the protocol for new POCT requests and procedures

**Goals**

This committee shall:

1. Ensure that the responsibilities and authorities necessary for quality management of POCT are defined and communicated within the UHB organisation.
2. Assist the POCT Coordinator in evaluating and selecting POCT equipment and systems, using defined health care and patient outcomes consistent with the UHB PoCT Policy and Procedure, 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 POCT Standard, ISO 22870.
3. Evaluate end-user POCT proposals for the purchase and installation of POCT equipment.
4. Designate staff responsible for POCT in the various patient care areas.
5. Ensure that appropriate systems are in place for:
   - monitoring the training, certification and re-certification of POCT system operators
   - maintenance of machines and consumable supplies and reagents
   - appropriate quality assurance and record keeping
   - security from unauthorised or inappropriate use of POCT devices.
6. Provide input for the identification of POCT improvement opportunities including equipment upgrades and replacements, connectivity options, documentation requirements.
7. Advise changes to POCT policies, processes and procedures when appropriate.
8. Participate in the review of External Quality Assessments