Point of Care Testing (POCT) Policy

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<tr>
<td>CLASSIFICATION:</td>
<td>Governance</td>
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<tr>
<td>PURPOSE</td>
<td>The 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.</td>
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<td>Controlled Document Number:</td>
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<td>Chief Medical Officer</td>
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<td>Point of Care Testing Manager</td>
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<td>Chief Executive</td>
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<td>25th May 2022</td>
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<td>Review Date:</td>
<td>25th May 2025</td>
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<tr>
<td>Distribution:</td>
<td>All users of Point of Care Testing Systems and Instrumentation</td>
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<td>Essential Reading for:</td>
<td>All staff</td>
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<td>Point of Care Testing (POCT) Policy</td>
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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 Medicines and Health Regulatory Agency (MHRA) and the United Kingdom Accreditation Service (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.

2.2 This policy covers both existing and new procedural documents.

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 bank/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 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. This service is not provided in patients’ homes.

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. 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).

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 misuse is identified, the POCT will raise a DATIX incident and where appropriate or necessary disciplinary action may be taken in line with the appropriate Trust procedure.

3.6 Definitions

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

| **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. |
| **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. |

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 Management meetings.

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. Further information can be found in the Procurement Policy.

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 compatible systems shall be purchased that allow full traceability of testing and reporting. Such systems will be approved by IT before purchase (section 4.3.1).

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 3.14)

3.13.2 Risk Assessment (para 3.15)

3.13.3 User Instructions (para 3.16)

3.13.4 Notices affecting a medical device (para 3.17)

3.13.5 Training (para 3.18)

3.13.6 Maintenance and Cleaning (para 3.19)

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, using which device, and on which patient. The use of a non-genuine PID number by a staff member performing a test (i.e. 123456789 or 999999999) means the test results will not appear in the patient’s medical record. This is considered as using the equipment outside of approved procedures.

3.14.3 Any use of the equipment by staff outside of the approved procedures will be assessed by the relevant manager with HR advice to decide if the matter can be managed informally or whether there are grounds for further investigation, restrictions and/or formal action in accordance with the UHB Disciplinary procedure.

3.15 Risk Assessment

All new POCT systems (i.e. of a type/model that is not in current use in the Trust) shall be assessed prior to purchase and implementation, to identify any risks associated with their use. This risk assessment will be carried out 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.
POCT team will assess the risk and take any necessary steps to deal with and reduce the risk. The team will notify the users and suppliers as appropriate. If required by a safety notice, the product will be removed immediately by the POCT team and replaced with an appropriate alternative.

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; or

b) They are doing so under supervision as part of such training or assessment.

c) Only trained staff are added to the POCT management database and can use the POCT systems. Staff must re-train at an interval specific to the instrument to allow their access to continue.

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. This is due to the different instruments in use. Training may be provided through Moodle, by the training specialist from instrument suppliers, trained POCT staff or cascade trainers.

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. Without evidence of up to date training, access to the specific devices cannot be given to the staff member.

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 as soon as possible 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 Procedures.

3.20 Validation and Verification

All POCT agreed and approved instruments must be validated or verified prior to it being put into routine use. This will be led by the POCT team and this along with the installation and training will be costed and sent through to the Clinical area leads and finance for approval as part of the agreement. No equipment can be used until the verification or validation has been completed and technically and clinically accepted as fit for purpose.

Ongoing internal quality checks (IQC) and External Quality Assurance (EQA) for most systems will be implemented as part of quality assurance and governance monitoring. Details for each system are included in the individual SOPs and training documentation.

Any issues identified with these assurance quality checks will result in further investigation led by the POCT team. There is potential for the system to be quarantined or removed from service if a concern is identified. This may lead to the clinical area incurring an additional cost if this is found to be operator induced and the system needing to be replaced or repaired.

Some POCT devices require an IQC while others require additional calibration through the use of Third Party IQC materials that users are required to use whilst performing checks on instruments as per the training guide.

Instructions are provided during training to test the accuracy. Instrument lockout if IQC procedures are not followed to prevent inappropriate use of the device.
The POCT Team is responsible for registering appropriate instruments with different EQA schemes. These schemes are used to compare accuracy and bias within the laboratories in the Trust and outside the Trust. The results of EQA schemes are acted upon by the POCT Team.

3.21 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. For some devices the training is provided directly from the POCT team. However for some devices, specific training can be found through the Trusts online learning system - Easylearning.

4. Duties

4.1 Chief Medical Officer

The Chief Medical Officer approves the policy.

4.2 Divisional Management Teams

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

4.2.2 DMTs will ensure that all POCT systems used within their Division are procured appropriately.

4.3 General Managers, Matrons, Ward Managers and Line Managers

4.3.1 General 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, and that staff are appropriately trained;

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.

4.3.2 General 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.

4.4 **Director of IT Operations**

The Director of IT Operations shall ensure that:

4.4.1 IT will approve POCT systems for connection to the IT network and will configure them appropriately in collaboration with the supplier and specific to the individual instrument.

4.4.2 In Vitro Diagnostic Medical Devices which are approved for connection to the Trust network meet local procedures for interoperability and security management as part of the Trust-wide implementation; and

4.4.3 Any requests for equipment are from an approved list.

4.5 **Director of Procurement**

The Head of Procurement shall ensure that:

4.5.1 No POCT is purchased or leased without prior approval from the POCT Steering Group; and

4.5.2 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.

4.6 **Chair of the Point of Care Testing Steering Group**

4.6.1 The role of the POCT Steering Group at UHB 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.

4.6.2 See Appendix B for Terms of Reference for the POCT Steering Group.
4.7 Clinical Laboratory Service (CLS) Lead for POCT (Chair of POCTSG and POCT Management Group)

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

4.7.1 Identifying risks in relation to POCT and liaising with Directorates, Clinical Directors and Managers to agree appropriate management plans; and

4.7.2 Chairing the POCT Steering Group. This duty may be delegated to a nominated representative.

4.8 Point of Care Testing Lead/Manager

4.8.1 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.

4.8.2 The POCT Lead/Manager may also be the nominated Laboratory Discipline Specific POCT Lead.

4.8.3 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.

4.9 Laboratory Discipline Specific Point-of-Care Testing Leads

4.9.1 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.
4.9.2 The Laboratory Discipline Specific POCT Leads will also be responsible for developing the relevant SOP for the applicable system.

4.10 All staff involved in Point of Care Testing

All Staff are responsible for:

4.10.1 Making themselves aware of this policy and any associated procedural requirements;

4.10.2 Not sharing with others individually issued barcodes or passwords for access to the instruments;

4.10.3 Reporting any issues identified with equipment as soon as identified and escalating the same;

4.10.4 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;

4.10.5 Ensuring they are competent to operate any piece of equipment as deemed necessary for their department and role;

4.10.6 Undertaking Local Inductions which will include the use of POCT systems as required by a role and/or department; and

4.10.7 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.

4.10.8 Ensuring they remain up to date with their training. When the user’s training certification for a specific device expires, the access it automatically revoked.

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
## 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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<tr>
<td>Monitor system down times/engineer visits/supply/loan requests reported to the POCT Lead and ensure they are dealt with in the set timescales</td>
<td>Point of Care Testing Lead</td>
<td>Point of Care Testing Steering Group</td>
<td>Reported routinely to Laboratory Ops Group with exceptions being reported to POCT Steering Group</td>
<td>By exception</td>
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<tr>
<td>Monitor management of incidents and management of safety alerts</td>
<td>Point of Care Testing Lead</td>
<td>Point of Care Testing Steering Group</td>
<td>Report provided to POCT Steering Group</td>
<td>Quarterly</td>
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| Monitor correct use of POCT systems throughout the Trust | Point of Care Testing Lead | Pathology Quality Management Meeting/Point of Care Testing Steering Group | A schedule of audits for the year is agreed and they are reported when finalised:  
- Supplier audits  
- Quality Audits – including Operational Use and Traceability | Throughout the schedule and as the Audit become finalised. |
| POCT systems perform in line with supplier specifications | Laboratory discipline Specific Point of Care Testing Leads reporting to Point of Care Testing Lead | Pathology Quality Management Meeting | IQC/EQA review | Quarterly |
# Appendix B

## Point of Care Testing Terms of Reference

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<tr>
<th><strong>Point of Care Testing (POCT) Management Group</strong></th>
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<tr>
<td><strong>Terms of Reference</strong></td>
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<td>Approved by: POCT Steering Group</td>
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<td>Review date: March 2025</td>
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### Purpose

- To ensure that Point of Care Testing (POCT) devices management in the trust complies with relevant regulations, legislation and guidance.
- To oversee the procurement and purchase of new POCT devices in the Trust.
- Provide a forum to discuss and approve operational procedure regarding POCT devices.
- Provide a forum to monitor and analyse incidents, complaints and claims where POCT devices have been involved.
- Provide expert advice on POCT devices to Investigation teams.

### Membership

**POCT Operational meeting:**
- Chairperson (POCT Manager or a nominated representative)
- All POCT Staff
- POCT training/ scheme leads as required.
- Secretary (If available)

**POCT Steering group meeting:**
- Chairperson (Clinical Service Lead or a nominated representative)
- Head Biomedical Scientist (Technical Lead)
- POCT Manager or nominated representative
- Quality Manager
- Pharmacy (as required)
- Nurse Managers and nursing representation: Deputy ADN, matrons
- Clinical Educators
- Medical representation
- IT representative (optional)
- Procurement (as required)
- Risk
- Finance Accountant
- Secretary (If available)

### Secretary

Currently no designated secretary for POCT group
Quorum
The POCT group will be quorate when a minimum of four core members are present including the Chairperson or a nominated representative.

Types and Frequency of meetings
The POCT Operational meeting is chaired by POCT Lead or other nominated person and accountable to Laboratory Medicine Group, meets regularly on monthly basis.
POCT business review meeting with manufacturers chaired by Laboratory manager or a nominated person on quarterly basis.
POCT steering group meeting chaired by Clinical Service Lead or a nominated representative on quarterly basis.

Notice of meetings
Date and Time will be notified electronically to all members of the Group giving sufficient notice.

Minutes of meetings
Minutes will be produced for the transaction of the group. Minutes should be concise and should include all decisions made by the group with a brief summary of all discussions. An appropriate action sheet should be circulated within a week prior to the POCT operational/group meeting with the agreed actions at the previous meeting. Regular reports should be made available to the Laboratory management meetings.

External Considerations
- POCT Blood Gases, HbA1c, Pregnancy testing, Urine testing, INR, D-Dimer, Total Hemoglobin: Managed Service Contract or Contracted Suppliers.
- POCT Blood glucose and Ketones: Managed Service Contract or Contracted Suppliers.

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 Team 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:
   a. Monitoring the training, certification and re-certification of POCT system operators.
   b. Maintenance of machines and consumable supplies and reagents.
c. Appropriate quality assurance and record keeping.
d. Security from unauthorised or inappropriate use of POCT devices.
e. Provide input for the identification of POCT improvement opportunities including equipment upgrades and replacements, connectivity options, documentation requirements
f. Advice changes to POCT policies, processes and procedures when appropriate.
g. Participate in the review of External Quality Assessments

Accountability
The POCT group is directly accountable to Laboratory management group.

Responsibilities
(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)

• To ensure the responsibilities, authority and interrelationship of all personnel involved in POCT are specified and communicated within organisation.
• To ensure that the POCT device management in the Trust complies with relevant regulations, legislation, standards and guidelines.
• To ensure that any proposals to introduce any product, device or system of POCT are evaluated for their clinical and cost efficiency. Selection of POCT devices and systems should consider their practical usefulness and comparability of results with previously used devices and external quality assessment schemes.
• To ensure that no POCT device is purchased in the hospital unless it has passed through the POCT committee.
• To establish a system for the continuing audit and assessment of POCT
• To ensure that users are appropriately trained, supervised and certified competent in the use of POCT devices and that they are fully aware of all contra-indications and limitations;
• To ensure that the results of the POCT quality assurance programmes (internal quality control (IQC) and external quality assessment (EQA)) are employed effectively and reviewed by the group and advice on improvement is provided and implemented.
• To set up a quality hierarchy to ensure that there is a direct link between the person performing the analysis via the POCT committee, Laboratory management committee and up to Trust board level.
• To include representatives from primary care and the community where necessary
• Risk management – compliance to trust policy
• Any other business deemed appropriate by the Committee.

Reporting
The POCT group provides regular reports to monthly Clinical Chemistry and Immunology Operational meetings, Laboratory Management meetings and quarterly Clinical compliance meetings.