Trust Policy

Point of Care Testing Audit Policy

Issue Date	Review Date	Version
November 2017	Extended to November 2021	2.1

Purpose

The Point of Care Testing service requires close monitoring to ensure that the standard of care delivered to our patients is optimised. Regular audit of Point of Care Testing systems is essential to maintain the high standard of patient care.

Who should read this document?

All Trust staff who perform, or are likely to perform Point of Care Testing as part of their normal duties.

Key Messages

The Chief Executive of the Trust is responsible for the safe use and management of medical devices within the Trust. This responsibility has been delegated to the POCT co-ordinator guided by a multidisciplinary committee acting within the framework of a Trust POCT policy and responsible to the Trust via clinical governance.

The Trust POCT audit policy aims to safeguard a high standard of care by ensuring that procedures put in place by the POCT team are complied with.

Core accountabilities	
Owner	The Point of Care Testing Co-ordinator
Review	The Point of Care Testing Governance Group
Ratification	Medical Director
Dissemination	The Point of Care Testing Governance Group
Compliance	The Point of Care Testing Governance Group

Links to other policies and procedures

Medical Devices Training Policy

The Management and Use of Medical Devices.

The Point of Care Testing Policy

The Point of Care Testing Training Policy

Service Level Agreement for Point of Care Services

Version History

1	June 2012	New format used. Addition of the terms POCT Governance Group and the Effective Care Group.
2	November 2017	Reviewed and Updated
2.2	January 2021	Extended to November 2021

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Contents

Section	Description	Page
1	Introduction	4
2	Purpose, including legal or regulatory background	4
3	Definitions	5
4	Duties	5
5	Main Body of Policy	6
6	Overall Responsibility for the Document	9
7	Consultation and Ratification	9
8	Dissemination and Implementation	9
9	Monitoring Compliance and Effectiveness	10
10	References and Associated Documentation	10
Appendix 1	Dissemination Plan and Review Checklist	11
Appendix 2	Equality Impact Assessment	13

1 Introduction

Point of care testing (POCT) is defined as any analytical test performed by a healthcare professional or non-medical individual outside the conventional laboratory setting. POCT is currently performed in many clinical areas using non-instrumental systems (e.g. urinalysis strips), small analysers (e.g. blood glucose meters) or desktop analysers (e.g. machines for blood gas measurement). Advances in technology are eliminating the need for sample preparation procedures and allowing the use of whole blood for analysis and it is likely that the demand for and scope of POCT will increase.

The Point of Care Testing service requires close monitoring to ensure that the standard of care delivered to our patients is optimised. Regular audit of Point of Care Testing systems is essential to maintain the high standard of patient care.

2 Purpose

The Chief Executive of the Trust is responsible for the safe use and management of medical devices within the Trust. This responsibility has been delegated to the POCT co-ordinator guided by a multidisciplinary committee acting within the framework of a Trust POCT policy and responsible to the Trust via clinical governance.

The Trust POCT audit policy aims to safeguard a high standard of care. Part of ensuring that is gaining accreditation from UKAS.

The POCT department is guided by ISO 22870:2016 (E) and ISO 15189:2012, the following clauses will be satisfied by audit under this policy.

ISO 15189.2012: 5.3.2.2 and 5.2.3 Meet by audit of wards storage of reagents and presence of sharps disposal containers

ISO 15189.2012: 5.2.6 Meet by audit of wards for clean areas of work

ISO 15189.2012: 5.2.3 Meet by audit of wards for cleanliness of devices and temperature of storage and working areas

ISO 15189:2012 5.3.2.5 Meet by ward audit for presence of appropriate guidance documents

Other audits may be performed these may include but are not limited to:

- all users of POCT in the Trust have documented training and competency records
- all results generated at the point of care are recorded in the appropriate places, in a format acceptable to the trust
- all performance and recording of quality control is audited including external quality assurance
- all staff using POCT have access to the current version of trust POCT documents
- all POCT staff have a personal professional portfolio to record training in
- all POCT equipment is employed for its intended use
- all local policies are followed such as infection control policy
- all results are acted on appropriately
- all POCT equipment is maintained to a standard set by the POCT team
- all maintenance records are up to date and complete

 all equipment and consumables are stored in an appropriate way

 all equipment and consumables can be accessed at all times by users of the service

 all equipment, where the functionality exists, are password protected to ensure access by trained users only

 the need for POCT at each site is reviewed on as regular basis

 all clinical incidents are reviewed by the POCT section lead as they occur and a regular review of clinical incidents will be conducted and reported back to the POCT Governance Group. Incidents may be escalated and reported to the Quality governance and improvement group.

 incidents of non-conformance will be raised by the POCT team in the Quality Management System QPulse, whereby corrective actions and preventive actions will be actioned

 only POCT equipment which has been through the trust approval process as detailed in the trust Point of Care Testing Policy is in use

3 Definitions

Point of Care Testing (POCT)- this term refers to any analytical test performed outside of the traditional laboratory by a trained operator in a clinical area near to the patient.
Point of Care Testing Team- The team consists of management and clinical leads, biomedical scientists, associate practitioners and assistant technical officers who are responsible for the provision and support of the point of care testing service. The team is based in the Derriford Combined Laboratory (DCL).
Point of Care Testing Governance Group- this group is responsible for the governance of the point of care testing service within the trust as detailed in section 4 of the POCT Policy.

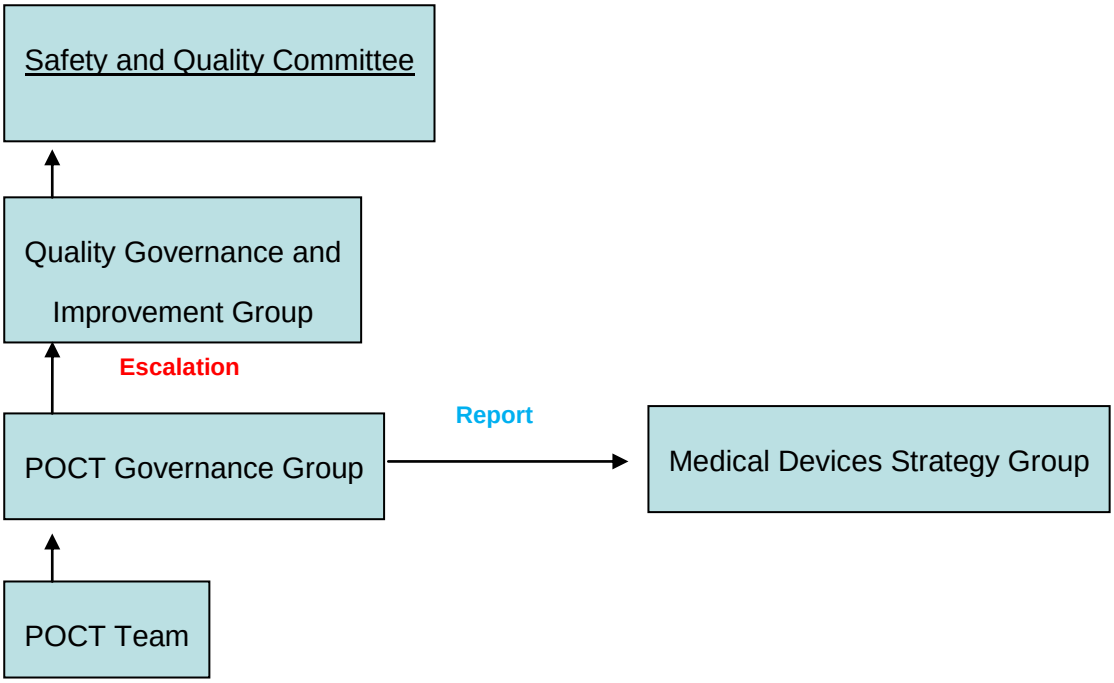
Non-Conforming Work Reports (NCWRs)- Reports generated from the quality management system, Q Pulse.

4 Duties

The POCT Team are responsible for conducting regular audits of point of care testing processes as detailed in this policy.

Audit findings, non-conforming work reports (NCWRs) and Datix clinical incidents are escalated through the trust clinical governance structure as detailed below. Such escalations shall proceed until such a point as they can be appropriately actioned. It may still be appropriate to highlight an incident or finding even if the immediate problem was resolved without the need for further escalation.

The clinical governance structure within the trust is constantly evolving and is currently under review. The POCT governance group escalates any serious POCT governance issues to the Quality, Governance and Improvement Group as detailed above.



The clinical governance structure within the trust is constantly evolving and is currently under review. The POCT governance group escalates any serious POCT governance issues to the Quality, Governance and Improvement Group as detailed above.

5 Main Body of Policy

5.1 Audit

The POCT team consists of state registered Biomedical Scientists, Associate Practitioners and Assistant Technical Officers. These staff members will conduct audit on a regular basis in areas of the acute trust, primary care trust and private ventures.

Audit may also be provided by the manufacturer of any given point of care test used within the areas covered by the POCT team. This audit will be delivered by an individual employed by the manufacturer or distributor of the point of care test.

Where necessary the POCT team will conduct spot checks without prior warning, for any part of the POCT service.

5.2 Audit types

It is trust policy that all point of care activities are subject to audit in order to maintain the high quality and safety of the service provided to our patients.
Audits may take different forms depending on the process being audited.
The frequency of audit may also differ depending on the process being audited.

The POCT team may choose to perform either unannounced audits or scheduled audits which are horizontal or vertical in nature in order to assess compliance with trust policies and procedures relating to point of care testing.

5.3 Q Pulse Audit Calendar

The POCT team will use a quality management system (QMS) to schedule and record audit activity.

5.3.1 Audit Strategy

Audit Calendar structure:
Each POCT area within Derriford shall be audited annually for:

Cleanliness
Storage temperature
Availability of consumables
Presence of quick guides (if applicable)
Device/system specific checks

Device specific checks:

Blood Gas:
Labelling of devices indicating the need for cleanliness

Pregnancy:
Log book

Other items by special requirement

The POCT team perform the following monthly audits:
Point of Care Testing Training Audit
Point of Care Testing Cleanliness Audit
POCT Monthly Task Checklist

5.3.2 Quarterly Audits within Department
Point of Care Testing Health and Safety Audit
Point of Care Testing Slips Trips and Falls Audit

5.3.4 Yearly Auditing
A report is produced on a yearly basis as part of the Annual Management Review. This report is presented to the Combined Laboratory management team at the annual management review meeting.

5.3.5 Further Auditing
The Point of Care Testing team will also carry out any number of audits which are not regularly scheduled. These shall be performed as required by corrective actions or by standing order of the POCT governance committee. These will include the following:

5.3.6 Cross sectional audits of point of care testing sites. This will entail randomly selecting a number of POCT sites for a full horizontal service audit.

5.3.7 Equipment audits such as blood gas analysers, urinalysis meters, glucose meter workstations, ESR racks, urine pregnancy testing, hemocue meters.

5.3.8 Software audits such as Gem Web and UniPOC to remove users who have shown lengthy periods of inactivity or are abusing badge codes/patient ID.

5.3.9 Audit of patient notes to ensure POCT results are being recorded in accordance with trust policy.

5.3.10 Audit of patient result logbooks typically pregnancy testing.

5.3.11 Audit of External Quality Assurance compliance.
There shall be a visit to each external (non PHNT) site each year and their services shall be audited using the strategy agreed with that non-PHNT sites. The audit results shall be communicated in writing to the manager of each site. It shall be the responsibility of each external site to act upon the results of these audits.

5.3.12 POCT vertical audits documenting the robustness of the service from obtaining a sample to the recording of, and actioning of, a POCT result.

The audit reports or will be stored on QPulse on the POCT audit calendar as attachments or comments as appropriate.

5.4 POCT Questionnaire

User satisfaction is assessed by the Pathology User Survey.

From time to time it is necessary to gather additional information regarding POCT testing through use of a widely distributed questionnaire. This action allows the team to collate information from the users of the service with particular emphasis on:
-service awareness
-current activity at point of care sites
-needs of the users and future requirements
- user satisfaction
-feedback about the service
Responses will be stored in the POCT office in the Combined Laboratory. Questionnaires will be stored on QPulse.

This process shall be performed when required by the POCT governance group. Inclusion in the Pathology User Survey is required as a minimum level of participation and further questionnaires and surveys can be initiated independently if required.

5.5 Monitoring

The Fridges and Freezers are monitored in the POCT section by Chemistry Special investigations department using Sensilla software.

5.6 Q Pulse Corrective Action/Preventive Action (CA/PA)

It is anticipated that regular auditing will identify areas of the point of care testing service that are non-compliant with trust policies and procedures. If a site is found to be non-compliant with any trust policy or procedure the POCT team will raise a non-conformance in QPulse (lab quality system). A letter is drafted and sent to the Point of Care site Manager explaining the failure and the measures that are required to address the failure i.e. re-training of staff, improve compliance with EQA, ways to improve EQA performance, etc. A member of the POCT team will write a short description of the non-compliance in QPulse and record a corrective action (steps taken to resolve the issue) and a preventive action (steps taken to ensure the issue does not recur) along with a follow-up action. Once the steps have been put in place to prevent the issue recurring the record is closed and permanently held on QPulse for audit purposes.
Depending on the severity or frequency of these occurrences the non-conformance may be reported to the Quality Governance and Improvement Group for action.

5.7 DATIX Reporting

If a serious operational issue is discovered it may warrant reporting through the Datix clinical incident reporting system.

Examples of incidents which may be reported include misuse of equipment, loss or damage to equipment, failure of equipment which directly affects the ability to provide a service, non-compliance with EQA, poor EQA performance, inappropriate reporting of patient results, patient results not acted on appropriately or in a timely manner, although this list is not exhaustive.

The non-conformance is sent via the trust email system to individuals responsible for clinical activities at the point of care site. These individuals then respond to the non-conformance, which is returned to the POCT section leader for review.
Responses will include details of any investigation performed as a result of the non-conformance and any measures taken to prevent the recurrence of the problem.
Datix reports involving the POCT service can be reviewed by requesting a report from the clinical management team or the patient safety manager.

6 Overall Responsibility for the Document

The development of the document is the responsibility of the section lead for POCT.

This document is subject to ratification by the POCT Governance Group and the trust medical director

7 Consultation and Ratification

The Point of Care Testing Audit Policy is subject to the approval of the following Groups-
POCT Governance Group
The Medical Director

All issues regarding Point of Care equipment are subject to consultation with the following Groups-

Quality Governance and Improvement Group

Medical Devices Strategy Group

8 Dissemination and Implementation

This policy will be published electronically in the Trust Document Network Share Folder (G:\TrustDocuments).

The issue of a new version of this document will be communicated to staff through the IG StaffNet Page and the quarterly POCT email as appropriate.

Implementation of the policy will be driven by the section lead for POCT in partnership with Service Line Managers through to Ward Managers.

It is the responsibility of all trust staff who engage in POCT activities to be aware of the content of this document, which will be enforced during training sessions provided by the POCT team.

9 Monitoring Compliance and Effectiveness

Compliance with the policy will be monitored by the POCT section lead. Audits are scheduled on the Q Pulse audit calendar which prompts members of the POCT team when the audits are due.

Audits will be performed by members of the Point of Care Testing team or individuals appointed by them to conduct them on the team's behalf. The findings of the audit programme will be held electronically within the Combined Laboratory quality database and the actions generated from these audits will be carried out by point of care staff. Preventive and corrective actions will be recorded on the quality database also.

Audits will include compliance with quality programmes, maintenance and upkeep of equipment, recording of patient results, reporting of problems through Datix or to the POCT team and involvement of the POCT team in developing new services. The failure to comply with the policy may result in reports being presented to the Effective Care Group or the POCT Governance Group for action. The effectiveness of the policy and point of care issues are discussed at the Point of Care Testing Team meetings and the Point of Care Testing Governance Group meetings which are held on a regular basis.

10 References and Associated Documentation

TRW.POC.POL.354.5 Point of Care Testing Policy

ISO 15189:2012 and ISO 22870:2016 (E)

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan	
Document Title	Point of Care Testing Policy
Date Finalised	October 2017
Previous Documents	
Action to retrieve old copies	Electronic copy removed from Trust Documents. No paper copies exist.

Dissemination Plan			
Recipient(s)	**When**	**How**	**Responsibility**
All Trust staff	Nov 2017	IG StaffNet Page	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	Y
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Y
	Does the style & format comply?	
Rationale	Are reasons for development of the document stated?	Y
Development Process	Is the method described in brief?	Y
	Are people involved in the development identified?	Y
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Y
	Is there evidence of consultation with stakeholders and users?	Y
Content	Is the objective of the document clear?	Y
	Is the target population clear and unambiguous?	Y
	Are the intended outcomes described?	Y
	Are the statements clear and unambiguous?	Y
Evidence Base	Is the type of evidence to support the document identified explicitly?	Y
	Are key references cited and in full?	Y
	Are supporting documents referenced?	Y
Approval	Does the document identify which committee/group will review it?	Y
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	Y
	Does the document identify which Executive Director will ratify it?	Y
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Y
	Does the plan include the necessary training/support to ensure compliance?	Y
Document Control	Does the document identify where it will be held?	Y
	Have archiving arrangements for superseded documents been addressed?	Y
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y
	Is there a plan to review or audit compliance with the document?	Y
Review Date	Is the review date identified?	Y

	Is the frequency of review identified? If so is it acceptable?	Y
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Y

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	15th April 2014 (reviewed 2017 – still valid and relevant)
Title	Point of Care Testing Policy
What are the aims, objectives & projected outcomes?	Point of care testing (POCT) is defined as any analytical test performed by a healthcare professional or non-medical individual outside the conventional laboratory setting. POCT is currently performed in many clinical areas using non-instrumental systems (e.g. urinalysis strips), small analysers (e.g. blood glucose meters) or desktop analysers (e.g. machines for blood gas measurement). Advances in technology are eliminating the need for sample preparation procedures and allowing the use of whole blood for analysis and it is likely that the demand for and scope of POCT will increase. The Trust POCT policy aims to safeguard a high standard of care by ensuring that • all POCT in the Trust is regulated • regulated POCT adheres to applicable statutory directives • all staff using POCT are adequately trained and that training formally recorded However, whilst an individual may take formal charge of a POCT programme, individual users trained and approved for POCT have legal responsibility for the results they produce. Incorrect use of POCT leading to wrong results could have medico-legal implications and, under the Consumer Protection Act (1987), the use of instruments for purposes other than those for which they were intended can lead to liability transfer from manufacturer to user.

Scope of the assessment
This assessment covers the impact the policy will have on patients and staff. Unable to show data

Collecting data	
Race	There is no evidence to suggest there is a disproportionate impact on race. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Religion	There is no evidence to suggest there is a disproportionate impact on religion and belief. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.

Disability	There is no evidence to suggest there is a disproportionate impact on religion and belief. Consideration for reasonable adjustment requests from staff for training will be made. Data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Sex	There is no evidence to suggest there is a disproportionate impact on sex. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Gender Identity	There is currently no data collected for this area, however, data collection will be monitored through incidents and complaints on Datix.
Sexual Orientation	There is no evidence to suggest there is a disproportionate impact on sexual orientation. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Age	There is no evidence to suggest there is a disproportionate impact on sex. However, data collection will be monitored through incidents and complaints on Datix. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.
Socio-Economic	There is currently no data collected for this area, however, data collection will be monitored through incidents and complaints on Datix.
Human Rights	There is no evidence to suggest that there is a disproportionate impact on human rights regarding this policy
What are the overall trends/patterns in the above data?	There is no data or trends identified at this time
Specific issues and data gaps that may need to be addressed through consultation or further research	There is no data currently collected for gender identity or socio-economic

Involving and consulting stakeholders	
Internal involvement and consultation	
External involvement and consultation	No external consultation was undertaken on this policy
Impact Assessment	
Overall assessment and analysis of the evidence	Consideration for reasonable adjustment requests from staff for training will be made. Engineers from sub-contractor organisations that are required to repair equipment will adhere to Trust policy regarding equality & diversity.

Action Plan

Action	Owner	Risks	Completion Date	Progress update
No Action planned				