

POINT OF CARE TESTING (POCT) POLICY

		POLICY	
Reference	CPG-TW-POCT		
Approving Body	V2.0, Pathology Clinical Governance Group V2.1, Pathology Clinical Governance Group		
Date Approved	V2.0, June 9 th 2022 V2.1, July 11 th 2024		
For publication to external SFH website	Positive confirmation received from the approving body that the content does not risk the safety of patients or the public:		
	YES	NO	N/A
	X		
Issue Date	23 rd July 2024		
Version	2.1		
Summary of Changes from Previous Version	<ul style="list-style-type: none">V2.1, Update of ISO 15189 Standard reference to 2022 version. Removal of obsolete ISO 22870:2006 standardV2.0, Reviewed and updated, no changes made. Accepted as current format		
Supersedes	V 2.0, issued June 2022 to Review Date June 2025		
Document Category	<ul style="list-style-type: none">Clinical		
Consultation Undertaken	<ul style="list-style-type: none">V2.1, Pathology Clinical Governance Group, as nomenclature of ISO standard changes to previous documentV2.0, Pathology Clinical Governance Group, as no changes to previous document		
Date of Completion of Equality Impact Assessment	December 30 th 2021		
Date of Environmental Impact Assessment (if applicable)	N/A		
Legal and/or Accreditation Implications	<ul style="list-style-type: none">UKAS ISO 15189:2022 Medical laboratories – Requirements for quality and competence		
Target Audience	This policy applies wherever Point of Care Testing Devices are used throughout the Trust by clinical, nursing, midwifery or AHP staff.		
Review Date	June 2025		
Sponsor (Position)	Dr S Haroon - Pathology Governance Chair		
Author (Position & Name)	Dr M Griffiths - Consultant Clinical Scientist		
Lead Division/ Directorate	CSTO		
Lead Specialty/ Service/ Department	Pathology		
Position of Person able to provide Further Guidance/Information	Consultant Clinical Scientist		
Associated Documents/ Information		Date Associated Documents/ Information was reviewed	
Not applicable		Not applicable	
Template control		June 2020	

CONTENTS

Item	Title	Page
1.0	INTRODUCTION	
2.0	POLICY STATEMENT	
3.0	DEFINITIONS/ ABBREVIATIONS	
4.0	ROLES AND RESPONSIBILITIES	
5.0	APPROVAL	
6.0	DOCUMENT REQUIREMENTS (POLICY NARRATIVE)	
7.0	MONITORING COMPLIANCE AND EFFECTIVENESS	
8.0	TRAINING AND IMPLEMENTATION	
9.0	IMPACT ASSESSMENTS	
10.0	EVIDENCE BASE (Relevant Legislation/ National Guidance) and RELATED SFHFT DOCUMENTS	
11.0	KEYWORDS	
12.0	APPENDICES	
Appendix 1	Point of Care Testing Proforma	
Appendix 2	Equality Impact Assessment Form	

1.0 INTRODUCTION

The use of Point of Care Testing (POCT) has a number of benefits for clinicians and patients. These include rapid turnaround times, ease of use, and the ability to perform serial patient monitoring. Thus POCT can be an important addition to laboratory-based analysis. Whilst the use of POCT devices can aid successful outcomes for patients, there is also a significant potential for causing patient harm. A number of Clinical Governance issues must be addressed to ensure quality and patient safety. Staff that perform these procedures need to be appropriately trained in the use and limitations of the devices. The analytical performance of devices must be adequate and rigorously quality controlled using both internal and external Quality Assurance systems. Furthermore, the devices and their use must conform to national and international standards for Health & Safety and good practice.

Point of Care Testing services are now considered an extension of the clinical laboratory testing services and as such should be developed and delivered in line with UKAS accreditation standards for the clinical laboratory ISO 15189. The development of this document and its implementation supports accreditation of the POCT services in The Trust.

The Trust is committed to minimising risks to patients by the promotion and use of robust systems designed to achieve this. In addition, the Clinical Negligence Scheme for Trusts require hospitals to reduce risks associated with the use of all medical devices including POCT devices. This is achieved by promoting correct and appropriate use of equipment and by implementing competency based approaches to training. In order to minimise risk it is imperative that the use of all POCT system in the Trust is supported by a comprehensive policy. Furthermore it is essential that suitably qualified Trust personnel oversee all aspects of POCT evaluation, procurement and use.

Any Department or individual in the Trust seeking to purchase POCT equipment must present a case of need to the POCT Team in Pathology to ensure that the necessary processes are in place to allow the safe use of POCT equipment before placing an order. Final approval will be sought by the Medical Device Equipment Group (MDEG). Advice on preparing a case of need can be obtained from the pathology POCT clinical lead.

The Trust is committed to ensuring the safe and appropriate use of all POCT devices in accordance with national standards and guidelines. This is being achieved by a cross professional group, led by pathology and including all major stakeholders, to advise and recommend policies and procedures for the procurement and management of POCT devices.

2.0 POLICY STATEMENT

The Trust will have systems in place to ensure that point of care testing (POCT) is undertaken in a safe manner, in line with other Trust policies, ensuring equipment is safe and available for the delivery of the Trust's services to the benefit of patients. This will be achieved by having robust procedures covering the following areas in the Policy:

- Selection and procurement
- Standardisation of operation and practice
- Quality Assurance
- Monitoring and Audit

- Management of record keeping and results.
- Clinical Governance

3.0 DEFINITIONS/ ABBREVIATIONS

Trust: Sherwood Forest Hospitals NHS Foundation Trust

Staff: All employers of the Trust including those managed by a third party on behalf of the Trust

Point of Care Testing: A clinical test involving the analysis of a substance or tissue in a patient sample by a healthcare professional outside the clinical laboratory.

Clinical Laboratory: An area set aside for analysing patient specimens that is managed by a registered scientist and which is led by a Clinician who is accountable for the service via an appropriate Trust clinical governance mechanism.

Point of Care Testing (POCT) devices include for example simple urine dipstick tests, drug testing strips, pregnancy tests, blood glucose and ketone meters, coagulation meters, haemoglobin meters and more complex instruments such as blood gas analysers, HbA1c analysers and small bench top analysers. For the purposes of this document the definition of POCT does not include indwelling monitoring devices such as in-line sensors used in Intensive Care Units.

4.0 ROLES AND RESPONSIBILITIES

Clinical users of POCT devices will:

- Be individually accountable for their practice ensuring that they acquire, and maintain skills in the use of POCT devices. This will require the maintenance of competence.
- Follow standard operating procedures for the use of POCT equipment.
- Perform IQC/EQA and housekeeping tasks on the POCT equipment where appropriate.

Managers of areas using POCT will:

- Ensure that all users of POCT are fully trained and authorised to use the devices
- Ensure that suitable policies and procedures for the use of devices are in place prior to their implementation.
- In conjunction with Pathology, withdraw access passwords from operators who do not comply with the jointly agreed guidelines governing the use of a particular piece of equipment.
- If necessary, withdraw a piece of equipment from use altogether where there is an indication that patient safety is compromised.
- Ensure that all requests for new POCT systems are made in accordance with the selection and procurement criteria ([Appendix 1](#)).

The POCT team in Pathology will:

- Provide a Lead professional for the Trust responsible for leading and co-ordinating POCT activities and liaison with other Healthcare professionals

- Be responsible for the overall quality of the POCT systems
- Co-ordinate the implementation and management of POCT devices.
- Provide evaluation of the analytical performance of POCT devices
- Provide advice concerning the limitations of POCT devices and the interpretation of results
- Provide staff education and training where appropriate and maintain records of this in accordance with Trust policy
- Provide technical support (including routine maintenance and repair), and advice regarding the use of POCT devices
- Perform internal and external Quality Control checks on POCT devices where required

5.0 APPROVAL

Pathology Clinical Governance Group v2.0, 9th June 2022, v2.1 11th July 2024

6.0 DOCUMENT REQUIREMENTS (POLICY NARRATIVE)

6.1 Equipment Procurement

All proposals to acquire POCT equipment require review from Pathology POCT team and a submission must be made using [Appendix 1](#) with the exception of straightforward replacements. Once reviewed the proposal will be submitted to the Medical Device Equipment Group (MDEG) for approval by the POCT Clinical Lead. All POCT equipment will be managed in line with the Trust Medical Device Management Policy.

6.2 Standardisation of operation and practice

Only appropriate personnel who have achieved satisfactory levels of competence will be allowed to use POCT equipment. All users must follow the associated Standard Operating Procedures, protocols and guidelines when using the devices and should understand the contra-indications and/or limitations associated with any POCT device measurement Training in the use of POCT devices will be delivered by competent healthcare professionals and where appropriate by commercial organisations.

6.3 Quality Assurance

Appropriate routine maintenance must be performed on the POCT devices this will usually be performed by the POCT team. Quality Control (IQC) & External Quality Assurance (EQA) performance is mandatory to ensure result validity. These must also be recorded and available for inspection. Wherever possible computer data systems will be used to automatically record and control IQC testing. Non-conformance with EQA testing by POCT clinical areas will result in a datix being raised against the area. Repeated non-conformance may result in equipment being withdrawn from the area.

Incorrect EQA results from an area may result in the temporary suspension of either the equipment or the operator pending review/retraining.

6.4 Monitoring and Audit

Where devices are registered with pathology, integrity of result records, training records and user logs will be inspected regularly via a programme of audit.

Where compliance is lacking, this will be brought to the attention of the manager of the clinical area concerned. Repeated non-compliance will be reported by the POCT team and, if necessary recorded as a clinical incident thus engaging the Trust's clinical governance arrangements.

6.5 Management and record keeping of results

Appropriate records must be kept to identify the results produced by POCT devices and of the operator performing the test. Patients requiring a point of care test must be identified by a minimum data set. This is normally the NHS or hospital number, full name and date of birth. Patients' results must be securely filed in their Health Record and if possible as an electronic patient record (EPR). Wherever possible all new POCT equipment will be interfaced to the EPR as a minimum requirement.

6.6 Clinical Governance

All incidents involving POCT devices should be reported to the POCT team in pathology and reported via the Trust's electronic Incident Reporting mechanism, with Clinical Engineering being alerted if a medical device is involved to ensure appropriate process is followed preserving evidence to facilitate the identification of root causes, from which collective learning can be disseminated. Clinical Engineering will take responsibility for reporting adverse incidents to the Medicines and Healthcare Regulatory Authority (MHRA). Devices involved in incidents should be quarantined pending investigation.

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
Equipment procurement	MDEG	Completed and approved POCT proforma	Annually	MDEG minutes
Training	POCT team	Monthly report to Training and Development and POCT Quality report	Monthly	POCT team-Quality report
Quality Assurance	POCT team	Monthly Quality report	Monthly	POCT team-Quality report
Audit	POCT team	Monthly Quality report	Monthly	POCT team-Quality report
Clinical Governance	POCT team	Monthly Quality report/Datix	Monthly	POCT team-Quality report Pathology Governance meeting minutes-Datix reports

8.0 TRAINING AND IMPLEMENTATION

There is no specific training for the application of this policy as relevant training will be specific to the individual POCT equipment/ device. However, relevant staff need to be aware of this policy and be able to access it on the trust intranet.

For queries or advice please contact the author of the policy.

The policy will be published for staff to access alongside other trust wide clinical procedural documents within the trust's 'Policies, Procedures and Guidelines' intranet site.

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at [Appendix 2.0](#)
- This document is not subject to an Environmental Impact Assessment

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base:

- Management and use of IVD Point of Care Testing devices MHRA MDA DB2002 (03) March 2002
- POINT OF CARE TESTING National Strategic Guidance for at Point of Need Testing May 2023
- Medical laboratories –Requirements for quality and competence BN EN ISO 15189:2022

Related SFHFT Documents:

- [Medical Equipment User Training Policy](#)
- [Medical Device Management Policy](#)

11.0 KEYWORDS

- Device; devices; UKAS accreditation standards; equipment; competency; POCT evaluation procurement use; POCT Team; Pro forma;

12.0 APPENDICES

[Appendix 1](#) – Point of Care Testing Request Pro forma

[Appendix 2](#) – Equality Impact Assessment Form

Appendix 1.0 – Point of Care Testing Request Proforma

In order for a decision to be made on the purchase of any Point of Care Testing (POCT) Equipment it is vital that the relevant information is provided for consideration by the Point of Care Team in Pathology to ensure that a safe and robust service is proposed, and all the requirements for a POCT service is met in line with UKAS ISO 15189:2022. For the purpose of this document, POCT is defined as any analytical test performed for a patient by a healthcare professional outside the conventional laboratory setting.

Please complete the following information, to ensure that an informed decision can be made as to whether the purchase and implementation of POCT is safe and meets Governance requirements. To receive administrative support for completing this pro forma, please contact Dr M Griffiths on ext 3611

Details of POCT Request

Name of POCT equipment e.g. blood glucose meter
Briefly, what will the test be for/what will it determine?
Name and contact details of Lead person for requesting/implementation of the equipment

Clinical Need

Which group(s) of patients need testing and what test(s) need to be performed?
How is the service currently provided and does it adequately meet the clinical need?
If clinical need has not been met, what has been done to try to rectify the problem?
Is access to a laboratory service difficult for patients with conditions requiring frequent monitoring? Has this been discussed with the laboratory?
Will POCT enable more rapid/effective diagnosis or treatment?
Can you provide evidence that POCT will provide a measurable clinical and economic benefit?
Will POCT provide a cost-effective alternative to laboratory testing?

Equipment

What is the expected workload?
Who is going to use the equipment?
What level of analytical accuracy and imprecision is required for the service?
Where will the equipment and consumables be sited?
Do you have adequate space in which to carry out POCT?
Are appropriate services available e.g. power, water, refrigeration?
Has the equipment been evaluated by an external professional organisation e.g. MHRA?
Are the results comparable to those of the local hospital pathology laboratory?
How are operator ID, patient ID and outcome recorded?
How are results stored within the POCT system and for how long?
If there are computer records how are they stored and backed up?
What are the limitations of the equipment?
Will the POCT service work satisfactorily with existing data handling systems and IT infrastructure?
Has consideration been given to Health and Safety issues such as the safe disposal of clinical waste and sharps?

Responsibility & Accountability

Who will take responsibility for interpreting and acting upon results?
Does the management structure include designated deputies capable of assuming the necessary responsibilities?
Who will be responsible for training users?
Who will be responsible for maintaining the equipment?

Quality Assurance

How will the service quality be maintained?
Is there a procedure in place to ensure that QC is performed at an appropriate frequency and that the results are recorded appropriately and in accordance with manufacturers' recommendations?
Is the manufacturer of the POCT device or the hospital laboratory able to provide appropriate QC material?
Is the POCT manufacturer or hospital laboratory able to provide support to ensure that any results outside of acceptance limits are investigated?
Is there a procedure in place for acceptance testing for both single use devices and instrumentation?

Costs (Including VAT)

Initial purchase cost
Accessories e.g. centrifuges and incubators
Consumables

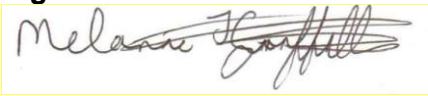
<i>Health and safety improvements or site alterations e.g. operator and storage space</i>
Interfacing with information management systems
Routine and preventative maintenance e.g. external service contracts with manufacturers
Internal quality control material and participation in external quality assessment scheme
Record keeping e.g. data-handling system
Waste disposal
Cleaning
Staff training
Operator time
Laboratory support
Any other costs

Upon completion of this information, the POCT Team will assess whether the proposal is acceptable and appropriate and make any necessary recommendations. The final version will be sent to MDEG for approval.

Following approval of the request, this information will form the basis of the full business case which will be completed to submitted for approval within the specialties own Division.

APPENDIX 2.0 – EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: Point of Care Testing (POCT) Policy			
New or existing service/policy/procedure: New			
Date of Assessment: 30/12/2021			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?	b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?	c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality
The area of policy or its implementation being assessed:			
Race and Ethnicity	No	n/a	None
Gender	No	n/a	None
Age	No	n/a	None
Religion	No	n/a	None
Disability	No	n/a	None
Sexuality	No	n/a	None
Pregnancy and Maternity	No	n/a	None
Gender Reassignment	No	n/a	None
Marriage and Civil Partnership	No	n/a	None

Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)	No	n/a	None
What consultation with protected characteristic groups including patient groups have you carried out? <ul style="list-style-type: none"> Not applicable as does not affect any protected characteristic group 			
What data or information did you use in support of this EqIA? <ul style="list-style-type: none"> The Policy has been developed using accumulated professional knowledge and UKAS ISO standards 			
As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments? <ul style="list-style-type: none"> No 			
Level of impact Low Level of Impact			
Name of Responsible Person undertaking this assessment: Melanie Griffiths			
Signature: 			
Date: 30/12/2021			