York and Scarborough Teaching Hospitals NHS Foundation Trust

Reference: LABMED11

Point of Care Testing Policy

Version: 6

Summary	Policy for the use of Point of Care Testing devices in York & Scarborough	
Keywords	Point of Care Testing, POCT	
Target audience	All staff	
Date issued	19th December 2024	
Approved & Ratified by	YSTHFT POCT Committee Executive Committee	**Date of meeting:** **16/07/2024** **18/12/2024**
Next review date	December 2026	
Author	Deepak Chandrajay	
Executive Director	Chief Nurse	

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Version Control

Change Record

Date	Author	Version	Page	Reason for Change
05/12/08	Gary Barker	1		New Policy
17/12/12	Gary Barker	2		Updated format to conform to new NHSLA standards and reviewed.
18/10/14	Anne Penrice	3		Updated format to new Trust template and reviewed.
22/11/16	Joanna Andrew	4		Updated format to new Trust template and reviewed.
05/05/22	Rachel Lampard	5		Updated to new Trust template, change of reference of CPA to UKAS, change reference of Directorate Manager to Care Group Manager, general review & update.
19/08/24	Deepak Chandrajay	6		Updated format to new Trust template and reviewed.

Reviewers/contributors

Name	Position	Version Reviewed & Date
Gary Barker	Head Biomedical Scientist Biochemistry	1 (05/12/08)
Anne Penrice	POCT Coordinator	2 (17/12/12)
Anne Penrice	POCT Coordinator	3 (18/10/14)
Joanna Andrew	Head Biomedical Scientist Biochemistry	4 (22/11/16)
Rachel Lampard	Senior Biomedical Scientist in POCT	5 (05/05/22)
Deepak Chandrajay	Consultant Chemical Pathologist & Clinical Lead for POCT	6 (19/08/24)
Mark Hajjawi	Head Biomedical Scientist in POCT	6 (19/08/24)
Rachel Lampard	Senior Biomedical Scientist in POCT	6 (19/08/24)
Maria de Ferrars	Clinical Scientist	6 (19/08/24)

Contents

1. Introduction

Biological specimens are typically sent to clinical laboratories for analysis by laboratory trained staff to aid in the diagnosis and management of disease. There are occasions when it would be advantageous to patient care to perform a range of diagnostic testing outside the laboratory by clinical staff who have undertaken appropriate training and competency assessment, at the point of care. Point of Care Testing (POCT) is defined as to “any analytical test performed for a patient by a healthcare professional outside the conventional laboratory setting”.

This POCT Policy highlights guidance set forward by MHRA (Medical and Healthcare products Regulatory Agency) and ISO Standard 15189:2022 for the introduction and ongoing use of POCT. Strict adherence to this framework not only ensures the highest quality of service for patients and healthcare professionals but also avoids poor practice, which is associated with the generation of erroneous results and significant risks to patient safety.

2. Scope

This policy is aimed at:

- All employees of York and Scarborough Teaching Hospitals NHS Foundation Trust
- who perform analytical tests for any patient outside the conventional laboratory setting (regardless of where the POCT device is used)
- Trust employees or departments considering introduction of near-patient testing methods.
- Scarborough Hull York Pathology network services (SHYPS) staff based at York, Scarborough, or Bridlington sites.

Point of care tests that are currently in use within the Trust include (but are not limited to):

- Tests carried out to determine infectious disease status.
- Measurement of blood glucose or ketones, blood gases, HbA1c levels, INR, haemoglobin levels
- Urine pregnancy testing and urinalysis.

3. Duties and responsibilities

Responsibilities of the POCT Committee

- Ensuring compliance with relevant regulatory bodies.
- Review of all business cases associated with POCT.
- Standardising all POCT equipment within the Trust.
- Review and updating of the POCT policy.
- Oversee adherence to the POCT policy.
- Review of internal audit findings and subsequent CAPA.
- Ensure identified, necessary change is implemented in a timely manner.

- Ensure service changes/developments are undertaken within a governance framework.
- Review staff suggestions
- EQA Performance
- Risk Management

Responsibilities of the POCT Department

- Liaise with users and manufacturers in the introduction of new POCT devices and methodologies.
- Define the training process for all operators, including those who deliver cascade training.
- Manage registration and compliance to EQA schemes.
- Review IQC performance on a regular basis.
- Investigate poor performance and manage corrective and preventative actions to ensure high quality POCT service.
- Investigate and manage adverse incidents related to POCT & coordinate any response.
- The POCT team have the authority to revoke the user's access to POCT devices where there are clear breaches of this policy. This will only be done as a last resort and following consultation with the Chairperson of the POCT Committee and/or the Medical Director.
- The POCT team have the authority to remove a POCT device from a ward or unit because of breaches of the policy or because of persistent poor performance. This will only be done as a last resort and following consultation with the Chairperson of the POCT Committee and/or the Medical Director.
- Provide interpretive advice on results and equipment.
- Provide advice when POCT results do not fit the clinical picture, when there is difficulty in interpretation or when the results are bought into question.
- Manage, control, and maintain service documentation.
- Ensure POCT equipment and consumables are stored appropriately in clinical areas, according to manufacturer's guidance.

Responsibilities of Operators

- Operators of POCT equipment must undertake initial face to face training, prior to being given access for patient testing. All trained operators will be issued a unique operator ID for their sole use and sharing of this is strictly prohibited. Re-assessment of competency is performed every 2 years to ensure operators remain competent to use POCT equipment.
- All POCT operators have a professional responsibility to ensure that their training, competency assessment and recertifications are up to date.
- Use equipment in a way which is safe to themselves, colleagues, and patients.
- Ensure that all aspects of the Standard Operating Procedure (SOP) are adhered to, including: - carrying out any routine maintenance & cleaning; using the correct

sample; the correct procedure; any IQC is within acceptable limits; results are documented as appropriate.

- Patient results should be documented clearly in their notes and be distinguishable from a laboratory result.
- Participation in EQA programmes is a mandatory requirement, and samples should be analysed within the time frame stated on the documentation provided at distribution.
- All POCT operators are responsible for interpretation of results within the clinical setting and documenting in the case notes.
- All Link trainers in the Trust to lead on training and competency assessment of staff using POCT devices within the clinical area.
- Staff should report faulty or malfunctioning POCT equipment immediately to the POCT team to allow for troubleshooting

Responsibilities of link trainers

- Ensure their own training and competency assessment is up to date.
- Lead on training and competency assessment of clinical staff using POCT equipment.
- Ensure training is cascaded to a high standard and incorporates all elements of pre-analytics, analysis and post analytical aspect of the device, as trained to do so by the POCT team.
- Ensure all relevant paperwork is completed and returned to the POCT team in a timely manner.

Responsibilities of Pharmacy

- Ordering, handling, and distributing POCT reagents / consumables.
- Liaise with service users and POCT department regarding the ordering and distribution of specific POCT reagents / consumables.

4. POCT Testing Policy Details

The Scarborough Hull York Pathology Service (SHYPS) is the pathology service network for the York and Scarborough Teaching Hospital NHS Foundation Trust (YSTHFT) and Hull Teaching Hospitals NHS Trust (HUTH). SHYPS is a clinically led service that incorporates a range of laboratory disciplines across 4 acute hospital sites and covers numerous community, specialist, and primary care facilities across a wide geography. SHYPS is managed in line with BS EN ISO 15189:2022 standards: Medical laboratories- requirements for quality and competence through United Kingdom Accreditation Service (UKAS) and other regulatory and accreditation standards applicable for pathology laboratories.

4.1 POCT service provision

The Point of Care Testing department serving YSTHFT is part of the SHYPS Blood Sciences Department. The Blood Sciences laboratories comprise of Haematology

including Blood Transfusion, Clinical Biochemistry, and Point of Care Testing (POCT) services at York, Scarborough and Bridlington Hospitals, and Community services.

Central Services which support the central pathology functions common to all laboratory services: Quality Management, Training, IT, Innovation, Finance, and business management for each clinical department.

Point of Care Testing is led by two POCT committees, one at York and Scarborough Teaching Hospital NHS Foundation Trust (YSTHFT), and one at Hull University Teaching Hospitals NHS Trust (HUTH). Issues for escalation from the POCT Committee are discussed at the SHYPS Governance Committee and the SHYPS Blood Sciences Operational Delivery Group. The POCT Clinical Lead is accountable to the SHYPS Pathology Group Director.

The following criteria for POCT services at YSTHFT should be met to ensure patient safety and uphold the aforementioned quality standards:

- POCT service should be compatible and complementary to the service provided by the core Pathology laboratory.
- Each instrument must be sponsored by a clinician who is responsible for ensuring compliance with the policy and procedure. Where relevant, a business case for the equipment should be made with the support of the appropriate Divisional General Manager and Clinical Director.
- Equipment to be acquired for the purpose of Point of Care Testing must be approved by the Point of Care Testing Committee to ensure appropriateness and satisfactory standards of performance and safety.
- POCT devices should be suitable for the intended purpose and meet the clinical needs and requirements of the service.
- All members of staff using POCT equipment are responsible for following the relevant policies and procedures (including this one) related to the testing of patients.
- Pathological tests and procedures on patients may only be performed by staff in clinical areas which have been trained to an appropriate level of competence and are competency assessed as such. Thus, before using the equipment in service, staff must be trained in accordance with the arrangements made by the Pathology Point of Care Testing Manager (or named deputy). Once competence has been assured, individuals thus trained will be placed on a list of "authorised users".
- The Pathology Point of Care Testing Manager (or named deputy) will be responsible for ensuring all appropriate consumables are available for testing to be carried out in an appropriate manner.
- Pathology staff must initiate appropriate quality control procedures, supply quality control materials, monitor performance and give advice when necessary. Full written instructions on internal quality procedures including limits of acceptability must be available to staff who perform tests and procedures. Patient results may only be accepted when quality control information is within designated limits.

- Any faults, repairs and corrective action taken for any POCT instrumentation must be recorded, either on the POCT error log or electronically, dependant on the type of equipment.
- All POCT equipment will be subject to an approved Quality Assurance Programme and will be operated in accordance with the requirements of the quality standards.
- All POCT equipment used to perform pathological investigations will be monitored by the Pathology POCT Manager (or named deputy) to ensure compliance with the Quality Assurance Testing Programme.
- Unless otherwise arranged all costs associated with POCT are to be borne by the equipment user and their relevant Health or Care Group. This will involve the full cost of servicing, repairs, reagents (including quality control material), quality assessment and scheduled replacement as well as their own and the Pathology staff costs associated with these activities.
- All staff involved in POCT will be trained in proper instrument use, safe working practices (comply with the local infection control, health and safety standards), quality control procedures, appropriate recording of results and regular assessment of the competence of staff certified as authorised users by the link trainer.
- All staff involved in POCT need to comply with all Trust and department Information governance and data transfer policies.
- All results, including those obtained with quality control material, must be recorded and patient identification details must comply with the Pathology departmental policy. All results of patient analyses must be recorded in the clinical notes. All entries must include unequivocal operator identification.
- In the areas where the equipment will be used, an individual (or deputy) must be responsible for the day to day care of the instruments, ensuring that they are kept in good and safe working order, that valid stocks of disposables are maintained within their shelf life, that quality control procedures are observed, and that any instrument not performing to specification is immediately withdrawn from service and not used again until the appropriate remedial action has been taken.
- The nominated individual must comply with any hazard warnings and/or safety bulletins and ensure compliance with any policy relating to hazard warnings.
- Arrangements must be made for disinfection / decontamination and repairs and recalibration as and when necessary. The equipment should be checked regularly at intervals laid down by the manufacturer and approved by the POCT team.
- When an instrument is on loan, the primary users take on the responsibility for ongoing compliance for the duration of the loan.

4.2 Key Performance Indicators

The POCT service has developed bespoke Key Performance Indicators (KPI) to monitor current performance, identify areas of improvement, to monitor internal audit arrangements and training needs and delivery. The POCT KPIs are reviewed and updated periodically every year. The current KPI's can be seen upon request to the POCT department or the POCT committee. The KPIs are reviewed regularly within

the POCT department meetings and committee meeting. (PC/MIN/YS-1, PC/MIN/YS-2).

4.3 Implementation of POCT

When addressing the utility of POCT provision in a setting it is important to establish a clinical need, to ensure POCT in that location will contribute to patient's clinical care in the most clinical and/or cost-effective way.

Key strengths of POCT include:

- improved turnaround time
- smaller sample volume
- readily accessible in clinical area
- Improved visibility of results to patients

Weaknesses to consider typically include:

- Cost (capital and operational)
- Potential duplication of equipment (and non-equivalence of results)
- Risk of quality issues and/or kit wastage due to test performed by non-specialist staff.
- Challenges associated with record-keeping and IT connectivity.

4.4 Approval of new POCT service provision

All POCT devices are subject to review by the POCT Committee irrespective of whether the equipment has been purchased (including from charity funds), hired or loaned. Proposals to introduce POCT must be supported by a financial assessment produced by both the clinical department and the POCT department before being submitted to the POCT Committee. The financial assessment should give a clear indication of the setting, with the introduction of a POCT service addressing the clinical need, appropriate External Quality Assessment schemes, the need for the new service to be compatible with existing laboratory and medical equipment and any IT networks, both in the laboratory and in other areas of the organisation and the overall implementation and management costs needed to provide and maintain the service. The POCT new device request form (PC/FOR/YS-26) needs to be completed and sent for approval to the POCT committee. The POCT Committee will evaluate if the proposal is clinically and cost effective before approval. The extension of existing POCT provision to a new "delivery point" will be reviewed and approved using the same procedure as above.

4.5 Procurement

All procurement follows the Trust's standing financial instructions and procurement policies. A final decision on the device of choice will be made jointly by the POCT team and the clinical department, overseen by the POCT Committee.

4.6 Device evaluation, method validation and verification

A full verification of the device(s) includes analytical comparison with the laboratory test and/or the current POCT device will be undertaken and recorded to ensure that the performance of the device meets the manufacturer's specification and service needs and to ensure that the device is compatible with existing laboratory services. Evaluation of devices should also include but not be limited to; how practical it is for the device to be placed in service, maintenance, consideration of clinical users, IT connectivity, ease of use and stock management. Method validation data and assay performance should be reviewed and signed off by the POCT Clinical Lead prior to clinical use of the new POCT device. Further guidance can be found within the Blood Sciences method performance qualification SOP.

4.7 Standard Operating Procedures

Once the equipment has been procured, Standard Operating Procedures (SOPs) are drafted in line with ISO 15189. Within the SOP, the scope of the POCT device, device methodology and operation of the equipment, quality control, consumables, limitations of clinical use and roles and responsibilities of all personnel involved in the management will be identified, along with all information related to sections 8.3 and 7.3 of ISO 15189. Instruction sheets for the operation of the devices may be displayed near to the device, where appropriate, and kept free from infection risk. All relevant SHYPS SOPS for POCT are available on the YSTHFT intranet. All information regarding safe operation of POCT equipment and waste disposal must be easily accessible to the operator.

4.8 Budget Control

The budget holder for each clinical service will be responsible for authorising the budget and resolving any financial issues jointly with the POCT department within the SHYPS network. The roles and responsibilities of the SHYPS budget holder are covered in detail in POCT: Organisation, Communication and Laboratory Activities (Y&S) [PC/INF/YS-1], which supports the overarching SHYPS Quality Manual [QM/INF/SHY-1].

4.9 Maintenance of POCT device

All POCT equipment must be regularly maintained to ensure it is kept in correct working order. Maintenance of the device should be outlined in the SOP and relevant maintenance procedures incorporated into user training. The POCT department is responsible for liaising with the supplier regarding equipment failures or problems, as well as organising service visits and preventative maintenance as needed. All faults / errors with POCT devices including the respective corrective action taken and preventative steps put in place are recorded and discussed at the POCT Senior meetings held monthly and discussed at the quarterly POCT committee meeting. The records in turn are kept up to date, accessible and available for inspection by relevant bodies and remain the responsibility of the POCT department.

4.10 Incident Management

All incidents, errors and non-conformances to the standards are managed in line with the SHYPS quality management arrangements in SHYPS (QM/INF/SHY-8), and the SHYPS Quality Manual (QM/INF/SHY-1). All clinical incidents and errors are managed by the POCT Manager who assumes responsibility for reporting these on the incident management system in SHYPS and as appropriate reported on the Trust incident management system (Datix). The POCT Manager is responsible for any Datix raised by clinical staff which involves POCT equipment and any clinical incidents relating to the POCT service. National safety alerts relating to POCT devices will be responded to by the POCT Manager in conjunction with clinical and managerial staff in Pathology as appropriate.

4.11 Annual Management Review

There is an annual POCT management review (AMR) which is held within the SHYPS Annual Review. Quality objectives for the following year are set at this meeting and objectives set the previous year are reviewed. Test repertoire and activity is reviewed as a part of the annual management review.

4.12 Quality Management

Quality assurance is a mandatory component of POCT and is in place to ensure the correct use and working order of the POCT device in order to produce accurate and reliable results. Two key components to quality assurance are internal quality control (IQC) and external quality assessment (EQA). It is the POCT department's responsibility to implement an effective quality control programme which includes user awareness of quality assurance through training programmes, regular analysis of IQC, record keeping, troubleshooting and participation in an accredited EQA scheme. Having these measures in place ensures that the devices are used safely and effectively in line with MHRA and ISO standards. Regular review of IQC performance is performed by the POCT team and documented. Should the IQC results fail to meet the acceptable standard then appropriate action (as outlined in the SOP or as advised by the POCT department) should be taken.

The POCT Department is responsible for registering and ensuring the devices participate in accredited EQA scheme, where available. Samples are purchased from an external body and are logged by the POCT department who will distribute them to the departments where the devices are located. Users of the device and/or the POCT team are responsible for analysing the samples, following the relevant instructions, and returning the results to the POCT Department, where they are reported electronically to the external body. The external body evaluates the results and returns a report to the POCT Department which is reviewed to assess performance. In the event of unsatisfactory results, the POCT team will log the EQA failures, and reviewed by a clinical member of the POCT team. All EQA failures above an agreed threshold, as defined in the POCT EQA SOP (PC/SOP/YS-2), are reported on DATIX and investigated further with liaison with the appropriate

department providing relevant feedback and performing any corrective action. The POCT Department regularly reviews and audits the performance of the devices to ensure necessary performance checks are in place and ensure that the devices are kept in good working order.

4.13 Data Recording

All patient results generated using POCT devices must be recorded in the patient's notes and where possible patient results should be automatically transferred to the patient's electronic records. All results that are transferred from POCT devices electronically into a patient record, must be distinguishable from results generated from the core laboratory service. Results manually transcribed into patient paper records must identify the result as being generated from a POCT device and identify the operator who performed the test.

4.14 Risk Management

No POCT device is completely free from risk and those that are automated and can be linked directly to the hospital electronic network are the preferred choice as this helps risk to be managed and minimised. Both HUTH and SHYPS risk registers can be used to capture risk as appropriate. Incorrect/mismatched patient identification details, user bar code sharing, QC results, instrument and sampling errors can be reviewed by the POCT Department and risk managed as appropriate. National safety alerts relating to POCT devices, risk assessment and management of EQA failures, Internal Quality control measures and operator lockouts are options to address and minimise clinical risk.

4.15 Health and Safety

The Pathology service is responsible for developing and enforcing local policies consistent with current guidance and legislation.

- The Health & Safety at Work Act 1974,
- Consumer Protection Act 1987,
- The Control of Substances Hazardous to Health (COSHH) Regulations 2002,
- Safe Working and the Prevention of Infection in Clinical Laboratories – Model Role for Staff and Visitors, HSC 1981,
- Protection against Blood-born infections in the workplace: HIV and hepatitis (ACDP) 1995.

Health and Safety officers for SHYPS at the site of the device should work closely with Pathology to ensure that COSHH assessments are carried out as appropriate.

4.16 Dissemination and Implementation of POCT Testing Policy

Updated versions of the POCT Policy can be found on the SHYPS quality management database and the YSTHFT intranet. Pathology and POCT Committee staff will be alerted of updated versions of the POCT Policy at departmental meetings. The POCT Committee is responsible for ensuring the effective implementation of the

POCT policy.

4.17 Identification of Stakeholders

All Trust personal who work with POCT instruments or who manage a service that includes POCT.

4.18 Consultation and approval process

Consultation has been sought and this policy has been approved by: Consultant Chemical Pathologist & Clinical Lead for POCT, Head Biomedical Scientist for POCT services, POCT Coordinator, Pathology Quality Manager and ratified by the POCT Committee. The policy has been formally approved by the SHYPS Governance Committee and noted by Cancer, Specialist & Clinical Support Services (CSCS) Care Group Board.

5. Training Requirements

This is an informative document - There are no specific training to support this policy.

6. Monitoring Compliance

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Production of a documentary controlled policy drawn up according to the Development and Management of Policies template	Policy Manager	Audit	2 years	
Inventory held within Q-Pulse of all reusable medical devices	POCT Team	Audit	As per audit schedule on Q-Pulse	
Records of maintenance and repair of all POCT equipment	POCT Team	Audit & automatic renewal reminders by Q-Pulse	Reviewed monthly for access expiry	
A list of trained and competent staff for the various POCT instruments and/or procedures	POCT Team	Records held on POCT middleware	2 years	

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Written training requirements for type of instrument and frequency of recertification	POCT Team	2 yearly review of documents held on Q-Pulse and Staffroom	Every 2 years	
A list of diagnostic tests exist as a series of SOPs	POCT Team	Q-Pulse	As new equipment is procured	
Any known risks associated with POCT will be documented	POCT Team	Via Datix, FSN, H&S quarterly audit, risk assessment	As they occur	

7. Document Review

This document should be reviewed every 2 years.

8. Associated Trust Documents

- POCT: Organisation, Communication and Laboratory Activities (Hull) [PC/INF/YS-1]
- SHYPS Quality Manual [QM/INF/SHY-1]
- POCT new device request form (PC/FOR/YS-26).
- Key Performance Indicators (PC-INF-KPI).
- Terms of reference for POCT Committee [PC/INF/YS-24]

9. References

- ISO Standards **ISO 15189:2022**
- Management and Use of IVD Point of Care Test Devices, MHRA DB2010(02), February 2010 Available from www.mhra.gov.uk
- Guidelines on Point of Care Testing, Royal College of Pathologists 2004 Available from www.rcpath.org/resources/pdf/point-of-caretesting-updatedoct04.pdf

10. Definitions

Term	Definition
POCT	Point of Care Testing
IQC	Internal Quality Control
EQA	External Quality Control
CAPA	Corrective Action/ Preventative Action

Term	Definition
UKAS	United Kingdom Accreditation Service
MHRA	Medicines & Healthcare Products Regulatory Agency

11. Equality Impact Assessment

This policy adheres to the Equality and Diversity Strategy to ensure that SHYPS and YSTHFT workforce implement this policy in a non-discriminatory and appropriate way in its delivery of modern healthcare. See Appendix **1** for Stage 1 Equality Impact Assessment Screening.

12. Due Regard Impact Assessment

A Due Regard Impact Assessment (DRIA) has been completed, **DRIA Register Number 2024-29**. The outcome of the DRIA was there was no potential for unlawful discrimination or adverse impact on equality, and the policy could be implemented as planned.

Appendices

Appendix1

DRIA Register Ref Number		2024-29	
Title	Point of Care Testing (POCT) Policy		
Relevant Documents (tick as appropriate)			
☐	Business Case	Number	Click here to enter text.
☒	Policy/Procedure	Name and Version	POCT Policy V6
☐	Service Review/Development/ System Change	Click here to enter text.	
☐	Other(please specify)	Click here to enter text.	

What are the intended outcomes of this work? Include outline of objectives and function aims
To set out the roles and responsibilities of those involved in POCT and POCT as a service

Who will be affected? e.g. staff, patients, service users etc
All staff who use POCT equipment or patients who have analytical procedures using POCT equipment

1. Evidence and Assessing Impact (see guidance pages 10-14)

What evidence have you considered? List the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each equality group (protected characteristic). This can include national research, surveys, reports, research interviews, focus groups, pilot activity evaluations etc. If there are gaps in evidence, state what you will do to close them in the Action Plan on the last page of this template. For each group, assess the impact and how you will mitigate any negative impacts.

IBMS National POCT Guidance 2023
National POCT Guidance 2023 - Institute of Biomedical Science (ibms.org)

Now consider and detail below how the proposal's impact on elimination of discrimination, harassment and victimisation, advance the equality of opportunity

and promote good relations between groups, as outlined in the Public Sector Equality Duty		
Protected Groups	**Consideration**	**Impact** (positive/ negative/ neutral**)**
Age	All groups will have equal access to POCT, depending on clinical need.	Positive
Sex	All groups will have equal access to POCT, depending on clinical need.	Positive
Race	All groups will have equal access to POCT, depending on clinical need.	Positive
Religion or belief	All groups will have equal access to POCT, depending on clinical need.	Positive
Disability	All groups will have equal access to POCT, depending on clinical need.	Positive
Sexual orientation.	All groups will have equal access to POCT, depending on clinical need.	Positive
Gender reassignment	All groups will have equal access to POCT, depending on clinical need.	Positive
Pregnancy and maternity.	All groups will have equal access to POCT, depending on clinical need.	Positive
Carers.	All groups will have equal access to POCT, depending on clinical need.	Positive
Other identified groups	All groups will have equal access to POCT, depending on clinical need.	Positive

Engagement and involvement

	Y/N	**Provide detail**
How have you engaged stakeholders in gathering evidence or testing the evidence available?	Yes	**Through quarterly POCT Committee meetings**
How have you engaged stakeholders in testing the policy or programme proposals?	Yes	**POCT Policy approved by POCT Committee**
For each engagement activity, please state who was involved,	Choose an item.	**Draft of POCT Policy has been provided for all POCT**

how and when they were engaged, and the key outputs?		**Committee members for comment/amendments prior to submitting to the Trust**
Are there barriers to engagement?	No	Click here to enter text.
Are there regional variations and what is the combined impact?	No	**No variation for our Trust, across all sites.**

Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work.

POCT equipment is widely used across the Trust. It is accessible to all who have had training and patient testing is dependant on clinical need.

Mitigation

Consider any negative impacts and document how you plan to address any inequalities identified through the evidence. You may wish to use the action plan template overleaf if there are multiple actions to document.

No inequalities. Testing is dependant on clinical need

Where there have been no impacts identified on any protected group you can proceed to sections 3, 4 and 5 of this form. Throughout the development of your proposal you should continue to be mindful of any impacts emerging, which should be update on your assessment and addressed accordingly.

2. Due Regard Action Plan

Please give an outline of the key actions based on any gaps, challenges and opportunities you have identified. Actions to improve the policy/programmes need to be summarised (An action plan template is appended for specific action planning). Include here any general action to address specific equality issues and data gaps that need to be addressed through consultation. You might want to change the categories in the first column to reflect the actions needed for your policy.

Characteristic	Actions Required	Timescale	Person Responsible
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
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Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

3. Decision Making and Overall assessment

Does our due regard impact assessment hold true?	Yes
Do the affected groups agree with our assessment? What else have they told us	No
Have unforeseen impacts emerged as the project or policy has been implemented? How are we responding to them?	No
Dos the action we are taking actually addressing the issues we identified? How do we know?	No
Comments There are no groups affected. Use of POCT is determined depending on clinical need.	

Once you have considered the findings of your DRA, you can make a judgement about what it means for your activity. There are four likely courses of action:	
Go ahead as planned: Where there is no potential for unlawful discrimination or adverse impact on equality, you can continue as planned	☒
Adjust: If you have identified actions or adjustments that will ensure no adverse impacts on equality, or that will enhance any benefits for protected or vulnerable groups, you can make changes accordingly. **You will be required to provide evidence of your completed Action Plan demonstrating the any adverse impacts have been addressed.**	☐
Continue regardless: If you have identified that there are adverse impacts, or missed opportunities to advance equality, you can continue, providing you are certain that the impact can be justified and does not constitute unlawful discrimination. **This justification must be documented in the 'Next Steps' section of this Assessment which will be formally shared with the Fairness Forum.**	☐
Stop: If there are adverse impacts that cannot be justified or mitigated and therefore constitute unlawful discrimination, you must not proceed with the activity. If you do, you will leave the Trust open to legal challenge.	☐

4. Next Steps

Please give an outline of your next steps based on the challenges and opportunities you have identified.

All staffing groups have access to POCT equipment following full initial training. E- learning is available for recertification which must take place every 2 years.

5. Sign Off

Name of the individuals who carried out this assessment:

- Rachel Lampard
- Click here to enter text.
- Click here to enter text.
- Click here to enter text.
- Click here to enter text.
- Click here to enter text.

Date of assessment: 11/09/2024

Name of Sponsoring Manager: Deepak Chandrajay

Date assessment was approved by Sponsoring Manager: 11/09/2024