The Royal Wolverhampton NHS Trust

CP51
POINT OF CARE TESTING (POCT) POLICY FOR THE DUDLEY GROUP NHS FOUNDATION TRUST, SANDWELL AND WEST BIRMINGHAM NHS TRUST, THE ROYAL WOLVERHAMPTON NHS TRUST AND WALSALL HEALTHCARE NHS TRUST

Contents

1.0 Policy Statement (Purpose / Objectives of the policy)

This document describes how point of care testing (POCT) must be performed in the Trusts. It also describes the role of the POCT governance group in the approval, implementation, and maintenance of POCT services so that it may provide assurance to the Trusts of adherence to current standards.

The objectives of this policy are to ensure that:

- the POCT governance group is aware of all POCT occurring in the Trusts, including community and primary care settings where the Trusts are responsible for governance oversight, and to provide a framework for the introduction of all POCT schemes; and
- all POCT performed in the Trusts adheres to ISO standards 15189 and 22870.

All aspects of this document regarding potential Conflicts of Interest should refer first to the Conflicts of Interest Policy for The Royal Wolverhampton NHS Trust and Walsall Healthcare Trust and the Conduct Policy for Dudley Group NHS Foundation Trust. In adhering to this document, all applicable aspects of the Conflicts of Interest Policy and Conduct Policy must be considered and addressed. In the case of any inconsistency, the Conflicts of Interest Policy or Conduct Policy as applicable must be considered the primary and overriding Policy (see Appendix 2).

2.0 Definitions

External Quality Assurance (EQA)

EQA is a system designed to objectively assess the quality of POCT results by means of an external agency and involves analysis of specimens of unknown concentration.

Internal Quality Control (IQC)

IQC is a system to detect deficiencies in the POCT process and to prevent incorrect results from being acted upon. It often involves analysis of samples of known concentration.

POCT

POCT is any *in vitro* analytical test, or group of tests, performed for a patient by a healthcare professional outside the conventional laboratory setting on specimens such as bodily fluids and tissue. Other terms commonly used to describe POCT are near patient testing (NPT), bedside testing, extra-laboratory testing and disseminated laboratory testing.

POCT Device

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. This may range from complex analysers to simple glucose meters and includes all 'dipstick' tests.

POCT Scheme

One or more of the same type of POCT device which is the responsibility of one POCT area lead.

Quality Assurance

Quality assurance is an essential component of POCT and includes all the measures taken to ensure that investigations are reliable, such as 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 and documenting all procedures for reference.

3.0 Accountabilities

3.1 **The Chief Medical Officer or Medical Director** at each Trust has overall responsibility for POCT at that Trust.

3.2 **The Black Country Pathology Service (BCPS) Clinical Reference Group** (attended by Chief Medical Officers and Medical Directors from all partner Trusts) will address the governance issues referred from the POCT governance group (PGG).

3.3 **The multidisciplinary POCT governance group (PGG)** is responsible for the creation, maintenance and dissemination of Trust policy and procedure for POCT and for the assessment of compliance of POCT schemes with ISO 15189 and 22870. The group will have the authority to make an immediate proportionate response to incidents and risks and to implement any remedial actions. The group will be responsible for alerting the oversight group to risks associated with the POCT service and ensuring that there is stakeholder involvement in decision making. The terms of reference of the group may be obtained from the BCPS administration manager.

3.4 **The POCT team** co-ordinate training and competency assessment; advise on the procurement of, verify and implement new POCT devices; troubleshoot POCT devices; devise and complete a POCT audit programme; issue EQA samples; monitor IQC and EQA performance, including return rates; act on safety notices; maintain the POCT quality management system; attend the PGG; and highlight performance issues and risks to the PGG and POCT area lead.

3.5 **The POCT area lead** is operationally responsible for staff adhering to the POCT policy in their area. This will include, but is not limited to, ensuring that all staff are trained and competent before undertaking POCT (including the provision of link trainers), all devices are situated in a location approved by infection prevention, all local health and safety and infection prevention policies (see Appendix 2) and procedures are followed when using POCT devices, appropriate IQC is performed, and all EQA results are returned to the POCT team. The POCT area lead will ensure that all POCT governance and device issues are reported to the POCT team.

3.6 **Medical staff and appropriately trained nursing staff, for nurse-led services and appropriately trained allied health professions (AHP) staff, for AHP led services** will be responsible for therapeutic decisions, based on POCT results.

3.7 **Clinical and Operational Managers** are responsible for overseeing the safe and effective implementation of POCT within their areas of responsibility at a local level and ensuring that these areas comply with all aspects of the Trust's POCT policy and procedures. This responsibility includes ensuring that the PGG is aware of all POCT schemes that are in existence.

3.8 **All staff** have a responsibility to ensure that they follow the POCT policy, local infection prevention and health and safety policies and procedures (see Appendix 2), and standard operating procedures, and are competent to use the devices and act

appropriately on results as required by their roles.

4.0 Policy Detail

4.1 **The implementation of all POCT projects must be authorised by the POCT governance group (PGG)** whether the Trust is funding the procurement of a POCT service or is obtaining materials to carry out such activities free of charge, for example as part of a clinical trial or an equipment trial. For the latter, please also refer to the policy related to the introduction of new techniques (see Appendix 2). All POCT procurements must ensure that standardisation of devices is maintained. The procedure for applying for POCT approval is detailed in Appendix 1.

4.2 **The PGG has the authority to stop or modify any POCT practices,** including removal of the POCT device, that do not comply with ISO 15189, ISO 22870 and Trust Policy. The PGG will work with the affected team to mitigate any risk caused by the change and to identify alternative processes where required

4.3 **Each ward or department must have one person taking overall operational responsibility** for POCT in their area. This person will be known as the POCT area lead. The POCT team maintains a list of POCT area leads.

4.4 **Once authorised, there must be no changes to POCT schemes** without the permission of the PGG. Any unauthorised changes may result in withdrawal of the scheme and removal of the POCT device.

4.5 **Reporting incidents** involving a POCT scheme must be in accordance with the Trust's incident reporting policy (see Appendix 2). In addition, they must be reported to the POCT team to enable review by the PGG. In the event of an adverse incident the Trusts require an immediate appropriate response to maintain patient safety, which may involve removal of user access to equipment and withdrawal of the POCT device or the POCT Scheme. This will be until such time as a full investigation is completed and the POCT area lead is authorised by the PGG chair to resume testing.

4.6 **All users of POCT devices must be trained** in the function and use of the devices as described in the standard operating procedure (SOP), and in accordance with the medical devices policy and information policy (see Appendix 2). Users must not be allowed to perform tests that will alter clinical management unless the trainer is satisfied with the competence of the user. POCT training for individual devices is provided in one or more of the following ways: link trainers; supplier training sessions; the POCT team; and on-line training. Upon completion of the training, all users must sign to say that they are competent. A list of trained and authorised users must be maintained by the POCT team and training updates arranged as appropriate.

4.7 **All devices must be verified,** and the results compared to the laboratory method. The verification must include an assessment of device practicality.

4.8 **All devices must be located** in an area approved by the Infection Prevention Team and used in line with the infection prevention policy (see Appendix 2).

4.9 **All equipment must be managed** in line with the medical devices policy (see Appendix 2).

4.10 **A Standard Operating Procedure** must be in place wherever POCT is performed. It is essential that there is a document control system to ensure operators only use the

current version. The SOP must include infection prevention and health and safety considerations and be supplemented with Risk Assessments and relevant COSHH documentation. The SOP and COSHH documentation must be reviewed biennially. The Risk Assessment must be reviewed annually.

4.11 **Records must be kept of the lot numbers** of test kits and quality control materials used including date received, date opened and expiry dates. All new reagent lots must be verified to ensure that they are producing accurate results. This is achieved by testing an internal quality control sample.

4.12 **Internal quality control, external quality assurance and audits must be performed,** and adequate performance defined. Failure to achieve adequate performance must result in corrective action, including, if necessary, removal of the POCT device from use. All IQC results, EQA results and corrective actions must be documented. Records must include the device that produced the results, date and time of test, result including units, identity of the user, lot numbers, and expiry dates of consumables. IQC and EQA results must be reviewed by the PGG, non-conformances noted, and corrective action instituted. Retention of IQC and EQA records must be in line with Royal College of Pathologist guidelines.

4.13 **POCT results must be permanently recorded** in the patient's medical records. Records must include the device that produced the results, date and time of test, result including units, identity of the user, lot numbers, and expiry dates of consumables.

4.14 **Where networked equipment is available for a particular application**, it must be installed to allow faster troubleshooting and storage of patient, user and IQC data and to facilitate transfer of results to the electronic patient record and to prevent untrained users from accessing the equipment.

4.15 **Correct input of patient ID must occur** for networked equipment to allow patient results to transfer to the electronic patient record. Failure to enter correct patient ID will be audited and reported to the line manager in the first instance. Evidence of persistent non-compliance will result in action under the disciplinary policy (see Appendix 2).

4.16 **If access to POCT equipment involves use of a password**, staff must not share their password. Failure to comply will result in action under the information policy. Breaches in this policy will result in action under the disciplinary policy (see Appendix 2).

4.17 **All measurements made as part of the treatment plan** must be made on devices owned by the NHS Trust by trained NHS staff. It is acceptable for patients to use their own devices whilst in hospital, but the results obtained must not be used by staff to make alterations to treatment.

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources	No
2	Does the policy require additional implementation revenue resources	No
3	Does the policy require additional implementation manpower resources	No

4	Does the implementation of this policy release any manpower costs through a change in practice	No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff.	No
	Other comments	

6.0 Equality Impact Assessment

6.1 An equality analysis is not required.

Tick	Options
√	A. There is no impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.
	B. There is some likely impact as identified in the equality analysis. Examples of issues identified, and the proposed actions include:

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7.0 Maintenance

7.1 The policy will be reviewed, by the chair of the PGG, every three years or earlier, following recommendation of changes by the PGG.

8.0 Communication and Training

8.1 Dissemination of the policy will be via staff bulletins; targeted emails; and presentation at the Trust Medical Devices group.

8.2 The responsibilities, authority, inter-relationships, and contact details of all POCT personnel can be found at Black Country Pathology Services Home Page (bcpathology.org.uk)

8.3 The POCT manager will conduct an annual review of POCT and this report will be presented to the PGG.

8.4 Please refer to section 4.6 for training requirements.

9.0 Audit Process

The following key performance indicators are monitored to ensure delivery:

Criterion	Lead	Monitoring method	Frequency	Committee
Percentage of users **NOT** entering correct	POCT Manager	Audit	Quarterly	PGG

hospital number* *0% green; >0-5% amber; >5% red.*				
Percentage EQA returns made on time. *≥95% green; 90-94.9% amber; <90% red*	POCT Manager	Surveillance	Monthly	PGG
Percentage EQA returns within consensus. *100% green; 95-99.9% amber; <95% red*	POCT Manager	Surveillance	Monthly	PGG
Number of Incidents	POCT Manager	Surveillance	Every 2 months	PGG
Number of Complaints	POCT Manager	Surveillance	Every 2 months	PGG

This policy, with the exception of the * contained in this section, is applicable to Trust Primary Care Locations

10.0 References - Legal, professional or national guidelines

Medicines and Healthcare Products Regulatory Agency. Management and use of IVD point of care test devices. v1.2. January 2021 Amendments made February 2021. (online) https://www.gov.uk/government/publications/in-vitro-diagnostic-point-of-care-test-devices/management-and-use-of-ivd-point-of-care-test-devices [Accessed 18/07/2022]

Royal College of Pathologists (2020) Guidance for use of point of care testing equipment in positive patients and those with a suspected diagnosis of COVID-19 (online) https://www.rcpath.org/uploads/assets/01333d92-14cf-4160-bf55109c8e8f8d60/97493597-3cdb-4d65-8356273d4d7fb464/G204-Guidance-for-use-of-POCT-equipment-in-COVID-19-positive-patients.pdf [Accessed 18/07/2022]

ISO 22870: 2016. Point of Care testing (POCT) – requirements for quality and competence. https://www.iso.org/standard/71119.html

ISO 15189: 2012. Medical Laboratories – requirements for quality and competence. Amendments made in 2014 https://www.iso.org/standard/56115.html

Part A - Document Control

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and Policy version: CP51 6.0	**Policy Title:** Point of Care Testing (POCT) Policy	**Status:** Final		**Author:** Chair POCT specialist working group (group to be renamed POCT governance group) **Chief Officer Sponsor:** Medical Director
Version / Amendment History	Version	Date	Author	Reason
	1	Oct 2009	Chair POCT specialist working group	Original policy
	2	Oct 2012	Chair POCT specialist working group	3 yearly review
	3	Sep 2014	Chair POCT specialist working group	Addition of guidance on disciplinary actions
	4	Nov 2017	Chair POCT specialist working group	3 yearly review
	5	Nov 2020	Chair POCT specialist working group	3 yearly review
	5.1	July 2022	Chair POCT specialist working group	Updates made to section 10.0
	6	Aug 2022	Chair POCT specialist working group	Combined POCT policy for the partner Trusts that the Black Country Pathology Service (BCPS)serves
Intended Recipients: Clinical Directors, Directorate Managers, Matrons, Ward Managers, Departmental Managers, all staff who perform POCT				
Consultation Group / Role Titles and Date: Point of Care Testing (POCT) specialist working group 30/05/22 Black Country Pathology Service (BCPS) POCT workstream meeting 30/05/22 Black Country Pathology Service Chief Medical Officer 30/05/22 Divisional Governance Meeting – Division 1 17/6/22				

Divisional Governance Meeting – Division 2 22/6/22 Divisional Governance Meeting – Division 3 Circulated by email by Joanne Hughes for responses by end June 22 Dr McKaig 1/6/22	
Name and date of Trust level group where reviewed	Trust Policy Group – September 2022
Name and date of final approval committee	Trust Management Committee – September 2022
Date of Policy issue	October 2022
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	September 2025 (every 3 years)

Training and Dissemination:

Dissemination of the policy to Trust managers will be via staff bulletins; targeted emails and senior management briefings. The responsibilities, authority, inter-relationships, and contact details of all personnel involved in POCT can be found at Black Country Pathology Services Home Page (bcpathology.org.uk).

POCT training for individual devices is provided in one or more of the following ways: link trainers; supplier training sessions; the POCT team; and on-line training. Some POCT devices such as blood gas and blood glucose warn staff about the imminent requirement for re-training.

Publishing Requirements: Can this document be published on the Trust's public page:

Yes

If yes you must ensure that you have read and have fully considered it meets the requirements outlined in sections 1.9, 3.7 and 3.9 of OP01, Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines, as well as considering any redactions that will be required prior to publication.

To be read in conjunction with:

- Conflicts of Interest Policy (OP109)
- Introduction of New Clinical Techniques and Interventional Procedures (OP 95)
- Risk Management and patient Safety Reporting Policy (OP10)
- Management of Medical Devices Policy (HS11)
- Decontamination of Re-usable Medical Devices Policy (HS12)
- Management of health and Safety (HS01)
- Disciplinary Policy (HR03)
- Information Security Policy (OP12)
- Hand Hygiene (IP01)
- Standard Precautions (IP12)
- Blood and body fluid spillage management (IP19)

Initial Equality Impact Assessment (all policies): Completed No Full Equality Impact assessment (as required): Completed No Advised that not required for this policy By Mohan Sandhar	
Monitoring arrangements and Committee	Audits are performed by POCT manager and reported to POCT governance group.
Document summary/key issues covered Requirements that must be adhered to for new and existing POCT schemes including clinical and equipment trials. Procedure for approval of new POCT scheme.	
Key words for intranet searching purposes	POCT, point of care, near patient testing.
High Risk Policy? **Definition:** • Contains information in the public domain that may present additional risk to the public e.g. contains detailed images of means of strangulation. • References to individually identifiable cases. • References to commercially sensitive or confidential systems. If a policy is considered to be high risk it will be the responsibility of the author and chief officer sponsor to ensure it is redacted to the requestee.	**No (delete as appropriate)**

Part B **Ratification Assurance Statement**

Name of document: Point of Care Testing (POCT) Policy

Name of author: Clare Ford Job Title: Consultant Clinical Scientist

I, the above named author confirm that:

- The Strategy/Policy/Procedure/Guidelines (please delete) presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.
- I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.
- The document meets the requirements as outlined in the document entitled Governance of Trust- wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).
- The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.
- I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.
- I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.
- I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author: 

Date: 08/07/22

Name of Person Ratifying this document (Chief Officer or Nominee):
Job Title:
Signature:

- I, the named Chief Officer (or their nominee) am responsible for the overall good governance and management of this document including its timely review and updates and confirming a new author should the current post-holder/author change.

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version CP51	**Policy Title** Point of Care Testing (POCT) Policy	
Reviewing Group		**Date reviewed:**
Implementation lead: Print name and contact details Julie Edge Ext 88260		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	N/A	
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	Training on POCT devices including the content of the POCT policy is an on-going process and occurs at their implementation. Recertification occurs after a defined period; usually three years. This is managed from databases within Pathology. Records are maintained by the POCT team.	POCT manager
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	No development of forms is required as they have already been produced. These are held within the Qpulse system and updated biennially. Any additional forms needed are developed when a new scheme is approved.	
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	Message: 'All POCT must adhere to the requirements within the policy. A procedure is contained within the policy for the approval of all new POCT' Who: Clinical Directors,	POCT manager (Sept 2022)

	Directorate Managers, Matrons and Ward/Departmental Managers. Medical Device Group How: Senior managers briefing, all user email, targeted email.	
Financial cost implementation Consider Business case development	A business case to fund the implications of the policy was approved at introduction in 2009. There are no additional cost implications of the revision.	
Other specific Policy issues / actions as required **e.g. Risks of failure to implement, gaps or barriers to implementation**	Integration of VI Practices	PGG chair Dec 22

Procedure for the approval of a new POCT scheme

1.0 Procedure Statement

As per policy above

2.0 Accountabilities

As per policy above

3.0 Procedure Detail / Actions

3.1 **Stage 1**: **Read the considerations prior to the introduction of a POCT scheme** in Attachment 1 before submitting a proposal. This will help with the decision of whether POCT is necessary and aid with completion of the proposal.

3.2 **Stage 2: Submit a proposal** using the template in Attachment 2 supporting documentation to the POCT manager. Black Country Pathology Services Home Page (bcpathology.org.uk).

3.3 **Stage 3: Write the standard operating procedure** using the template in Attachment 3.

3.4 **Stage 4: For successful applications written authorisation** will be sent from the PGG to the POCT lead for the scheme using the authorisation form in Attachment 4.

3.5 **Stage 5: The POCT area lead must forward a copy of the signed authorisation sheet,** along with a requisition**,** to the Procurement Department in order for any purchase request to be processed.

3.6 **Stage 6: The PGG will review all new POCT schemes post implementation** to ensure adherence to the POCT policy.

4.0 Equipment Required

Not applicable

5.0 Training

As per policy above

6.0 References

As per policy above

CP51 Appendix 2

Details of Trust policies referred to in this policy

Not all Trusts have all policies referred to in this document.

The Dudley Group Foundation Trust

Conduct Policy

Incident Reporting and Management Policy

Medical Devices Maintenance Policy

Medical Devices Procurement Policy

Decontamination and Decontamination of Medical Devices Policy

Medical Devices Training policy

Health & Safety

Disciplinary Policy

Information Governance and Data Protection Policy

IT User Acceptable Use Policy

Standard (Universal) Infection Control Precautions Policy

Sandwell and West Birmingham NHS Trust

Policy for the Introduction of a Clinical Intervention Procedure New to the Trust (ORG/056)

Policy for the Management of Medical Devices (Including Medical Equipment) (ORG/065)

Policy for the Reporting, Management, and Investigation of Incidents (ORG/050)

Health & Safety (ORG/089)

Disciplinary Policy (HR/003)

Information and Cyber Security Policy (HIS/05)

Infection Prevention and Control Policy (COI/001)

The Royal Wolverhampton NHS Trust

Conflicts of Interest Policy (OP109)

Introduction of New Clinical Techniques and Interventional Procedures (OP95)

Risk Management and patient Safety Reporting Policy (OP10)

Management of Medical Devices Policy (HS11)

Decontamination of Re-usable Medical Devices Policy (HS12)

Management of Health and Safety (HS01)
Disciplinary Policy (HR03)
Information Security Policy (OP12)
Hand Hygiene (IP01)
Standard Precautions (IP12)
Blood and body fluid spillage management (IP19)

Walsall Healthcare NHS Trust
Conflicts of Interest Policy
Medical Devices Policy
Incident Reporting, Learning and Management Policy
Health and Safety Policy
Disciplinary Policy
Information Governance Policy and Management Framework
Administration of Infection Prevention and Control Policy

CP 51 Attachment 1

Considerations prior to the introduction of a POCT scheme

Clinical need and effectiveness must be based on establishing that the perceived need is valid and will be clinically effective. The following points must be considered when assessing clinical need.

- Which group(s) of patients requires 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 the patients with conditions requiring frequent monitoring? Has this been discussed with the laboratory?
- Will POCT enable more rapid or effective diagnosis or treatment?
- Can evidence that POCT will provide a measurable clinical and economic benefit be demonstrated?

Cost effectiveness must entail considering the cost implications for the POCT in comparison to laboratory testing.

Support of the POCT Team must be obtained and responsibilities e.g., for ordering, stock control, troubleshooting, training etc. established. The proposal must detail how the investigation will be provided if the POCT scheme is withdrawn for any reason.

Choosing the Most Appropriate POCT Device

The following points must be considered when choosing the device.

- Is it compatible with existing provision to ensure standardisation is maintained?
- What is the expected workload?
- Who is going to use the device?
- What level of analytical accuracy and precision is required for the service?
- Is it CE/UKCA marked for the purpose?
- Where will the device and consumables be sited and is this acceptable to the infection prevention team?
- Is there adequate space in which to carry out POCT?
- Are appropriate services available e.g., power and network points, water, and refrigeration?
- Has the device been evaluated by an independent organisation?
- Are the results comparable to those of the laboratory?

- What are the limitations of the device? Devices may not be suitable for all patients and medical conditions.
- How will the results transfer to the electronic patient record?
- What are the health and safety considerations e.g., safe disposal of clinical waste?
- What are arrangements for decontamination / cleaning and disposal of any equipment?

Arrangements must be made for the on-going service and repair of any equipment. Funding must be available either from a business case or an alternative stream for all components of the POCT service e.g., equipment, consumable, maintenance, and recurrent funding for staffing support from the POCT team.

Equipment standardisation is good professional practice and is in accordance with the principles of Clinical Governance as defined by the Healthcare Commission. Black Country-wide standardisation of POCT equipment minimises procurement, IT and running costs and makes the most efficient use of limited staff time for support, training, and risk management.

Potential Advantages and Disadvantages of POCT

It is essential to be able to demonstrate that the advantages of introducing POCT outweigh the disadvantages.

Some potential advantages and disadvantages are given below.

Advantages

- Improved turnaround time.
- Better monitoring of certain conditions.
- Small sample volumes so less clinically invasive.
- Beneficial in remote areas where access to the laboratory is limited.
- Easier access for patients, particularly for hard-to-reach groups.

Disadvantages

- Unnecessary duplication of equipment.
- Tests performed by staff with a non-analytical background who may have difficulty in interpreting results or detecting erroneous results.
- Difficulty controlling inappropriate testing.
- Fewer results may be recorded in patient records.
- Incompatibility with laboratory results making comparisons difficult.
- POCT testing is more expensive than laboratory testing but there may be whole pathway savings.

Quality Assurance

There are two essential components to quality assurance: IQC and EQA. Utilising both methods ensures the reliability of results but only if they are applied to the same standard as in the laboratory setting.

- IQC involves checking that results are reliable before they are used.

The analysis of an appropriate control material before analysing a set of specimens can provide reassurance that the system and operator are working correctly. IQC results outside limits suggest patient results may not be reliable and must not be acted on until the IQC results are back within acceptable limits. IQC results outside limits require investigation and if resolution does not occur this must be reported to the POCT team.

- EQA involves the analysis of samples with unknown values from an external source. Results are then subject to peer group assessment. The POCT team will be able to recommend appropriate EQA schemes**.** The external assessment is used to verify that internal procedures are robust.

In addition to EQA and IQC, the POCT team will initiate audits on a regular basis.

Training and Competency Assessment

Training must be provided by the suppliers of the medical device, a competent in-house trainer or through e-learning.

Training must include the following.

- The context and clinical utility of POCT and limitations.
- The theoretical aspects of the measuring system.
- Sample collection and handling.
- Reagent storage.
- Instruction on maintenance procedures.
- Calibration and quality control.
- Demonstration of the proper use of the equipment in accordance with the manufacturer's specification.
- Practical experience of the procedures, including a series of analyses that satisfy the instructor that the trainee is competent.
- Limitations of the measuring system.
- Response to results outside predefined limits.
- Documentation and reporting of results.
- Infection prevention and safety procedures.
- Waste disposal.
- Use of patient identification.
- Password security.
- Troubleshooting (where applicable).
- A date when recertification is required.

CP 51 Attachment 2

Proposal for the Introduction of a New POCT Scheme

Name of POCT Scheme	
Name of Area Lead	
Position of Area Lead	
Location of Testing (Trust and Area)	
Date	

Please answer the following questions and provide evidence where applicable.

1. Please give a brief overview of the proposed POCT scheme. Please include details of who will perform the test.

2. Reason for proposed introduction of POCT Scheme

What is the clinical need for the scheme?	
For which group of patients will this POCT scheme be used and how many patients per year will benefit?	
Is this investigation currently provided by a different mechanism? If so how?	
Why is the current method not	

adequate?	

3. Cost effectiveness of the proposed POCT

Please provide a detailed breakdown including capital costs (equipment etc.), revenue costs (reagents; IQC; EQA; consumables; maintenance), POCT support costs (please provide the budget code for the area funding the POCT support), annual workload and total annual costs. Please identify how these costs will be met. If the laboratory currently provides this investigation, what is the current annual cost?

The POCT scheme will not be implemented unless funding for POCT staffing support has been transferred to the POCT budget.

4. Contacting the POCT manager (01902 307999 Ext 88260) for support in carrying out POCT is mandatory.

Has POCT support been arranged?	

5. Equipment

Please list all equipment required together with potential suppliers and state if it is to be purchased, loaned, on trial or a gift.	
Please indicate the exact location of the equipment and confirm that adequate network points and power points are available, and that the location has been approved by the infection prevention team.	
How will transfer of results to the electronic patient record be achieved?	

6. Reagents

Please list all reagents required and state if they are to be purchased, loaned, on trial or a gift.	

Where will the reagents be stored?	

7. How will Internal Quality Control be performed?

8. To which External Quality Assurance scheme will you subscribe?

9. Who will provide the training and competency testing for users of the POCT scheme?

10. How will this investigation be provided to patients if the POCT scheme is temporarily or permanently unavailable?

Please attach the following documents to your proposal. Confirm inclusion by marking the appropriate box. Proposals will only be considered if all relevant documents are included, and boxes are completed.

Relevant SOP / Short user guide	
Risk Assessment	
COSHH Assessment	
Please confirm the funding stream. If a business case been approved to support funding, please send a copy of the business case. Please indicate if an alternative funding stream has been identified e.g., charitable funds.	
Training procedure and content. Ensure compliance with medical device policy (see Appendix 2).	
Please confirm compliance with medical device/ new techniques policies (see Appendix 2).	

Signature of POCT area lead Date

Signature of Budget holder Date

CP 51 Attachment 3

Standard Operating Procedure Template

Title	Standard Operating Procedure
Unique identifier	
Version	
Date issued	
Review frequency	
Authorisation	

The electronic copy of this document is the only version that is maintained. Printed copies must not be relied upon to contain the latest updates and amendments.

All processes and procedures described herein are mandatory within the Black Country Pathology Service

These are recommended headings which may not suit all SOPs please delete or add as appropriate.

Contents

CP 51 Attachment 4

POCT governance group Authorisation Form

POCT governance group use only.

Name & Location (Trust & Area) of POCT Scheme	
Name of POCT Area Lead	
Date	

Proposal declined ☐

Proposal accepted ☐

Proposal requires resubmission following amendments ☐

Suggested amendments

Signature: Name:

Chair of POCT governance group: