Somerset Partnership NHS
NHS Foundation Trust

POINT OF CARE TESTING DEVICES (POCT) POLICY

Version:	3
Ratified by:	Senior Managers Operational Group
Date ratified:	January 2016
Title of originator/author:	Clinical Skills Facilitator
Title of responsible committee/group:	Clinical Governance Group
Date issued:	**February 2016**
Review date:	**January 2019**
Relevant Staff Group/s:	All staff who use point of care testing devices in Somerset Partnership

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Reference Number	Version	Status	Author
JD/Dec12/POCTP	3	Final	Clinical Skills Facilitator
Amendments	3 yearly review. Updated to reflect changes within Somerset Partnership and MHRA recommendations.		
Document objectives: To provide standardised management of POCT devices and procedures throughout the Trust, as recommended by the Medicines & Healthcare products Regulatory Agency (MHRA) thereby providing a cost efficient and clinically effective analytical service.			
Intended recipients: All Trust staff who are involved with point of care testing			
Committee/Group Consulted: Point of Care Testing Group			
Monitoring arrangements and indicators: Monitoring to be undertaken by Point of Care Testing Group			
Training/resource implications: Medical Devices Training already delivered by Training Department			
Approving body and date	Clinical Governance Group	Date: January 2016	
Formal Impact Assessment	Impact Part 1	Date: January 2016	
Clinical Audit Standards	**NO**		
Ratification Body and date	Senior Managers Operational Group	Date: February 2016	
Date of issue	**February 2016**		
Review date	**January 2019**		
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1. INTRODUCTION

1.1 Point of care testing (POCT) is a medical test performed outside the normal laboratory, at or near the site of patient care. The driving principle behind POCT is to bring the test conveniently and immediately to the patient in order to generate a result quickly so that appropriate treatment can be implemented.

1.2 There are advantages with POCT compared with conventional laboratory testing. For example, results are available more quickly as time is not lost by transporting samples to the laboratory. This can be vital when managing critically ill patients. Also, in some settings, particular POCT results can be used to adjust patient's medication resulting in the convenience of less frequent clinic appointments.

1.3 There are also disadvantages with POCT compared with conventional laboratory testing such as the cost per test being more expensive for POCT. Therefore, any new POCT service must provide significant patient benefits to ensure resources are used appropriately. The quality of results can also be affected by inadequate training or inappropriate use of devices and failure to carry out with recommended quality control procedures and inadequate servicing and checking of equipment where indicated .

2. PURPOSE & SCOPE

2.1 The purpose of this policy is to provide standardised management of POCT devices and procedures throughout the Trust, as recommended by the Medicines & Healthcare products Regulatory Agency (MHRA) thereby providing a cost efficient and clinically effective analytical service. This policy should be read in conjunction with the Trust's policy for Management of Clinical Diagnostic Tests or Screening Procedures and Medical Devices Policy.

2.2 Each Standard Operating Procedure (SOP) specific to POCT must be read in conjunction with this policy prior to use.

2.3 This policy applies to all Trust employed staff involved in the use of POCT services, including Students, Temporary, Locum, Bank, Agency and Contracted staff as appropriate.

2.4 This policy applies only to POCT devices that are loaned to, owned or rented by Somerset Partnership.

3. DUTIES AND RESPONSIBLITIES

The Chief Executive

3.1 Chief Executive has overall responsibility for the implementation of all measures needed to ensure safe working with POCT devices. These duties are delegated through the Chief Executive to Clinical and Service Directors for their areas of responsibility.

The Head of Risk

3.2 The Head of Risk and Medical Devices Group is responsible for the monitoring of all medical devices, risk assessments relating to medical devices and will also highlight areas where equipment may need reviewing. They must ensure adequate arrangements are implemented to ensure the safe management of all medical devices e.g. procurement, maintenance, disposal etc. The POCT group are responsible for reporting to the Medical Devices Group. The Head of Risk is also Medical Devices Safety Officer as required by Medicines and Healthcare products Regulatory Agency (MHRA)

Point of Care Testing Lead and Group

3.3 The POCT Lead is the Senior Nurse for Clinical Practice**.** The multidisciplinary Committee is responsible for considering the clinical need for all POCT services along with their benefits and disadvantages to patients and the Trust, and standardising POCT devices and Internal Quality Control (ICQ) and External Quality Assessment (EQA) procedures.

3.4 The systems and processes for monitoring and improving services for POCT will be considered through the Lead for Point of Care Testing.

3.5 All incident reports relating to POCT devices and or procedures will be discussed through the Medical Devices and POCT groups. Where necessary, POCT adverse events will be reported to the MHRA where applicable.

Local Pathology

3.6 The Local pathology laboratory can play a key role in the development and management of POCT services, providing advice on a range of issues including purchasing of devices, quality control, training, interpretation of results, troubleshooting, quality assessment and health and safety. Currently the pathology department do not cover all POCT devices used through the Trust.

Line Managers

3.7 Line Managers should be aware of their responsibility for clinical governance and of the medico-legal implications of an erroneous result. Liability under the Consumer Protection Act (1987) will only remain with the manufacture or supplier if the user can demonstrate that the equipment has been used in strict accordance with the manufactures instructions.

3.8 **All staff** using POCT devices/systems have a responsibility to ensure they have received appropriate training and competency assessment specific to the POCT device/system being used. The user must also ensure they have received continual support and update where necessary.

3.9 The Training Department are responsible for monitoring of mandatory Medical Devices training, and training rates are monitored through the Medical Devices Group.

4. EXPLANATIONS OF TERMS USED

4.1 The MHRA (2010) define POCT as “any analytical test performed for a patient by healthcare professionals outside the conventional laboratory setting. This may comprise of; non instrumental systems that are disposable systems or devices that vary from reagent test strips for single analyte to sophisticated multi-analyte reagent strips; small analysers usually hand or palm held devices such as blood glucose meters; and desktop analysers which are larger and include systems designed for use in clinics or small laboratory”.

4.2 Quality Assurance (QA) – includes all the measures taken to ensure that investigations are reliable. It also incorporates IQC and EQA.

4.3 Internal Quality Control (IQC) – is a means of checking that patient results are reliable before they are issued. The analysis of an appropriate control material or result, before analysing a set of specimens to provide reassurance that systems are working correctly.

4.4 External Quality Assessment (EQA) – involves analysis of samples with unknown values from an external source or provider. Results are subject to peer group assessment and statistical analysis to compare results across different sites.

4.5 Standard Operating Procedures (SOP) - SOPs are in place for all specified POCT performed throughout the Trust. The purpose of a SOP is to carry out the operations correctly and consistently. A SOP is a compulsory instruction.

5. POINT OF CARE TESTING (POCT)

5.1 POCT may be undertaken by diagnostic laboratory personnel, by non-laboratory trained health care practitioners and by lay individuals, for personal or commercial purposes. The user may be a person responsible for the care of a patient or otherwise acting on the carer’s behalf.

5.2 The Trust must have a contract in place with all EQA providers which includes responsibility of the laboratory in the management and process of the EQA service.

Consent

Prior to undertaking any Point of care testing on a patient, health care practitioners must ensure the patient is able to understand the information given to them and are able to give their informed consent. This may necessitate the use of a professional interpreter and the translation of written information (Interpreting and Translation Policy). A capacity assessment should be considered for those patients who are unable to consent to the procedure and reference should be made to the Consent and Capacity to Consent to Examination and Treatment Policy.

Standard Operating Procedure (SOP)

5.3 It is the responsibility of Line Managers to ensure staff using POCT devices follow the specific SOP which has been written to the standard of Clinical Pathology Accreditation (UK) (Royal College of Pathologists, 2004) is in place for each POCT device and procedure. SOPs for each device will cover;

- clinical background
- analytical principle
- health and safety, including: COSHH (Control of Substances Hazardous to Health); safe disposal of waste; infection control; adverse incident reporting
- pre-analytical considerations
- equipment
- reagents, standards, controls and quality assurance
- test procedure
- sample
- analysis
- calculation of results
- assay performance
- record keeping

5.4 Please refer to the intranet under Medical Devices for available SOPs for the devices used within Somerset Partnership.

5.6 Procurement of new devices must comply with Trust procedure and involve discussion with the POCT Group and agreement by the Medical Devices Group.

Documentation

5.7 Where achievable, results from POCT devices should be integrated with the laboratory record. Procedures should be in place to clearly identify those generated at the point of care and these results must not be overwritten by the laboratory generated results on the same specimen. Where this is not achievable, results must be recorded as recommended by the device specific SOP and service specific policy.

Quality Assurance

5.8 Results derived from POCT home devices/patient's own may not be entered into documentation in the patient's record or used for any decision making or treatment, as there is no way to determine what quality control processes have taken place. POCT devices approved for home use may be used to educate patients for home testing and monitoring only.

Internal Quality Control (IQC)

5.9 The analysis of an appropriate control material (often supplied by the manufacturer) before analysing a set of specimens can provide reassurance as to the quality and accuracy of the results obtained, thus ensuring patient safety.

5.10 It is essential that the specific IQC procedures set out in each POCT SOP are followed and are carried out at an appropriate frequency.

5.11 Each POCT SOP will detail:

- the provider of IQC materials (if being used) or other IQC methods if appropriate
- department/individual responsible for providing support to ensure any results outside of acceptance limits are investigated
- guidelines for interpretation of results
- procedures to deal with IQC results that fall outside the specified limits for the ICQ materials being used

5.12 All test results from calibrations, controls and patient samples must be recorded as instructed by the POCT device SOP. Details must include:

- the name of the patient, hospital number, date and time of analysis, sample type, analyser ID, result (with units) and operator ID
- in some situations the batch number of reagents may need to be recorded
- the device Quality Control book, if recommended, should be used or procedures put in place to enable full audit trails in the event of a product recall
- patient confidentiality must be maintained at all times

External Quality Assessment (EQA)

5.13 EQA schemes may be operated by the manufacturer or by a dedicated EQA provider. The MHRA recommends EQA participation from all managers of POCT, as part of Clinical Governance.

5.14 Each POCT SOP details the specific EQA arrangements for the device and must be followed at all times.

Infection Control

5.15 The use of POCT requires clearly defined procedures for infection control, storage and disposal of clinical waste, needle stick injuries and spillages, hand washing etc.

5.16 Each device manufactures' instructions on infection control procedures must be followed, in conjunction with the Trust's policies for Infection, Control, Needlestick and Contamination Injury, Sharps and Blood Borne Viruses.

Maintenance

5.17 Regular planned preventative maintenance should follow manufacturer's guidelines. This is essential for the safe and effective use of POCT devices. The Trust's policy for Medical Devices and each specific device SOP will detail actions to be taken in the event of the POCT device becoming damaged or unable to use.

5.18 A maintenance record book should be kept for each POCT device which includes a record of regular maintenance checks, faults and repairs.

5.19 Each POCT SOP will give details for how the manufacturer can be contacted in the event of a technical problem or breakdown.

Incidents

5.20 All accidents or incidents with POCT devices must be reported to the health care professional in charge and reported on the Trust incident reporting system, DATIX, in line with Trust Incident Reporting policy, clearly identifying 'POCT' device. Incidents involving user error or a device malfunction must all be reported.

5.21 The Head of Risk will report any adverse events relevant to POCT devices to the MHRA.

Register of POCT Equipment

5.22 All POCT devices must have been agreed for inclusion on the Trustwide Core Equipment List, and be added to the Medical Devices register with the following information:

- device name, serial number, supplier (contact name and phone number) and purchase date
- date of installation
- location (Clinical Unit)
- designated Trainer
- unit Clinical Manager
- link person (contact name & phone number)
- dates of service

Lay person use for self-testing

5.23 This policy is not primarily intended for health care practitioners educating their clients/patients in the use of 'self-testing' and 'direct to consumer testing'. However this policy and the associated SOPs may be useful to support health care professionals involved in patient education.

5.24 Health care practitioners using lay person POCT results to aid their clinical decision making must consider the following before interpreting the results:

- issues such as quality control and assurance
- limitations of the device, the test and device user
- quality of sample and result
- general maintenance of the device and associated components

5.25 Where POCT is being used directly by patients or their carers, they must be provided with the necessary information and training so that they can perform the test and interpret the results.

5.26 Staff providing patient education in self-management using POCT devices, must themselves have completed the necessary training and competency assessment (Royal College of Pathologists, 2004).

6. TRAINING REQUIREMENTS

6.1 The Trust will work towards all staff being appropriately trained in line with the organisation's Staff Mandatory Training Matrix (training needs analysis). All training documents referred to in this policy are accessible to staff within the Learning and Development Section of the Trust Intranet.

6.2 Users of POCT must receive formal training and competency assessment (where risk assessment indicates the need for competency to be assessed) in the operation of POCT devices to ensure quality results, and have an understanding of the results obtained appropriate to their medical use (please refer to specific SOP).

6.3 Users of POCT devices must also ensure they have completed mandatory Trust training on Medical Devices and completed the Medical Devices competency assessment located on the Trust Intranet.

6.4 All staff performing POCT must be familiar with manufacturer's instructions for use and the specific SOP to that device and procedure, with particular reference to:

- the intended purpose of the device
- performance characteristics
- interpretation of results
- limitations of use
- infection control and disposal of POCT equipment
- sampling requirements, including sample type
- storage or reagents and samples
- expiry dates
- quality assurance procedures
- health and safety issues

7. EQUALITY IMPACT ASSESSMENT

7.1 All relevant persons are required to comply with this policy and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the Equality Act 2010. In addition, the Trust has identified Learning Disabilities as an as an additional tenth protected characteristic. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Equality and Diversity lead who will then actively respond to the enquiry.

8. MONITORING COMPLIANCE AND EFFECTIVENESS

8.1 This policy will be reviewed every 3 years or sooner if appropriate.

Incidents, complaints and feedback relating to POCT devices or processes will be monitored by the Point of Care Testing Group, and themes reported and

monitored at the Medical Devices Group. Good practice and lessons learned will be shared with the appropriate Best Practice Groups, and in What's On.

Every other month EQA results and non-returns will be monitored by the Senior Nurse for Clinical Practice. Poor results and poor compliance will be followed up by the appropriate operational lead. Consistent non-compliance will be raised as a risk on local and the Trust corporate risk register, supported by an action plan. This will be overseen by the Point of Care Testing Group, and appropriate risks reported to Clinical Governance group.

9. COUNTER FRAUD

9.1 The Trust is committed to the NHS Protect Counter Fraud Policy – to reduce fraud in the NHS to a minimum, keep it at that level and put funds stolen by fraud back into patient care. Therefore, consideration has been given to the inclusion of guidance with regard to the potential for fraud and corruption to occur and what action should be taken in such circumstances during the development of this procedural document.

10. RELEVANT CARE QUALITY COMMISSION (CQC) REGISTRATION STANDARDS

10.1 Under the **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3), the fundamental standards** which inform this procedural document, are set out in the following regulations:

Regulation 9:	Person-centred care
Regulation 10:	Dignity and respect
Regulation 11:	Need for consent
Regulation 12:	Safe care and treatment
Regulation 15:	Premises and equipment
Regulation 16:	Receiving and acting on complaints
Regulation 17:	Good governance
Regulation 18:	Staffing
Regulation 19:	Fit and proper persons employed
Regulation 20:	Duty of candour
Regulation 20A:	Requirement as to display of performance assessments.

10.2 Under the **CQC (Registration) Regulations 2009 (Part 4)** the requirements which inform this procedural document are set out in the following regulations:

Regulation 18:	Notification of other incidents

10.3 Detailed guidance on meeting the requirements can be found at http://www.cqc.org.uk/sites/default/files/20150311%20Guidance%20for%20providers%20on%20meeting%20the%20regulations%20FINAL%20FOR%20PUBLISHING.pdf

11. RELEVANT NATIONAL REQUIREMENTS

MHRA Device Bulletin February 2010 Management and Use of IVD Point of Care Test Devices

Report of the review of NHS pathology services in England. August 2006

12. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

12.1 References

Medical Devices Agency (2013). Management and Use of IVD Point of Care Test Devices. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/371800/In_vitro_diagnostic_point-of-care_test_devices.pdf [Accessed 16 December 2015]

Cross reference to other procedural documents

Clinical Diagnostic Tests or Screening Policy and Procedures

Consent and Capacity to Consent to Examination and Treatment Policy

Development & Management of Organisation-wide Procedural Documents Policy and Guidance

Infection Control Policy

Interpreting and Translation Policy

Learning Development and Mandatory Training Policy

Medical Devices Policy

Record Keeping and Record management Policy

Risk Management Policy and Procedure

Staff Mandatory Training Matrix (Training Needs Analysis)

Untoward Event Reporting Policy and procedure

All current policies and procedures are accessible in the policy section of the public website (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet.

13. APPENDICES

13.1 For the avoidance of any doubt the appendices in this policy are to constitute part of the body of this policy and shall be treated as such.

Appendix A: Top Ten Tips Point of Care Testing. MHRA

Top Ten Tips
Point of Care Testing

1 Involve your local hospital laboratory
Your local hospital pathology laboratory can play a supportive role in providing advice on a range of issues including the purchase of devices, training, interpretation of results, troubleshooting, quality control, and health and safety.

2 Management
Many people will be involved in the creation, implementation and management of a POCT service. It is vital that an appropriate POCT coordinator is identified and a POCT committee established.

3 Health and safety
Be aware of the potential hazards associated with the handling and disposal of body fluids, sharps and waste reagents outside of a laboratory setting.

4 Training
Training **must** be provided for staff who use POCT devices. Only staff whose training and competence has been established and recorded should be permitted to carry out POCT.

5 Always read the instructions
…and be particularly aware of situations when the device should **not** be used.

6 Standard operating procedures (SOPs)
SOPs must include the manufacturer's instructions for use.

7 Assuring quality
The analysis of quality control (QC) material can provide assurance that the system is working correctly.

8 Results
Results should be reviewed by appropriately qualified staff with particular reference to the patient's history.

9 Record keeping
…is essential and must include patient results, test strip lot number and operator identity.

10 Maintenance
In order that devices continue to perform accurately they must be maintained according to the manufacturer's guidance.

December 2005