N.B. Staff should be discouraged from printing this document. This is to avoid the risk of out of date printed versions of the document. The Intranet should be referred to for the current version of the document.
# GOVERNANCE POLICY FOR POINT OF CARE TESTING

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POINT OF CARE TESTING GOVERNANCE POLICY

1 INTRODUCTION

1.1 GENERAL

The point of care testing (POCT) policy for Aneurin Bevan Health Board (ABUHB) is designed to reduce the risk to patients from clinical errors in the use of POCT devices. The reduction of risk is achieved through the policy by guidance on selection, training, quality assurance and management of the devices. Quality Assurance in the context of POCT is the process of assuring that the laboratory services involved in the delivery of patient care have been accomplished in a manner appropriate to maintain excellence in medical care. This draws attention to the need for a planned and systematic approach to Quality Assurance of POCT procedures (see Appendix A).

The technology and instrumentation for POCT has improved over the past decade however, the quality of results may be less than that provided in the accredited laboratory. This is due to the following:

1. the analytical process is often simplified, accuracy and precision being sacrificed for ease of operation;
2. there may be inadequate maintenance of the equipment;
3. the lack of analytically trained staff may lead to poor operator technique;
4. quality assurance procedures may not be built into the analytical process as they are in accredited laboratories.
5. Lack of understanding of the limitations of use of the devices and its interferences.
6. Lack of understanding of the pre and post analytical effects.

It is important, therefore, to acquire the right equipment for the tests required; establish maintenance procedures; educate and train non-laboratory personnel; and ensure that quality assurance procedures are implemented and understood.

In considering the medico-legal status, under clinical governance and controls assurance directives and standards, NHS organisations are subject to both legal and statutory requirements relating to the "Duty of Care." This requires employers to provide competent fellow employees, safe equipment and place of work and safe working practices.

The ABUHB has a legal obligation under the Health and Safety at Work Act 1974 and under various regulations to provide training to its employees in the use of work equipment in cases where lack of training will increase the risk of harm to employees or other persons. Other persons include patients.

POCT devices are covered by the ‘medical device management’ as part of the NHS Executive 2002 Governance in the new NHS. As part of the Health Care Commission 2006 and the Standards for Health Services in Wales 2010 (Standards 7 and 16), a
POCT service must satisfy the relevant standards related to Clinical Governance.

In order to be effective, this policy must apply to all testing performed on patients in the care of ABUHB, irrespective of who performs the test or where it is performed, including tests carried out on behalf of the ABUHB by persons employed within Primary Care and other outreach services. Ownership is secondary to safety.

1.2 DEFINITIONS

POCT is defined by the Medical Devices Agency in “Purchase Management and Use of IVD Point of Care Test Devices”, as “any pathology test performed for a patient by a healthcare professional outside the traditional centralised laboratory”. Other terms commonly used to describe POCT include:

- Near patient testing (NPT)
- Bedside testing
- Extra-laboratory testing
- Disseminated laboratory testing.

In this document, the term “user” refers to Registered Medical Practitioners, Nurses, Midwives, other Healthcare Professionals and, in some applications, Healthcare Assistants.

For the purpose of this document, POCT is a term that is applied to tests performed by non-laboratory staff outside an accredited diagnostic laboratory. These tests may be carried out in a wide range of non-laboratory sites, including: A&E, ITU, SCBU, general ward areas, theatres, clinics, outpatient departments, clinics, community care, general practice and pharmacy services (or other third party) commissioned by the ABUHB.

2 POLICY STATEMENTS


2.1 Within the ABUHB this policy is mandatory.

2.2 POCT devices must only be purchased after a case for clinical need has been approved by the POCT Committee. The enhanced Service Group will approve any applications for a Level 4 INR enhanced service. The surgery concerned, will then contact the POCT team for advice and support regarding instrument purchase and suitability. (See Flow chart Appendix B)

2.3 A designated, Laboratory POCT team will take responsibility for providing advice on the purchase of devices, training, maintaining and monitoring the quality of these services. An agreed “Operational Procedure”, which satisfies the site requirement and defines the User and POCT team obligations, is mandatory. This must be incorporated into a Service Level Agreement (SLA), as outlined in the Appendix C.

2.4 There must be close liaison between users and the Laboratory POCT team on all issues relating to POCT.
2.5 All staff who use POCT devices must be authorised, trained and have successfully completed a competency assessment for that specific device. In most instances staff will then be issued with a unique and traceable Operator password/barcode that they will use to gain access to the POCT device.

2.6 POCT which fails to meet the requirements of this policy will be suspended by the ABUHB until compliance can be demonstrated.

3 AIM

This policy and the accompanying procedures are intended to reduce the risk to patients, staff and the organisation that may arise from point of care testing activities.

4 OBJECTIVES

4.1 The policy seeks to ensure that all patients subjected to POCT receive the same high standard of care, and to reduce to a minimum the risk to patients from POCT.

4.2 The policy seeks to ensure that all areas performing POCT:
- follow best practice in all aspects of the procedures undertaken
- adhere to uniform standards across all ABUHB sites
- apply the principles of quality management and continuous improvement
- comply with all appropriate national standards, and demonstrate compliance.

4.3 The policy also seeks to ensure that Point of Care testing within the Health Board works towards attaining POCT UKAS accreditation, by ensuring that all POCT complies with the relevant ISO international standards.

5 RESPONSIBILITIES

APPLICATION OF POLICY

This Policy applies to ABUHB with effect from the 1st May 2012. This replaces the Gwent Healthcare NHS Trust POCT Policy, version 1.

The Policy applies to all new equipment and all existing activity will be reviewed in light of this Policy.

The Policy covers the management and use of all POCT devices as defined by MDA DB2002(03), and WAG (2008). For the purpose of the Terms of Reference outlined below, Point of Care Equipment is defined as those instruments, analysers or devices (except those performing physiological measurements) which are used by non-laboratory personnel and are able to produce test results which would normally be provided by the laboratory. Dry reagent test strips (dipsticks) and associated readers are also included.
The policy relates to all POCT devices used within the ABUHB irrespective of equipment ownership.

The Policy is designed to meet the requirements of the legislation and guidance and must be monitored by the POCT Committee.

The policy also assists in complying with the Standards for Health Services in Wales, (2010 - Standards 16 & 26) and the Welsh Risk Management Standards.

5.1 POINT OF CARE COMMITTEE

5.1.1 General

The appropriate use of POCT as an alternative to laboratory testing must be considered as a clinical governance issue and therefore subject to examination of clinical effectiveness. This is established by a POCT committee to consider these issues. This Committee should be responsible to the governing body of the organization and has the ultimate responsibility for defining the scope of POCT, taking into consideration the clinical need for POCT, its financial implications, technical feasibility, and in ensuring that appropriate measures are in place to monitor the accuracy and quality of POCT.

5.1.2 Terms of Reference

The terms of reference should be drawn up to comply with National guidelines on POCT including, WSAC, MHRA and relevant ISO standards. The Committee will co-ordinate the development and use of POCT devices for the ABUHB. The primary aim of the Committee is to ensure the appropriate use of POCT devices and that the principles of best practice are followed. Cost efficiency, clinical effectiveness and patient safety will be used as the guiding principal for the acquisition of devices.

The Committee will:

1. Agree specification for proposed acquisition of POCT devices or systems and their integration into care pathways. (clinical effectiveness, cost efficiency)
2. Review and advise on the appropriateness of existing POCT devices in the Health Board (clinical effectiveness).
4. Provide expertise and guidance in evaluating POCT devices and to determine their suitability and benefit to patient care (clinical effectiveness).
5. Advise the Health Board on all aspects of POCT including the preparation of Business Cases and specifications for local and OJEC procurements (cost efficiency).
6. Promote the development of technology to ensure accurate patient identification and the integration of POCT results into the patients' records (patient safety).
7. Promote clinical and financial audit of POCT systems to ensure continued value for money (cost efficiency).

The Committee should have the authority to require POCT activity to meet standards and take sanctions (including suspension or withdrawal of service), and the Chairperson should have the authority to take executive action if necessary. The Chairperson will report to the ABUHB Clinical Effectiveness Group.

5.1.3 Composition

The Committee shall consist of representatives of the stakeholders for POCT device use. This will include appropriate ABUHB Pathology Directorate staff, representatives from the Diabetes Specialist Nurses, Community Health and representatives from clinical areas using, or wishing to use POCT. From time to time other staff will be co-opted to the group where needs arise. These will include representatives from Health Board Informatics, Procurement, Pharmacy and Clinical Governance. Meetings will be chaired by a Consultant Chemical Pathologist/Clinical Scientist of the Aneurin Bevan Health Board.

5.1.4 Frequency of Meetings

A minimum of four meetings will be held annually.

5.1.5 Accountability

The POCT Committee is a sub-group of the Health Board’s Clinical Effectiveness Group, which reports to the Quality and Patient Safety Operational Group (see Appendix D for ABUHB Quality & Patient Safety assurance framework).

5.1.6 Communication

The POCT Group will circulate minutes of its Meetings to the Group membership and report to the Clinical Standards and Effectiveness Group.

5.2 MAKING A CASE FOR POCT

5.2.1 Identifying a Need for POCT

Before deciding whether to implement POCT it is essential for potential users to establish a genuine need. This must be evidence based and clearly identify the risks and benefits of introducing a POCT service.

In most cases the unit costs of providing a POCT service is greater than that of using a large scale laboratory. This increased cost must be justified by the benefits gained in the wider economic environment which the POCT activity supports, (e.g. clinical, patient experience). A potential POCT site must establish all the benefits and disadvantages for each POCT procedure, in consultation with the Laboratory POCT team, before proceeding further.
5.2.2 Acquiring the Right Equipment for Analysis

Once a need has been established, the next step is to identify the most suitable device.

Accuracy and imprecision of results, robustness of device and traceability of results all need to be evaluated before acquisition; the Laboratory POCT team will advise on the suitability of devices. Consideration will be given to ensuring comparability of results between POCT and those of the accredited laboratory where patient management is shared. All POCT equipment must comply with the IVD Directive.

Arrangements for back-up services must be established before a POCT service is introduced. The laboratory will be able to help and advise on back up services and may be able to provide confirmatory results when required.

A business case must be produced to demonstrate the clinical and economic benefits (such as potential savings made in consulting, nursing, management and patient time) of POCT together with details of all financial costs of providing the service. They must include all capital costs, including maintenance contracts, EQA and accreditation subscription, consumable costs including IQC and professional costs including staff training, management of POCT programme, operator time and Laboratory POCT team support. All business cases must be sent to the POCT Committee for approval, as outlined in Appendix E.

Within the organisation there is a preferred equipment and consumables list. Please contact the POCT team for further information.

6 RESOURCES

The Point of Care Testing Committee will implement the policy with due regard to the financial restraints on the ABUHB, and will endeavour to proceed so as to minimise the costs of implementation. Many areas within the ABUHB have already applied most aspects of the policy. The Committee and the POCT Co-ordinators will work closely with clinical areas to determine how best to move forward with outstanding aspect of existing POCT and to implement new POCT within available resource limits. A business case will be required for all proposed new POCT, and implementation will not proceed if adequate resources are not available.

7 TRAINING & COMPETENCE

7.1 GENERAL

The Laboratory POCT team has a responsibility to provide appropriate training and employers have a duty to ensure access to that training. Operators must not carry out procedures in which they have not been adequately trained.

Training and competence assessment must be undertaken by a member of the POCT team (or an approved trainer). The POCT supplier may have educators who will help
in training sessions. They will also have useful teaching literature. The POCT Manager has the responsibility to devolve training to an approved supplier. It is essential to agree training schedules for first timers, and establish retraining schedules.

The knowledge/skill requirements include the ability to demonstrate an understanding of the appropriate use of the device, which may include, the theory of the measurement system (chemistry and detector) and appreciation of the pre-analytical aspects of the analysis, including:

- sample collection;
- its clinical utility and limitations;
- expertise in the analytical procedure;
- reagent storage and stability;
- quality control and quality assurance;
- technical limitations of the device;
- response to results that fall outside of predefined limits;
- infection control practices;
- correct documentation and maintenance of the results.

7.2 CERTIFICATE OF COMPETENCE

All staff, including bank & agency staff, who use POCT devices must receive appropriate training, as approved by the POCT Committee, and be in possession of a valid training certificate and/or valid barcode/password before carrying out tests on patients. **Operators’ competence must be objectively and independently assessed** by a member of the POCT team or an approved trainer following the training session and further assessment undertaken at regular intervals.

In accordance with the ABUHB Password Management Policy, Section 3.5 Staff must not share their password with others and Section 3.6 Staff must not use other peoples passwords to access the system. Section 8.2 states that failure to adhere to the Policy may lead to Disciplinary action up to and including Summary Dismissal.


7.3 INTRODUCTION OF NEW POCT DEVICES

New types of devices must not be introduced into any ABUHB clinical area until a valid training programme has been completed. A minimum of 70% of staff who will use the devices to perform POCT in the clinical area, must be trained and assessed before the equipment is used in that area.
7.4 RESPONSIBILITY OF THE LABORATORY POCT TEAM

The Directorate of Pathology has a team of staff dedicated to provide support for POCT, a POCT Manager responsible for implementing and managing the POCT Policy and a Consultant Chemical pathologist/Clinical Scientist as POCT lead for the ABUHB and POCT co-ordinators responsible for the day to day implementation and support of all POCT devices.

The POCT team will:

- Provide advice on all aspects of POCT, including the selection and purchase of POCT devices
- Evaluate POCT devices in terms of trueness, precision, detection limits, interferences, compatibility with the laboratory, robustness of devices and practicability.
- Assist in the production of business cases for POCT
- Provide training for POCT and maintain training register.
- Monitor, evaluate and audit quality assurance and quality control of POCT
- Provide advice on frequency of internal quality control (IQC) and aid in problem solving.
- Carry out external quality assessment (EQA) and provide guidelines of acceptable performance criteria.
- Undertake regular audits to ensure that the quality system is being implemented.
- Monitor compliance with the Organisation’s POCT Policy
- Report to the Organisation’s Point of Care Committee

7.5 RESPONSIBILITIES OF THE POCT USER

POCT site Lead

All areas where POCT is performed must have a designated person (lead) responsible for ensuring implementation of the Policy. This person will be responsible for completing the business case and in ensuring that all operators, have attended a training course approved by the POCT Committee.

POCT User

Users must ensure that:

- Their training is kept up to date.
- Passwords are kept secure and not disclosed or shared
- Appropriate competencies are met
- All records are maintained as instructed. This requires that all patients’ results are recorded.
- IQC checks have been made and recorded. These must be available for review.
- They take part in the EQA programme.
- Lancets and other sharps are disposed of immediately after use, in accordance with the ABUHB Waste Disposal Policy and local Health & Safety Policies and procedures.
• The equipment and the workstation are kept clean and in good working order, and consumables are correctly stored.
• Problems with any aspect of the procedure are promptly identified recorded and reported to the POCT team. Any testing must cease until the problem is corrected and an incident form completed.

8 IMPLEMENTATION
All clinical areas performing POCT must work closely with the POCT Laboratory team, and be compliant with the standards.
The POCT Committee, will continue to monitor all activity including legacy systems and the POC team will endeavour to work with all clinical areas to assist them in fulfilling the requirements of the standards.

9 EQUALITY
Implementation of the policy will ensure that all ABUHB patients receive POCT to the same high standard, wherever they are seen.

10 QUALITY ASSURANCE
POCT operator performance shall be monitored as part of the quality assurance programme. Users of POCT should have a sound understanding of the principles of Quality Assurance such as internal quality control (IQC), External quality assessment (EQA) and audit.
The Laboratory POCT team will advise the user and provide training on quality procedures.

10.1 INTERNAL QUALITY CONTROL
IQC tests must be performed by the user on site at agreed intervals. These are tests done on control material with known values. A protocol to record the results must be agreed, which will include time, date, and operator details, and these must be made available for inspection. Control samples, however, only indicate instrument performance; they do not help in assessing that the sample collection has been done in a correct manner. As poor sample collection has been shown to be a major variable in POCT, all users must be trained and be shown to be proficient in sample collection.

Regular audits of the IQC procedure will be carried out and reports sent to the Directorate Managers. Poor compliance will be reported to the POCT Committee and persistent poor compliance to the Clinical Effectiveness Group.

10.2 EXTERNAL QUALITY ASSESSMENT
This is when samples with unknown values are tested and performance compared against other NHS organisations using the same devices. The Laboratory POCT team can either organise a local scheme or recommend appropriate accredited External Quality Assessment Schemes. Participation is mandatory and failure of a site to make returns on more than three occasions in a rolling year may result in removal of the point of care device by the pathology department. Performance of
the organisation will be monitored by an external agency (EQA organisation). In the case of persistent poor performing sites the matter will be referred to the National Quality Assurance Advisory Panel by the EQA organisers. Failure to improve after this contact will result in notification to the chief executive through the Clinical Standards and Effectiveness group.

10.3 ACCREDITATION

The ABUHB laboratories are registered with Clinical Pathology Accreditation (UK) Ltd and subject to their accreditation system. UKAS have specific standards relating to POCT and the ABUHB are working towards attaining these standards.

10.4 INCIDENT REPORTING

Any clinical incident involving POCT devices must be reported to the governance lead (through the line manager) and reported on DATIX. The POCT team must also be contacted to initiate an investigation.

10.5 CLINICAL EFFECTIVENESS

A quality assurance programme should also periodically review the relative benefits of POCT, monitor the test ordering patterns, carry out audits to verify record keeping, review critical value reports and regularly review IQC and EQA reports and report their findings to the POCT Committee.

11 SAFETY

Needle stick injuries and cross-infection can occur in POCT. Operators must be trained in safety procedures and know the correct procedure if a needle stick injury occurs. Wherever possible a safety device should be used and any injuries should be reported on DATIX. Training in these areas is outside the scope of the Point of Care team but should be covered by the relevant teams within the operators department. Laboratories should take an advisory role on health and safety matters. The requirements of the Health and Safety at Work Act 1974, the COSHH Regulations 2002, the Safe working and the prevention of infection in clinical laboratories and similar facilities 2003, and the Electrical Safety Code for Hospital Laboratory Equipment 1977 will apply to POCT sites.

12 DOCUMENTATION

As POCT is undertaken in wide ranging clinical situations, the policy should be published in a medium such as the organization’s intranet site that allows the widest possible dissemination of information. Documentation must include the management and technical procedures which provide practical detail on how the policy is implemented, with the forms and records providing the evidence of compliance to the policy.

12.1 OPERATIONAL PROCEDURE

A copy of the Operational Procedure for the equipment must be readily available at the workstation. This document must contain:
Principle of examination
Sample requirements
Reagent storage
Calibration procedure (if appropriate)
Testing procedure, use of equipment
Maintenance procedure (if appropriate)
Reading results
Competency and interpretation
Dealing with abnormal or unexpected results
Limitations of procedure
IQC and EQA procedures and Quality Control Record Sheets.
Health and safety
Recording results.

12.2 RECORDS
Records required include:
Training record
Competency assessment and/or certificate of competence
Reagent logs
Service/Maintenance records
Instrument printout/electronic report/hand written report
IQC records/EQA reports/Audit reports
Incident reports & action taken

12.2.1 Training Records
The ABUHB, through the POCT Team, will keep records of formal POCT training as follows:
   Name and location details
   Trainer’s name
   Date of last course attended
   POCT device on which trained and assessed
   Date of assessment
   Expiry date of training

12.2.2 Competence Records
Competency records must be held with the end-user. The records can also be incorporated into a Continuing Professional Development portfolio and act as evidence for the Knowledge and Skills Framework based practice.

12.2.3 Service/Maintenance records
An inventory shall be maintained of all POCT equipment including serial number and unique identification, manufacturer/supplier, date purchased, and service history, including dates out-of-service. Periodic and episodic maintenance of equipment shall be monitored and documented.
12.2.4 Reagent Log

Reagents, kits, and equipment shall be verified prior to routine use and records shall be kept of materials and reagents purchased for POCT that allows an audit trail with regard to any particular test performed. Records must be kept of the batch numbers of the test kits used, including expiry dates for all reagents.

12.2.5 QC records

The results of all quality assurance samples, time, date, and operator details must be recorded and made available for inspection. A procedure must be in place to ensure that the results of EQA and IQC results are readily accessible.

12.3 PATIENT RESULTS / CONNECTIVITY

All new POCT devices should have data processing capabilities, and meet the integration requirements identified by the National Committee for Clinical Laboratory Standards Connectivity Industry Consortium, that device must be linked to the ABUHB’s preferred POCT Data Management System. All POCT devices must conform to the ABUHB POCT IT strategy. This will facilitate patient verification against the appropriate Patient Master Index, and provide the device with accurate patient demographics and unique patient identifiers (e.g. case-note identifier and/or NHS number).

There must be an agreed protocol to record all patient results, including date, time, operator, and device used so that a clear audit trail is established back to the patient.

12.4 DOCUMENT CONTROL

All policies, procedures, protocols, record forms, etc must conform to the ABUHB Policy on Policies and Procedures. All documents must be controlled, including POCT site generated documents. The document control system must comply with recognised Quality Systems, such as relevant ISO Standards. All training manuals are controlled by the POCT Team in QPulse document control system.

13 USE, SERVICE & MAINTENANCE

Equipment that is simple to use will still require maintenance. It is essential that the routine maintenance and calibration of equipment is carried out according to the manufacturer’s instructions. Failure to properly maintain equipment may give misleading or dangerous results. The Laboratory POCT team can advise in setting up maintenance schedules and establish Operating Procedures. A logbook must be provided to document service or maintenance schedules and outcomes where required.

14 FURTHER INFORMATION

Any enquiries regarding this policy should be directed to the POCT Team. Contact details can be found on the ABUHB Intranet.
15 LEGISLATION AND GUIDANCE

15.1 SOME LEGISLATION CONTROLLING THE USE OF POCT DEVICES


11. WHN (Hazard) (87) 34: Blood glucose measurements; reliability of results produced in extra-laboratory area.

12. WHN (Hazard) (89) 64: Blood Gas Measurements; The need for reliability of results produced in extra-laboratory areas.


15. The Electrical Safety Code for Hospital Laboratory Equipment (ESCHLE), 1977


15.2 SOME PROFESSIONAL / NATIONAL / REGIONAL GUIDELINES


15.3 ABUHB POLICIES AND PROCEDURES
These can be viewed on the ABUHB intranet site http://howis.wales.nhs.uk/sitesplus/866/page/39730
APPENDIX A – QUALITY ASSURANCE CHECKLIST

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<tr>
<th>Identify clinical need</th>
<th>POCT site</th>
<th>Laboratory</th>
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</thead>
<tbody>
<tr>
<td>Contact laboratory for advice and consultation</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Prepare business case</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Contact POCT Committee to approve business case</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Agree SLA between laboratory and user</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Provide user training including quality assurance, health &amp; safety, certification</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Write procedures for use, training, documentation, result interpretation</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Secure supply of reagents &amp; consumables</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Interface devices with existing IT</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Staged rollout</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Monitor performance</td>
<td>✓</td>
<td>✓</td>
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APPENDIX B – PATHWAY FOR IMPLEMENTATION OF A LEVEL 4 INR ENHANCED SERVICE.

1. Proposer identifies clinical need for a level 4 enhanced service

2. Proposer contacts the Enhanced Service Group

3. Not agreed in principle
   - NO
   - Further action

4. Agreed in principle
   - Enhanced Service Group informs UKAS approved Laboratory

5. POCT Team contacts GP Surgery to give advice and support regarding Instrumentation suitability and agrees a programme for training and competency assessment.
   - POCT also sets up a SLA for EQA and IQC

6. POCT site prepared/
   - IT Data Management system installed/
   - Equipment/
   - Consumables ordered

7. POCT Team implements
   - Training and competence assessment programme

8. POCT team implements quality assurance programme

9. POCT Team monitors performance:
   - Audits/ EQA/ work patterns/ non conforrmities/ compliance to policy

10. POCT Committee reviews service

Hard Copy Location: (to positively indicate on the hard copy where it has come from)
Authorising Signature:

Status: Issue 2
Approved by: Clinical Standards & Policy Group

Issue date: 5 December 2014
Review by date: 5 December 2017
### SURGERY INFORMATION CHECK LIST

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<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
<th>Action/Date</th>
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<tbody>
<tr>
<td>Have you contacted an appropriate accredited Laboratory for advice and consultation?</td>
<td></td>
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<tr>
<td>Have you secured a supply of reagents and consumables?</td>
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<tr>
<td>Is there a Service Level Agreement between you and the Laboratory?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have agreed Standard Operating Procedures and a training matrix?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you arranged for all users to receive appropriate training and competency assessment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you addressed all Health and Safety requirements?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you able to interface with existing IT?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you arranged to monitor performance?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX C – EXAMPLE OF A SERVICE LEVEL AGREEMENT

This SLA requires a Quality Management System for the planned and systematic approach to POCT. Details to be agreed between the user and the Laboratory POCT team.

1. Specify each application, e.g. glucose testing in GP surgery; well-person screen in Occupational Health Department; Diabetic Clinic; etc.
2. Clearly specify the responsibilities of the Laboratory POCT team and users. Establishing that the methods to be used have been validated and are suitable for the purpose and that the laboratory has the capabilities and resources to support the service.
3. Specify the site, e.g. wards, accident and emergency, outpatient clinics.
4. Specify personnel involved.
5. Specify type of procedure covered
6. Specify the Contact person for: IQC, EQA, QC record books, training, lead trainer, problem solving, maintenance, IT, contracts, health & safety.
7. Define the Training Procedure
   Training must be undertaken by Laboratory POCT team personnel and, if appropriate, in conjunction with the equipment manufacturer. The training procedure must cover:
   a) Basic principles of the measurement.
   b) The intended purpose of the device and demonstration of the proper use of the equipment in accordance with the manufacturer's specification.
   c) Demonstration of the consequences of improper use.
   d) Limitations of use.
   e) Instruction in sample collection, preparation of the patient, Specimen collection and Application of the sample.
   f) Health and safety aspects.
   g) Instruction in the importance of complete documentation of all data produced.
   h) Practical experience of the procedures, including a series of analyses that satisfy the instructor that the trainee is competent.
   i) IQC and EQA procedures.
   j) Dealing with abnormal or unexpected results.
   k) Routine maintenance and calibration of the equipment.
8. Recording patient results
   There must be an agreed protocol to record all patient results, include date, time, and operator so that a clear audit trail is established back to the patient.
9. Specify quality assurance requirements
10. Specify cost of provision of Laboratory POCT team service.

The agreement must be signed by both parties to form a binding contract.
APPENDIX D – ABUHB Quality and Patient Safety Assurance Framework

[Diagram of quality assurance framework]

Hard Copy Location: (to positively indicate on the hard copy where it has come from)
Authorising Signature:

Status: Issue 2
Approved by: Clinical Standards & Policy Group

Issue date: 5 December 2014
Review by date: 5 December 2017
APPENDIX E

PROFORMA FOR BUSINESS CASE FOR INTRODUCTION OF A NEW POINT OF CARE TESTING (POCT) SCHEME

Proposer details:

Name: ..............................................................................................................

Position: .......................................................................................................... 

Directorate: .....................................................................................................

Department/Ward/Section: ................................................................................

Date: ................................................................................................................

POCT Scheme to be introduced: .................................................................

Name of POCT Lead person: .................................................................

Please answer the following questions and provide evidence where applicable.

Completed proposal forms should be forwarded to the Chair of the POCT Committee.

1. Proposed POCT Test.

Please give a brief overview of the proposed POCT scheme. Include information on which group of staff will be performing the testing, where the testing will be performed and which sites / Directorates will be using the POCT under your responsibility as POCT lead.
2. **Clinical Benefits**

Identify the need for this POCT by answering the following questions:

- **a)** What clinical benefits will this POCT Scheme provide?

- **b)** For which group of patients will this POCT Scheme be used and approximately how many patients will this benefit?

- **c)** Is this investigation currently provided by a different mechanism? If so how?

- **d)** Why is the current method not adequate?
3. Laboratory Evaluation

Has there been a Laboratory evaluation conducted on the proposed POCT test? Please provide either manufacturer or laboratory-based data.

4. POCT Equipment and Consumables and Costs.

Give details of all equipment and reagents required for this POCT scheme.

a) List equipment and reagents and state if they are to be purchased, or loan/trial/gift.

b) What is the cost of the proposed POCT? Please provide a detailed breakdown including:

<table>
<thead>
<tr>
<th>Total running costs</th>
<th>Cost per patient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
c) How will this cost be met?

<table>
<thead>
<tr>
<th>Capital Costs</th>
<th>Revenue costs</th>
<th>Professional costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase/lease of POCT equipment</td>
<td>Consumables: reagents / calibrators etc</td>
<td>Staff training</td>
</tr>
<tr>
<td>Ancillary equipment: centrifuges, incubators, pipettes etc.</td>
<td>routine maintenance (including service contract)</td>
<td>Management of the POCT programme</td>
</tr>
<tr>
<td>Working environment</td>
<td>Internal Quality Control material</td>
<td>Staff operator time</td>
</tr>
<tr>
<td>Depreciation</td>
<td>EQA Subscription</td>
<td>Conforming to legal requirements</td>
</tr>
<tr>
<td>Interfacing with information management systems</td>
<td>data-handling system</td>
<td>Laboratory support</td>
</tr>
</tbody>
</table>

|                          | Waste disposal                         |

5. **Laboratory Support**

Have you contacted Laboratory Medicine Directorate for support in carrying out this POCT?

Yes  [ ]  No  [ ]

a) If yes, to whom have you spoken?

b) Was support from the laboratory agreed?

c) If the laboratory presently provides this investigation, what are the annual costs?

d) Has a Service Level Agreement (SLA) been agreed?

e) Who will be providing ongoing service, calibration and repairs?
6. How will this investigation be provided to patients if the POCT scheme is temporarily or permanently unavailable?

   a) How will Internal Quality Control (IQC) be performed?
   b) Which External Quality Assurance (EQA) scheme/s will you subscribe?
   c) Who will provide the training and competency testing for users of the POCT scheme?
   d) Who will be undertaking audit of the service & how frequently?

8. IT and Data Management.
   a) Please describe how the POCT data will be recorded.

   b) Will this be entering the electronic patient record.

   c) Is there a Data Management System available with the proposed POCT Test and has this received Trust IT approval?
Please attach the following documents with 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
- Risk Assessment
- COSHH Assessment
- Training manual
- SLA with Laboratory
- IT approval
- Legal disclaimer for loan/trial/gift-N/A if not applicable.

**Signature of proposer:** ………………………………….. **Date**……………………

**Signature of POCT lead if different from proposer** ………………………………….. **Date**……………………

**Signature of Directorate Manager:** ………………………………….. … **Date**……………………

**Signature of Clinical Director** ………………………………….. **Date**……………………

**Signature of relevant Laboratory Manager:** ………………………………….. **Date**……………………

'Electronic signatures' through receipt of e-mail confirmation by these individuals of their approval would be acceptable to the POCT Committee as well as hard copy signed documents.
Flow Chart for Implementation of a New POCT Test.

Proposer completes proforma for the introduction or replacement of POCT equipment

Submits to POCT Working Group

POCT Working group acts on relevant clinical and management staff.
Cost Benefit analysis.
Staffing implications.
Identify site for equipment

POCT Working Group collects information on equipment

Literature search
ward evaluation
Investigate IT and risk management
Medico legal issues

POCT Working group submits to POCT Committee for Approval

Recommend to proceed

POCT Working Group notify proposer of outcome

POCT manager with training officer and quality manager arrange all SOP's

Implement Training and competence assessment

POCT site prepared/ IT Data Management system installed

POCT Committee monitor and review service

POCT Manager implements audits on patient care, quality (including EQA) and training

POCT commences
APPENDIX F – ABBREVIATIONS

COSHH    Control of Substances Hazardous to Health
UKAS     Clinical Pathology Accreditation (UK) Ltd
EQA      external quality assessment
IQC      internal quality control
IVD      in vitro diagnostics
JWPQA    Joint Working Party on Quality Assurance
MDA      Medical Devices Agency
NPT      near patient testing
POCT     point of care testing
QA       quality assurance
SLA      service level agreement
WHN      Welsh Hazard Notice