

Reference Number: UHB 366 Version Number: 1	Date of Next Review: 12 Sep 2020 Previous Trust/LHB Reference Number: N/A
Point of Care Testing (POCT) Procedure	
Introduction and Aim This document supports the Point of Care Testing Policy. This procedure describes how the Policy will be implemented across the Health Board	
Objectives .1 The procedure seeks to ensure that all patients subjected to POCT receive a high standard of care, and there is minimum risk to patients from inappropriate and misuse of POCT. .2 The procedure seeks to ensure that all areas performing POCT: <ul style="list-style-type: none"> • comply with all appropriate national standards • follow evidence based best practice in all aspects of the procedures undertaken • adhere to uniform standards across all UHB sites, reducing inappropriate variation • ensure that all staff are trained and can demonstrate competence • apply the principles of quality assurance and continuous improvement • maintain high quality records of all results and procedures • ensure the effective, collection, sharing and reporting of high quality data within a sound information governance framework • demonstrate compliance with the policy 	
Scope This procedure applies to all healthcare staff employed or contracted by the UHB to undertake diagnostic testing on patients. This includes those on honorary contracts, students working within the UHB, persons employed by Cardiff University, Public Health Wales, and independent contractors commissioned by the UHB to undertake testing . The procedure also applies to primary care services such as - community dental services, community nursing services, family planning clinics and GP out of hours services. GP contractors are not mandated to follow this policy as they are ultimately responsible for developing their own governance processes, policies and procedures for the quality and safety of POCT. However, it provides a framework for good practice with particular relevance to quality assurance and training, complementing existing guidance, WHC (2017) 034 relevant within that setting.	

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Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be a no negative impact.
Documents to read alongside this Procedure	Point of Care testing Policy Welsh Government, WHC (2017) 034 Policy on the Management of Point of Care Testing (POCT) : What, When and How? http://gov.wales/topics/health/nhswales/circulars/performance-delivery/?lang=en
Approved by	Point of Care Testing Group Quality Safety and Experience Committee

Accountable Executive or Clinical Board Director	Medical Director
Author(s)	POCT Head of Department

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the [Governance Directorate](#).

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	12/09/17	22/09/17	New document – previous Policy UHB 062 has been split into separate Policy and Procedure documents Main changes to UHB 062 <ol style="list-style-type: none"> 1. Reviewed in line with WHC (2017) 034 POCT Policy and Health and Care Standards 2015. 2. Section on information management added. 3. Amended training and competency assessment procedures. 4. Amended section on responsibility 5. Added information on WPOCT 6. Amended all Appendices 7. Added Estates, IM& T pre-installation checklist.

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1 INTRODUCTION

The Point of Care Testing (POCT) Policy and Procedure for Cardiff and Vale University Health Board is intended to promote evidence based practice and reduce the risk to patients from clinical errors in the use of these devices. An example of the devices is provided in Section 3 of this Procedure.

This procedure conforms to the Medicines and Healthcare Products Regulatory Agency (MHRA) guidance: Management and Use of IVD Point of Care Test Devices, the Welsh Government Policy and procedure on the Management of Point of Care Testing: What, when and how? WHC (2017) 034 and the relevant clauses (Standard 3.1, 5.1, 2.9, 2.1, 3.4, 3.5), Health and Care Standards for Wales, 2015.

2 DEFINITIONS

POCT is defined as any diagnostic test undertaken by staff other than a laboratory healthcare scientist, which can include health care support workers, nurses, paramedics, pharmacists, podiatrists, dieticians, dentists and medical staff. This is usually carried out near the patient, and can be in the home, a clinic, in general practice, screening venue, at the hospital, or during transit.

In this document, the term “operator” refers to any Healthcare Professional undertaking a POCT procedure.

3 SCOPE OF DEVICES

The policy and procedure applies to all new and existing equipment used within the UHB irrespective of ownership.

Examples of devices include:

Blood glucose and ketone devices, Urinalysis test strips and devices, Pregnancy test kits and devices, Coagulation analysers, Blood gas and co-oximetry analysers, HbA_{1c} analysers, Haemoglobin and Haematology analysers, Pre-term labour marker analysers, D Dimer devices, Bilirubin analysers, CRP devices, Creatinine devices, Lactate devices, Rapid test kits for infectious disease markers, Procalcitonin analysers, electrolyte analysers, lipid analysers, drugs of abuse kits and devices, alcohol meters, cardiac marker analysers and BNP analysers.

This is not an exhaustive list.

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4 ROLES AND RESPONSIBILITIES

4.1 POINT OF CARE TESTING GROUP

The POCT Group is responsible to the governing body of the organisation and has 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 quality and clinical effectiveness of POCT.

4.2.1 Terms of Reference

The terms of reference will comply with National guidelines on POCT including, WHC (2017) 034, MHRA and ISO 22870.

Patient safety, clinical effectiveness and cost efficiency will be used as the guiding principal for the acquisition of devices.

The Group has the authority to require POCT activity to meet standards and take sanctions (including suspension or withdrawal of service), and the Chairperson has the authority to take executive action if necessary.

The Group will:

- Agree specification for proposed acquisition of POCT devices and their integration into care pathways (clinical effectiveness)
- Evaluate effectiveness of training (patient safety)
- Evaluate effectiveness of Quality Assurance Programme (patient safety)
- Have responsibility for harmonisation of equipment throughout the organization
- Have responsibility for approval of business cases for introduction of POCT devices (cost efficiency)
- Have responsibility for ensuring compliance with the organisational policy and procedure on the management of POCT
- Have responsibility for ensuring compliance with Healthcare Standards in relation to POCT
- Provide an annual report and a summary for the lead executive Director
- Along with the POCT Team work closely with clinical boards to determine how best to move forward with existing legacy devices and to implement new POCT within available resource limits.

The POCT Group is chaired by the Medical Director or his appointee and consists of core membership from clinical users, the POCT Team, Clinical Directors, representation from the Executive Nursing Director, and the Quality and Safety Department. Representatives from other Departments will be co-opted as and when required as detailed in Appendix B. The Group meets 4 times a year.

4.2 RESPONSIBILITY OF THE POCT TEAM

The UHB has a dedicated team of POCT professionals who can provide advice on how to implement and manage the POCT service.

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The POCT team are responsible for:

- Providing advice on all aspects of POCT, including the selection and purchase of POCT devices, the suitability of devices, advice on connectivity requirement, infrastructure requirements and environmental factors.
- Evaluation of POCT devices in terms of trueness, precision, detection limits, interferences, ease of use and robustness to ensure that the device is appropriate for its intended clinical use, the results are compatible with the laboratory method (if indicated) and data integrity and security is maintained.
- Assisting in the completion of the proforma case for POCT.
- Organising and delivering appropriate training. For devices that are connected to all Wales POCT information Management System (WPOCT) a training register is held centrally by the POCT Team. The POCT team will monitor and inform the Clinical Director / Lead Nurse of any lapsed training.
- Developing and monitoring ongoing competency and re-validation of staff undertaking POCT.
- Managing the quality assurance (QA) process including monitoring internal quality control (IQC), registration, distribution and monitoring of external quality assessment (EQA) and audit of the service. See section 7
- Assisting in clinical incidence investigations.
- Monitoring, evaluating and auditing the clinical effectiveness of the service to the respective Clinical Boards including activity
- Reporting to the organization's Point of Care Testing Group.
- Escalating any clinical incidence issues, QA issues or concerns to the Clinical Director / Lead nurse.

4.3 RESPONSIBILITY OF THE CLINICAL BOARDS

4.2.2 Clinical Director (for the Directorate undertaking POCT)

The Clinical Director has a responsibility to:

- Ensure that there is a clinical requirement for POCT and the integration of POCT devices into care pathways is clinically effective. The Clinical Director will have ultimate responsibility for the patient result.
- Complete and ensure that the proforma case for POCT is authorised by the POCT Group before a POCT service is introduced.
- Identify arrangements for back-up services with the Pathology Laboratory (if appropriate) before a POCT service is introduced.
- Address any poor performance and non-compliance issues or failure to comply with the POCT Policy and Procedure.
- Report and investigate clinical incidences, with regards to POCT.
- Monitor clinical effectiveness.

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- Ensure that staff have access to training.
- Ensure that IQC checks are carried out on the devices as advised.
- Ensure that EQA checks are carried out on the devices as advised and address any poor performance issues.
- Ensure awareness of regulations with regards to EQA poor performance
- Ensure that all operators have undertaken a training course approved by the POCT Team. A training register of staff authorised to perform POCT should be maintained by each Directorate. For devices that are connected to WPOCT the training register is held centrally and therefore there is no requirement to hold a local register.
- Ensure that all the operators have the necessary skills and competence to undertake these tasks.
- Ensure that the infrastructure and working environment is appropriate to undertake diagnostic testing.

4.2.3 POCT Operator

Operators must ensure that:

- They do not undertake POCT unless trained and signed off as competent
- Their training is kept up to date. For most devices this is a 2 year period with either e-learning or an approved training course. For devices that are connected to WPOCT the operators will be alerted 3 months prior to their expiration date. Refer to Section 9. However, the operator should also keep a copy in their training file.
- They have a valid ID badge to use the devices. They must contact the POCT Team if they have either lost or replaced their ID badge.
- They **do not** share ID Badges with other staff.
- Appropriate competencies are met.
- The ID of the patient is confirmed before commencing the test – please refer to the UHB policy on patient ID.
- All patients' results are recorded on approved Health Board documentation, stating date, time of test and operator undertaking test. For devices that are connected to WPOCT a permanent record will also be available in the Wales Clinical Portal (WCP).
- At the required frequency, IQC checks have been made and recorded. These must be documented and available for review. For devices that are connected to WPOCT an electronic record is sufficient.
- At the required frequency, EQA checks have been made and recorded. These must be documented and available for review. For devices that are connected to WPOCT an electronic record is sufficient
- They comply with Health and Safety, UHB Waste Disposal, Decontamination and Infection, Prevention and Control Policies and Procedures
- The equipment and the workstation are kept clean and in good working order, and consumables are correctly stored.
- They escalate problems with any aspect of the POCT procedure: these must also be reported to the POCT team. Any testing must cease until the problem is corrected and an incident form completed.

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4.2.4 Independent Contractor

All independent contractors commissioned by the UHB to perform POCT must:

- Ensure that all operators have undertaken an approved training course. Maintain a training register of staff authorised to perform POCT.
- Ensure that all the operators have the necessary skills and competence to undertake these tasks.
- Ensure that all operators carry out IQC checks on the devices as advised.
- Carry out EQA checks and address any poor performance issues.

5 HOW TO IMPLEMENT A POCT SERVICE

5.1 IDENTIFY A CLINICAL NEED

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

There is good evidence that optimization of pathways using well designed use of POCT can be both clinically effective and cost efficient. However, POCT can offer little or no benefit in a poorly designed pathway and can be more costly than traditional laboratory tests. Potential sites must discuss their requirements with the POCT team before purchasing POCT equipment or kits.

5.2 IDENTIFY THE RIGHT EQUIPMENT

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 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 pathology laboratory where patient management is shared.

The Clinical Director or designated deputy must identify and agree arrangements for back-up services with the pathology laboratory before a POCT service is introduced (if 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 infrastructure costs such as building, electrical and IT port installation costs, maintenance contracts, clinical risk assessment, EQA fees, consumable costs including IQC and professional costs including staff training, management of POCT programme, operator time and POCT Team and Pathology Laboratory support. All business cases must be sent to the POCT Group for approval, Appendix E - Proforma for introduction of a new POCT.

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Within the organisation there is an approved list of equipment and consumables. Please contact the POCT team for further information. Only equipment and consumables approved by the Health Board must be used.

Once a device has been approved by the POCT Group the next step is to procure the device. Please follow the procurement process as detailed in the Standing financial instructions for Local Health Boards.

A Flow chart for the implementation of a new POCT service is provided in Appendix F. A new device must not be implemented until a minimum of 70% of staff have completed an approved training programme.

6 TRAINING AND COMPETENCE

6.1 TRAINING

All staff who use POCT devices must receive appropriate training and be in possession of a valid competence assessment certificate before carrying out tests on patients.

Training must be delivered by a member of the POCT team (or an approved cascade trainer). The POCT Manager has the responsibility to devolve training to an approved supplier. It is essential to agree training schedules for initial training, and establish retraining/refresher schedules.

For devices that are connected to WPOCT (see section 10) the training record is held electronically and operators are identified by their ID badge number. Operators must have a valid ID badge number to use the devices. **Please contact the POCT Team if you have either lost or replaced your ID badge.**

The knowledge/skill requirements include the ability to demonstrate an understanding of the appropriate use of the device, and appreciation of the pre-analytical aspects of the analysis, including:

- Intended purpose of the device
- Consequences of improper use
- Limitations of use
- Patient preparation, sample collection and application
- Health and Safety awareness
- Reporting & recording of results
- A practical demonstration
- How to deal with abnormal or unexpected results?
- What routine maintenance and (calibration) of the equipment is required?
- When and how to do IQC?
- What to do if the IQC fails?
- When and how to do EQA?
- What to do if the EQA fails?
- Competence assessment procedure

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- How and when to undertake refresher training or e-learning?

6.2 COMPETENCE ASSESSMENT

Operators' competence must be objectively and independently assessed by an occupationally competent healthcare professional until the appropriate number of practical observations have been met.

Nursing competencies are approved by the Professional Practice Development Nurse Group. Healthcare staff wishing to obtain credits for these competencies can do so via Agored Cymru. A wide range of competences on POCT are available from Agored Cymru as part of the Credit and Qualification framework, Wales (CQFW) competence based units.

6.2.1 Ongoing competence

Following assessment, the individual operator is responsible for maintaining their continued competence in the use of the device. E-learning and performance monitoring can be used to maintain competence.

For most devices the certificate of competence is valid for a 2 year period. For devices that are connected to WPOCT the training record is held electronically and operators will be alerted 3 months prior to their expiration date. If the operator has failed to undertake refresher training in that period, they will be unable to use the device.

7 QUALITY ASSURANCE, AUDIT AND PERFORMANCE MONITORING

Operators of POCT should have a sound understanding of the principles of quality assurance (QA). This is a systematic process of verifying that a product, or service, is meeting the specific quality requirements for that product or service.

For POCT this includes the measures taken to ensure investigations are reliable and safe and includes the following:

- Having the right governance structure in place
- Correct identification of the patient
- Choosing the right test
- Obtaining the right sample (at the right time)
- Undertaking the right test procedure
- Undertaking IQC and EQA checks
- Recording results promptly and correctly
- Interpreting results accurately
- Taking appropriate action
- Documenting all procedures and actions
- Identifying and preventing errors
- Implementing quality improvements

The tools used to assure and monitor these processes include:

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- IQC
- EQA
- Clinical audit
- Risk Management

The POCT team will advise and provide training on Quality Assurance procedures.

7.1 IQC

This is a means of checking that the results are safe before they are issued. The operator knows what value to expect and knows what range of values is acceptable for that control material.

If the value is within this range it provides reassurance that the system is working correctly. If the values are outside the range this alerts the operator that there is a potential problem with the test process.

IQC results will be automatically recorded on devices connected to WPOCT. This will include the time, date, operator details and any comments. Some devices will also alert the operator to perform the IQC test if it is outside the agreed frequency and prevent testing on the patient until this has been successfully completed. This process facilitates compliance with recommended IQC frequency and prevents the inadvertent use if the device fails.

7.2 EQA

This is when samples with unknown values are tested and reviewed by an external agency. They may compare results from operators within the UHB against those obtained from a number of other different organisations using the same device to determine the degree of variation and whether the results are within this acceptable variation. Alternatively, the results may be compared against a reference laboratory result, the “true” result. These agencies provide useful information on the degree of variation in diagnostic accuracy and reliability of POCT devices across the UK. The POCT Team will register the POCT service with the appropriate accredited agency (EQA provider), distribute the samples, report the results to the EQA provider and liaise with them and the respective Directorates on the performance of the UHB.

What happens if the individual operator or UHB site gets a poor report?

Non compliance (e.g. a no return) and poor performance reports (e.g. if the results were outside the acceptable limits) are monitored by the POCT Team in the first instance. However when the performance is outside the acceptable criteria on two out of three consecutive occasions, the EQA provider will contact the UHB. In the first instance they will work with the POCT team to provide assistance to resolve issues. Failure to improve performance over the next 3 months will lead to further contact by the EQA provider. In the UK persistent poor performance (i.e. no improvement after two contacts) will result in referral to the National Quality Assessment Advisory Panels (NQAAP). If no further improvement is made within a reasonable time period after NQAAP intervention, Health Inspectorate Wales is informed.

A flow chart on how poor compliance and performance is dealt with is indicated in Appendix G.

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7.3 INCIDENT REPORTING

Any clinical incident involving POCT devices must be reported to the line manager and the incident recorded in eDatix. The POCT team must also be contacted to initiate an investigation. The POCT device must also be quarantined until further notification.

7.4 CLINICAL EFFECTIVENESS AND AUDIT

The POCT Team will 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 Group.

However it is the responsibility of the Clinical Director to undertake regular clinical audit to monitor the clinical effectiveness of the service.

Compliance with the POCT Policy and Procedure will be monitored by the POCT Team as part of the Healthcare Standards Annual Review.

The following are examples of outcome based metrics.

Outcome	Metric
Has this intervention resulted in improved patient experience?	e.g. patient satisfaction surveys to identify whether more convenient, greater awareness or greater self motivation to manage condition.
Has this intervention resulted in improved disease outcome?	e.g. rate of secondary complications, improvement in symptoms, re-admission, urgent acute admissions, survival rate percentage of patients with improved diagnostic test .
Has this intervention resulted in improved treatment optimisation?	e.g. side effects, quality of life
Has this intervention resulted in a cost reduction?	e.g. reduction in staff resource, avoidance of transport cost, reduction of admission to secondary care, reduce length of stay.

8 ACCOMMODATION AND ENVIRONMENT

The working environment must be suitable to undertake POCT and the facilities allow for the correct performance of the test e.g. temperature and adequate lighting. There should be adequate facilities available for storage of kits and consumables and consideration given to patient privacy, comfort and needs during sample collection.

Work areas should be clean and well maintained and clinical samples and materials used in a manner to prevent cross infection. Appropriate decontamination procedures should be used in the event of clinical sample spillage and all devices and equipment should be decontaminated prior to moving to another area or returning to the manufacturer or to the POCT Team

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Adequate power and network ports should be available and installed in a safe manner. Please refer to Appendix H - Pre-installation Checklist - IM&T & Estates

9 INFORMATION MANAGEMENT

Wherever possible, POCT devices that allow connectivity to WPOCT must be used. This ensures that the operator ID, patient ID, patient results including the date and time is recorded in the Laboratory Information System (LIMS) and the Wales Clinical Portal (WCP). This minimises subjectivity, transcription errors and loss of information, ensures positive patient verification on the device, facilitates sharing of information, eliminates duplication, and provides a full audit trail of the data.

The system prevents untrained operators using the POCT device, can alert users to undertake IQC, or undertake refresher training, facilitates quality assurance monitoring, operator and equipment performance, and non-compliance surveillance thus reducing clinical risk to the organisation

The system facilitates workload monitoring and test ordering patterns providing business intelligence on POCT activity for each Clinical Board.

The appropriate IT network ports or wireless access point must be in place to enable connectivity.

9.1 PATIENT RESULTS

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.

10 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 in accordance with the Infection Control Protocol for Needlesticks and Other Injuries.

11 DOCUMENTATION

11.1 OPERATIONAL PROCEDURE

A copy of the Operational Procedure for the equipment must be readily available at the ward area. For most applications this is the "Red folder" provided by POCT Department.

Additional information for Cascade trainers should include:

- Guidance for assessors
- Training outline
- Cascade trainer certificate

11.2 RECORDS

Cascade trainers and Assessors must retain the following:

Record of staff training (Cascade trainers)

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Records of staff assessment completed

Directorates must retain the following:

- Warranty/ Service/ Maintenance records of equipment (including serial numbers). For equipment > £5K a record should also be made in the asset register.
- Reagent / strip lot number/ kit numbers (including expiry dates).
- Patient results (Instrument printout / electronic report)
- IQC records / EQA reports / Audit reports
- Incident reports & action taken

For most devices connected to WPOCT, training records, patient results, IQC records, EQA records and reagent/ strip lot numbers are held electronically in the database and it may not be necessary for Directorates to retain full paper copies. Please check with the POCT Team.

11.2.1 Training Records

There are a small number of devices where connection to WPOCT is not available. For these devices, Directorates must maintain records of formal POCT training as follows:

- Name and location details
- Trainer's name
- Date of training course POCT device on which trained and assessed
- Date of assessment
- Training content version
- Expiry date of training

11.2.2 Competence Records

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

11.2.3 Service / Maintenance Records

An inventory must 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.

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 POCT team can advise in setting up maintenance schedules. A logbook must be provided to document service or maintenance schedules and outcomes.

For devices connected to WPOCT, details of all equipment are held electronically in the database and it may not be necessary for Directorates to retain full paper copies.

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11.2.4 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 date opened and expiry dates for all reagents.

11.2.5 Quality Control (QC) Records

A procedure must be in place to ensure that the results of EQA and IQC are readily accessible which includes: time, date, and operator details.

12 DOCUMENT CONTROL

All policies, procedures, protocols, record forms, etc must conform to the UHB Management of Policies, Procedures and Other Written Control Documents Policy and Procedure. All documents must be controlled, including POCT site generated documents. The document control system must comply with recognised Quality Systems, such as ISO 22870. All training manuals are controlled by the POCT Team in Q-Pulse document control system.

13 IMPLEMENTATION

The Point of Care Testing Group will implement the policy and procedure with due regard to the financial restraints on the UHB, and will endeavour to proceed so as to minimise the costs of implementation. Many areas performing POCT already work closely with the POCT team, and are compliant with the policy and procedure.

14 FURTHER INFORMATION

This Policy and Procedure will be made available on the UHB Intranet and Internet sites.

Further information on POCT is available under **POCT services** on the UHB Intranet.

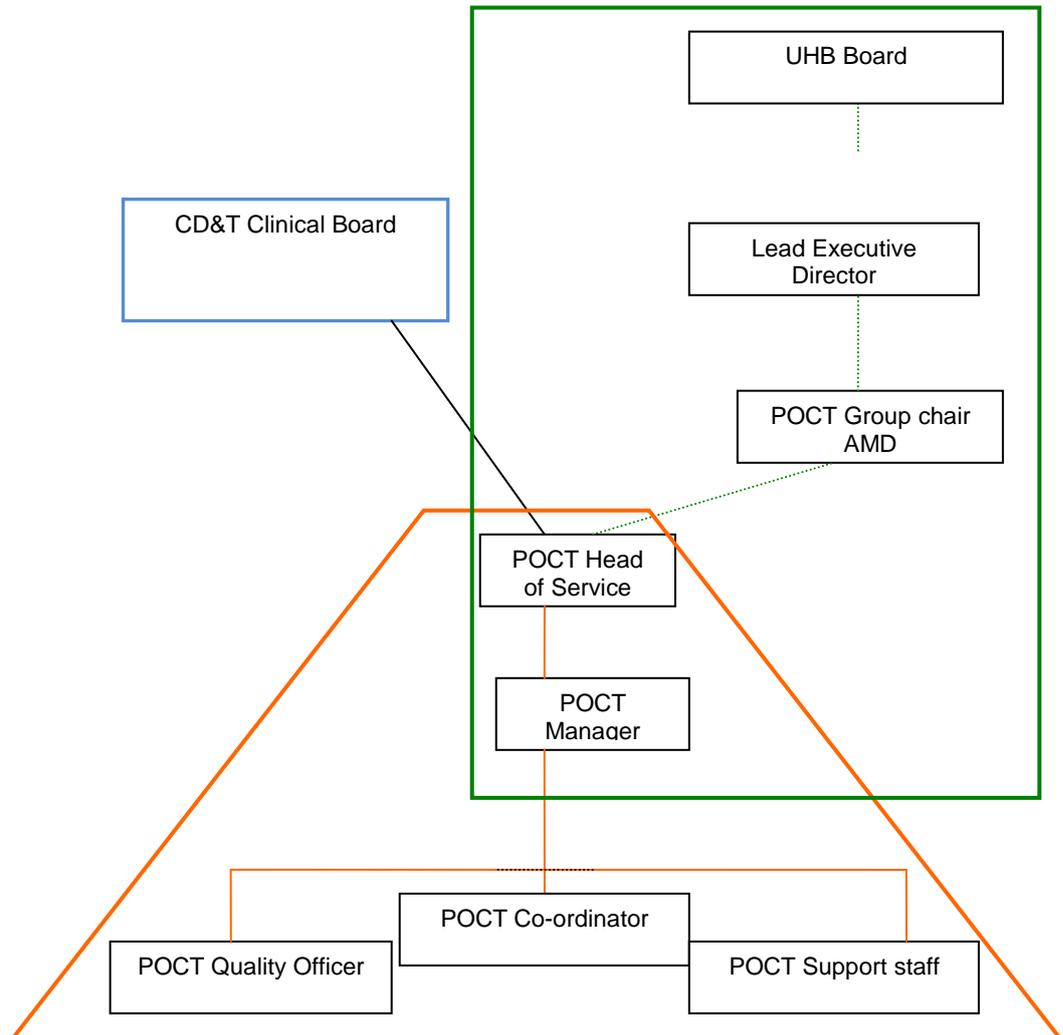
Any enquiries regarding this Policy and Procedure should be directed to:

POCT Head of Department	02920 748332	UHW ex 48332
POCT Manager	02920 745411	UHW ex 45411

15 APPENDICES

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APPENDIX A - POINT OF CARE TESTING SERVICE MANAGEMENT STRUCTURE



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APPENDIX B – MEMBERSHIP OF POCT GROUP

The POCT Group will consist of core membership of clinical users and the POCT team with representation from a wide variety of other departments co-opted as and when required.

Membership

The Medical Director or his appointee (Chairperson)	}	Core members
POCT Head of Department		
POCT Manager		
Clinical Directors – e.g. Director of Emergency Medicine, Director of Primary Care)		
POCT Nurse Lead (representing the Executive Nurse Director)		
Chair Medical Equipment Group		
Quality and Safety Manager		
Representative from:	}	Co-opted members
Learning and Education Department		
Information Management & Technology Department		
Clinical Engineering Department		
Pharmacy Department		
Laboratory Medicine Quality Manager Infection, Prevention & Control Department		

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APPENDIX C – PRE-IMPLEMENTATION CHECKLIST

Question	Yes/No	Action/Date
Have you identified a clinical need which is evidence based?		
Have you contacted the POCT Team for advice and consultation?		
Have you undertaken a cost assessment? Examples of what to consider are in App E		
Have you undertaken a Risk assessment?		
Is the device on the UHB approved list of equipment?		
Have you addressed all Health and Safety requirements?		
Are you able to interface the device with WPOCT?		
Have you undertaken a site assessment – App H		
Have you discussed a “back up contingency” service with the Pathology Laboratory?		
Is there an agreed Service Level Agreement between you and the POCT Team?		
Do you have written operating and training procedures in place?		
Have you arranged for all users to receive appropriate training and competency assessment?		

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APPENDIX D – EXAMPLE OF A SERVICE LEVEL AGREEMENT

This SLA requires for the planned and systematic approach for the implementation of POCT. Details to be agreed between the Directorate and the POCT team.

1. Specify the device, e.g. blood glucose, blood ketone, urinalysis, INR.
2. Specify the site, e.g. wards, accident and emergency, outpatient clinics.
3. Specify the staff group that will undertake the testing, e.g. HCSW, registered nurse, medical students, the proposed number of staff..
4. Specify the application of the device e.g. INR testing as part of stroke pathway in acute care, INR level 4 testing in general practice, HbA1c for diabetes diagnosis.
5. Specify the Directorate/ Site Contact person for POCT :
6. Specify the details of service provided by the POCT Team e.g.
 - Agree number of staff per training session and number of training sessions per year
 - Agree frequency of IQC and EQA
 - Agree frequency of audits and format
 - Agree troubleshooting support and turnaround time – telephone / face to face
 - Agree workload reporting and frequency
 - Agree any backup service (if appropriate).
7. Specify the responsibility of the Directorate e.g.
 - Agree who is responsible for providing ongoing maintenance, calibration and repairs?
 - Agree lines of communication and contacts
 - Agree who organizes training rooms/ training consumables
 - Agree whether cascade training can be used and how trained operators will be notified to the POCT Team
 - Agree frequency of contract review.
8. Agree cost of provision of service provided by POCT team as specified in 6.

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APPENDIX E - PROFORMA FOR INTRODUCTION OF A NEW POCT

Proposer details:

Name:

Position:

Clinical Board:

Directorate/ Site/Ward/:

Cost Centre code:

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 POCT Manager for submission to the POCT Group for approval.

1. Proposed POCT Test

Is the proposed test to be used in a routine clinical or R&D setting?

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 POCT under your responsibility as POCT lead.

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2. Proposed Benefits and Clinical Effectiveness

Please describe implementation of POCT into clinical pathway with proposed benefits to patient. Include any guideline /evidence/ audit information as deemed appropriate. Identify the need for this POCT by answering the following questions:

a) Please describe the current and proposed changes in the patient pathway

b) What health care benefits will this POCT Scheme provide?

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

d) Is this investigation currently provided by a different mechanism? If so how? And why is this inadequate?

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3. Evaluation of Proposed Device

Has the POCT Team undertaken an evaluation on the proposed POCT test?
Please provide data from either manufacturer or POCT Team.

Evaluation Checklist

Name of device and Supplier	
Details of method used by device	Type of assay e.g. immunoassay, HPLC etc. In house or kit (attach SOP or kit insert)
Source of reagents/analyser	(in-house/commercial)
Fluids that are valid	e.g. serum, urine, CSF, ascites, pleural
Relevant references	
Specimen requirements	Patient preparation Anticoagulant /preservative Minimum volume (include dead volume) Stability Sample handling
Comparison to laboratory method	Attach regression plot Attach difference (Bland-Altman) plot- <i>(usually provided by supplier or in-house evidence evaluation data inc. prepared and authorised by evaluation lead)</i>
Linearity	
Traceability Uncertainty	
Matrix effects	Lipaemia Hyperproteinaemia Icterus Haemolysis Ion suppression
Interferences / Cross-reactivity	
Precision	Intra and inter assay CV
Sensitivity / Technical limits of detection	state concentration and define method e.g. precision profile concentration relating to a CV of 20%, signal to noise ratio
Reference ranges Source of reference range	
Calibration and on-board reagent stability of automated assays	
Is the assay CE marked	
Internal Quality Control (IQC)	Source of material, Levels Please state clinical decision points
External Quality Assessment Scheme (EQA)	If no EQA details (numbers, frequency and centres participating). If none available please state.

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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:
Please refer to **Table 1** below to help calculate costs:

Total running costs	
Cost per patient	

c) How will this cost be met and has funding been agreed by the Finance Lead?
Please submit confirmatory documentation

a) Please describe the current and proposed changes in the patient pathway

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Table 1 Cost Considerations

Capital Costs		Revenue costs		Professional costs	
			Annual		Annual
Purchase/lease of POCT equipment/		Consumables: reagents / calibrators etc		Staff training	
Ancillary equipment: centrifuges, incubators, pipettes etc.		routine maintenance (including service contract/ Warranty agreement)		POCT Team support costs : <i>please refer to SLA:</i>	
Infrastructure - Network IT ports and connection costs. Power sockets / connector leads		Internal Quality Control material		Staff operator time	
Estates/ shelving/ construction work if required		EQA Subscription		Conforming to legal requirements	
New Interface for WPOCT		NWIS annual charge for WPOCT		Laboratory support (if appropriate)	
Depreciation		Waste disposal/ Decontamination/ IP&C possible costs			

5. POCT TEAM SUPPORT

If this is not being provided by the POCT Team, please provide details

Have you contacted the POCT Team?

Yes

No

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a) If yes, to whom have you spoken?
b) Was support from the POCT Team agreed?
c) If the Pathology laboratory presently provides this investigation, have you informed them of your intentions?
d) Has a Service Level Agreement (SLA) been agreed by all stakeholders?
e) Who will be providing ongoing maintenance, calibration and repairs? Details to be included in SLA agreement

6. QUALITY ASSURANCE

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

7. CONTINGENCY PLANNING / BACK-UP PROCEDURES

a) How is the test to be provided if POCT is unavailable?
b) Have you agreed a back up service from the Pathology Laboratory?. Please provide details.

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8 RISK ASSESSMENT

Refer to UHB Risk Assessment Procedure for scoring matrix

Activity / Tasks	Potential Risk What could go wrong?	Impact	Likelihood	What procedures have I implemented to mitigate risk?
identifying the patient	wrong patient			positive patient identifiers. name, date of birth electronic ID via CRN/ NHS no.
taking the correct sample	sample contaminated: <ul style="list-style-type: none"> • by food / drink • by alcohol wipe • by interstitial fluid • by IV fluid • wrong anticoagulant inappropriate sample • blood stained urine • patient dehydrated or in peripheral shutdown 			user understands pre-analytical effects competence assessed
undertaking the testing	<ul style="list-style-type: none"> • incorrect sample volume • incorrect filling • reagents / strips contaminated • stored at incorrect temperature or humidity • Device faulty 			user trained and assessed as competent electronic operator lock out IQC check of reagent strips and device – QC lock out if outside limits temperature indicators on reagent boxes. electronic recording of strip information / errors
recording the result	<ul style="list-style-type: none"> • transcription or transposition of results – poor light/ busy 			electronic transfer of data to clinical portal/ patient notes audit trail of date / time / operator
interpretation of the result	interferences <ul style="list-style-type: none"> • drugs • galactose / maltose • haematocrit effects dehydrated / shut down			user trained in limitations of procedure user aware of pre-analytical effects
acting on the result	Not acting on an abnormal result			user trained on critical ranges and alerts appropriate personnel.
Infection control	Not using lancing devices appropriately Devices not decontaminated Work area not clean			user trained and aware of decontamination, sharps and waste disposal policy and procedure
Assessors Name (s)		Signature (s)		
Position (s)		Review Period		

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If the risk is scoring 6 or above, using the Cardiff and Vale University Health Board Risk Assessment and Risk Register Procedure for a more in-depth assessment must be undertaken using the General Risk Assessment Form – Part 2 Please refer to UHB General Risk Assessment form Part 2

9. **INFORMATION MANAGEMENT**

Is the device interface available for connection to the All Wales POCT Platform (WPOCT)? If yes, has this been tested and approved by POCT Team?

If not, please describe how the operator details, patient results, IQC, maintenance and error logs will be recorded.

10. **AUDIT**

Once POCT has been implemented it will need to be audited against ISO standards for POCT and the Healthcare Standards. Please state nominated audit lead and describe any further audits demonstrating clinical effectiveness.

11. **GOVERNANCE AND CLINICAL INCIDENT REPORTING**

- a) What governance procedures are in place to ensure that clinical incidents/ adverse incidents are monitored?
- b) Nominated Quality and Safety Lead for incident investigation and Datix recording.
- c) Nominated Lead for EQA non-compliance and reporting to NQAAP, if necessary.

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Checklist:-

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.

- Risk Assessment
- Health and Safety Assessment
- POCT Documentation
- SLA with POCT Team
- IT approval
- Legal disclaimer for loan/trial/gift - N/A if not applicable

Signature of Proposer: **Date:**

Signature of Directorate Manager: **Date:**

Signature of Directorate Finance Manager: **Date:**

Signature of Clinical Director: **Date:**

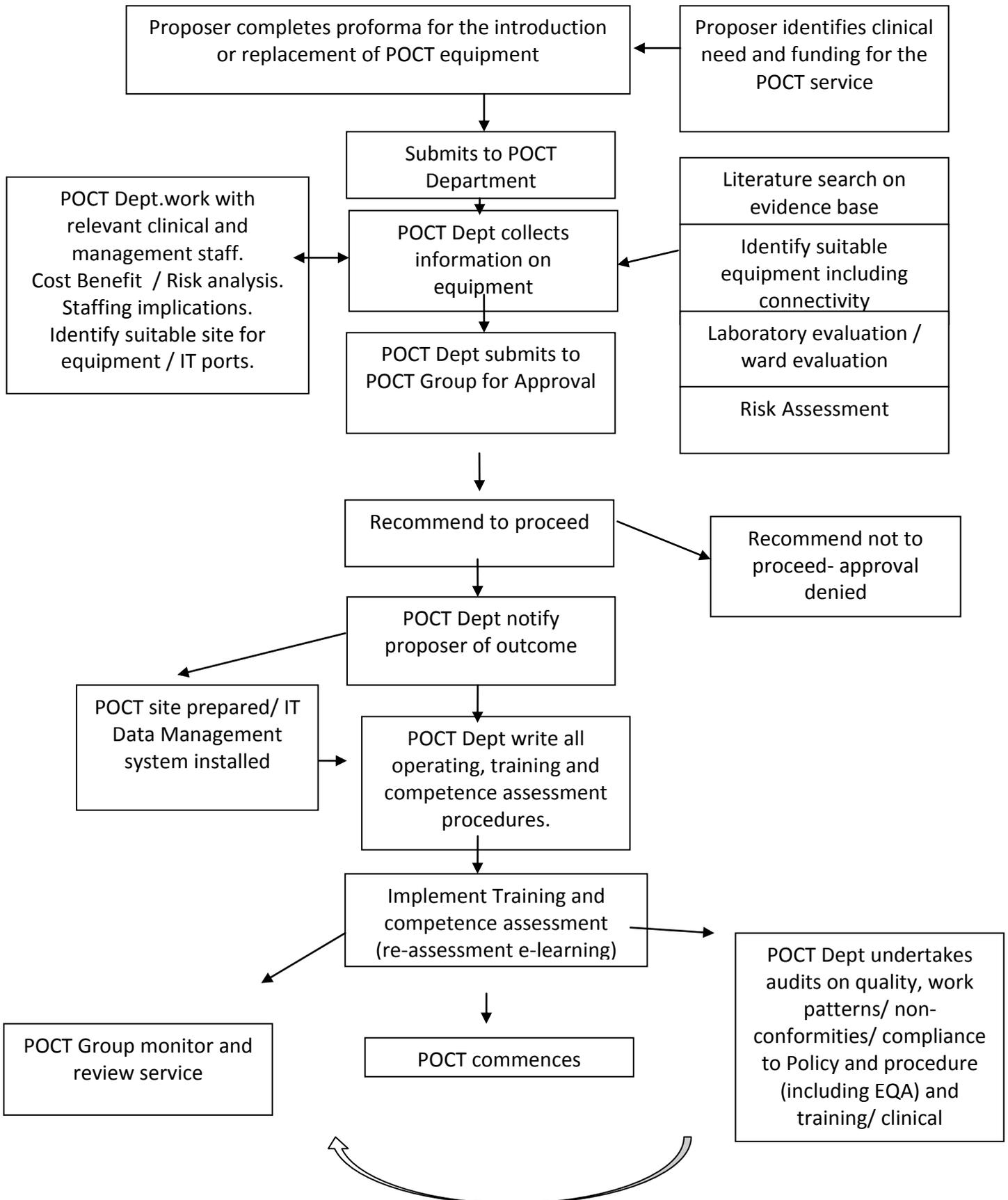
Signature of POCT Team Manager: **Date:**

'Electronic signatures' through receipt of e-mail confirmation by these individuals of their approval would be acceptable to the POCT Group as well as hard copy signed documents.

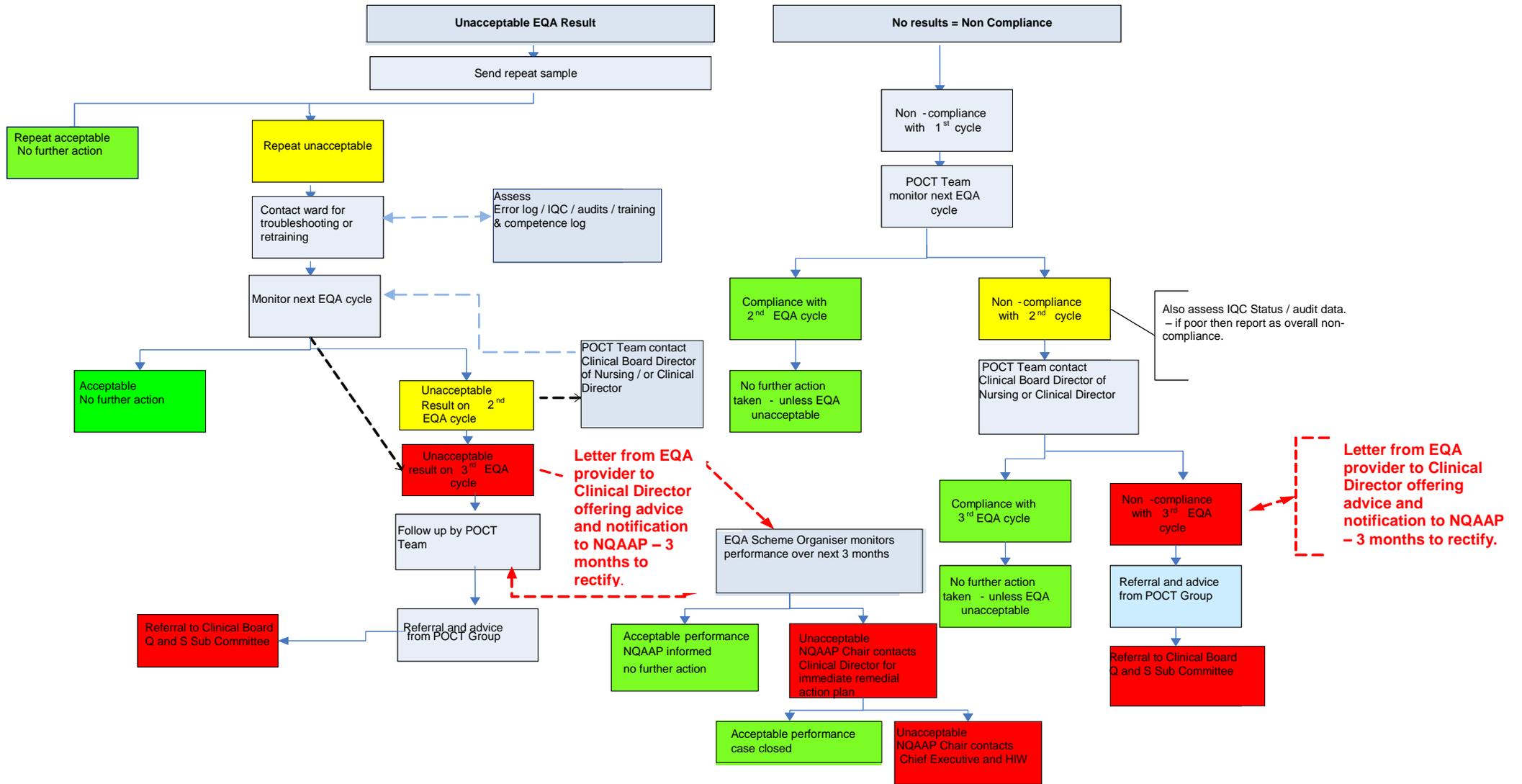
<u>Feedback from POCT Group / Date:-</u>
<u>Feedback from Clinical Lead / Date:-</u>

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APPENDIX F – FLOW CHART FOR IMPLEMENTATNG A NEW POCT SERVICE



APPENDIX G – NO RESULTS RETURNED AND POOR PERFORMANCE CHART



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APPENDIX H - POCT PRE-INSTALLATION CHECKLIST – IM&T AND ESTATES

ACCOMMODATION AND ENVIRONMENTAL CONDITIONS	Actioned / Date
Are storage space and conditions available and maintained to ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results, and any other items that could affect the quality of interpretation of results?	
Does the POCT facility have adequate storage and handling facilities to maintain reagents and consumables in a manner that prevents damage or deterioration and in accordance with manufacturer's specifications? Is extra shelving required and does Estates/ Planning Dept. need to be contacted? Is there an associated cost?	
Is the environment suitable for the tasks to be undertaken? (e.g. access to areas affecting the quality of examinations should be controlled; medical information, patient samples and POCT resources are safeguarded from unauthorised access). Is consideration given to the accommodation of patient privacy, comfort and needs during sample collection?	
Do the facilities allow for the correct performance of the examination i.e. temperature and light sensitive and adequate lighting for visual sources? Also consider impact of:- energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.	
Are clinical samples and materials used in examination processes stored in a manner to prevent cross contamination?	
Is the POCT facility maintained in a functional and reliable condition Are work areas clean and well maintained? e.g. housekeeping and cleaning	
Is there effective separation between incompatible activities i.e. multiple use of the room?	
IM&T / ESTATES / PLANNING REQUIREMENTS	
Are there adequate IT Network Points available? If so, are the ports live and functioning? <i>A walk through will identify if the area has sufficient outlets and if they are live, if not there is a charge. (see below)</i>	
If the port needs to be activated, is there an associated cost?	
If no ports available, is cabling required at extra cost? <i>If the work is carried out on a weekend there is an additional cost to cover weekend work, please contact IM&T</i>	
Is electrical power available? <i>If not please contact Estates</i>	
Consider possible logistical difficulties if considering implementing POCT in sluice rooms with no existing power or network ports. <i>If new outlets are required, IT would need to survey the nearest Hub to make sure there is spare capacity. If there is no capacity in the local Hub then a different hub would need to be identified, however there is a limitation on the length of the data run of <100m from Hub to outlet.</i>	

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APPENDIX I – ABBREVIATIONS

EQA	external quality assessment
IQC	internal quality control
ISO	international standards organisation
IVD	in vitro diagnostics
JWPQA	Joint Working Party on Quality Assurance
LED	Learning Education and Development
MHRA	Medicine and Healthcare Products Regulatory Agency
NMB	Nursing and Midwifery Board
NPT	near patient testing
POCT	point of care testing
QA	quality assurance
SLA	service level agreement
WHN	Welsh Hazard Notice
WSAC	Welsh Scientific Advisory Committee
WCP	Welsh Clinical Portal
LIMS	Laboratory Information Management System
WPOCT	all Wales POCT information Management System