# POINT OF CARE TESTING POLICY

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Compiled by: Pathology Department Ashford and St Peter’s Hospitals NHS Trust in conjunction with Partnership Pathology Services.

In Consultation with: Pathology Director & POCT Committee

Ratified by: Clinical Governance Committee

Date Ratified: November 2008

Date Issued: January 2009

Review Date: June 2010

Target Audience: All clinical and laboratory scientific and technical staff

Impact Assessment Carried Out By: POCT Group

Comments on this document to: David Cartwright; Consultant Chemical Pathologist and Chair of POCT Group
ASHFORD & ST. PETER’S HOSPITAL NHS TRUST

POINT OF CARE TESTING POLICY

See also: Policy for Clinical Staff Medical Devices Training
           Policy for management of Medical Devices
           Policy for the Management and Reporting of Incidents
           Performance Review and Development Needs Assessment (Appraisal)

1.0 PURPOSE

The purpose of this document is to detail Trust policy and procedures for the appraisal of requests to use Point of Care Testing devices and for their introduction and use.

2.0 SCOPE

This policy extends to the appraisal, introduction and use of Point of Care Testing (POCT) devices in wards, clinics and departments within Ashford and St Peter’s Hospital Trusts and in Community based services served by the Trust. The central involvement of the pathology department in such activities is recognised by the Trust as it has been recognised by the Medicines & Healthcare products Regulatory Agency, the Joint Working Group on Quality Assurance and by Clinical Pathology Accreditation Ltd., the body charged with accrediting UK Clinical Pathology Departments.

This policy only covers tests and analytical processes that would traditionally be performed by Pathology Departments.

3.0 DEFINITIONS

3.1 Point of Care Testing is any pathology analytical process performed for patient care outside the laboratory.

3.2 An analytical process covers tests and investigations using fixed or portable devices (such as blood gas analysers, urine stick analysers, glucose meters, coagulometers and blood count analysers) as well as eye readable technologies such as pregnancy testing and cardiac markers.

3.3 The Clinical Unit Manager is the person in charge of a specific clinical area, e.g. NICU.

3.4 The Specialist Nurse is the person with particular responsibilities for clinical areas, e.g. Diabetes.

3.5 The Technical Lead is a designated lead Healthcare Scientist in a Pathology specialty.

3.6 The Nurse Educator is a representative of the supplier who provides training in the use of the device.
3.7 The Certificated Operator is a person who has been formally trained in the use of a specific POCT device, has acknowledged this training and has a full understanding of their responsibilities.

3.8 The Link Person is an individual who has been trained and designated to carry responsibility for liaison with the Diagnostic Department and for maintaining a register of POCT users in their clinical area. This responsibility should be identified within their job description.

4.0 POLICIES AND PROCEDURES

4.1. AIM

To manage the introduction and regulate the use of POCT and thereby prosper a cost efficient and clinically effective analytical service under the supervision of qualified staff from a CPA Accredited Pathology Department.

4.2. OBJECTIVES

4.2.1 To ensure POCT is adopted only where it has proven clinical value.

4.2.2 To ensure the appraisal, introduction and use of POCT devices is carried out in full consultation with the directorate of pathology Ashford and St Peter’s Hospitals Trust through the POCT Committee.

4.2.3 To ensure personnel using POCT devices are given the appropriate training.

4.2.4 To ensure full quality assurance and maintenance practices and procedures are in place before and during the use of the device.

4.2.5 To ensure the use of the device complies with all appropriate regulations, codes of practice and Health & Safety guidelines.

4.2.6 To ensure that the policy is adopted and complied with throughout the Trust.

4.3. STANDARDS

4.3.1 A clinical need for POCT must be established and a business case prepared prior to acquisition of the device.

4.3.2 The business case for POCT devices must include consultation with the pathology department. An appropriate case proforma (see appendices 2 and 3) and a cost benefit analysis must be included.

4.3.3 After the establishment of clinical need and cost effectiveness following presentation of a business case to the POCT Committee, mutual agreement between the directorate of pathology and the Clinical Unit or directorate must be reached on the:

- responsibility of the laboratory in the management of the device
- arrangements for the delivery and implementation of the service
- financial arrangements for purchase, operation and maintenance of the device
• quality assurance, health & safety and maintenance procedures
• training of appropriate laboratory and non-laboratory staff
• action which should be taken in the event of analytical errors or the misuse of the device.

This should take the form of a service level agreement.

4.3.4 The appraisal of POCT devices must include a pilot study or sufficient supporting information to establish the numeric relationship with existing assays, the accuracy and reproducibility of results and safe working practices. Suitability of the device for specific clinical use must be assessed and reviewed (paediatrics, home use etc).

4.3.5 Procurement of new devices must comply with Trust procedure and involve discussion with the Directorate of Pathology, Trust Medical Equipment committee and the Supplies Department.

4.3.6 If a new interventional procedure is being proposed, this must comply with The Interventional Procedures Programme HCS 2003/011 (Department of Health 2003).

4.3.7 Quality assurance and maintenance practices and procedures must be in place before commencement of the use of the device.

4.3.8 All test results from calibrations, controls and patient samples must be recorded. 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 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.

4.3.9 Where achievable, results from POCT devices should be integrated with the laboratory record. Procedures should be in place to clearly identify those results generated at the POC and these results must not be overwritten by the laboratory generated results on the same specimen.

4.3.10 A named individual, the trainer, (healthcare scientist, specialist nurse, ward link person or a nurse educator) will be responsible for training users of new devices and for refreshing and recertificating existing users.

4.3.11 Tests and procedures should only be performed by staff who have been trained and designated as certified users. When barcodes or passwords are issued to certified users these are for the individual’s personal use only.

4.3.12 Staff training should include how the device is used, quality assured and maintained. Health & safety and data security issues should be included. Trained staff will be certified as operators and a current list of certified users must be maintained with the device and by the named trainer.

4.3.13 A designated person from the Pathology Department should oversee quality assurance, maintenance practices and procedures, and maintain a current register of devices and certified users.
4.3.14 A designated individual (link person) should be nominated in the clinical area to take responsibility for the day to day running of the device and for ensuring only trained staff use the device.

4.3.15 If a device is not used or cared for appropriately the Pathology Department will, after discussion with the Clinical Unit, remove the device from service.

4.3.16 If devices are used inappropriately by certified users their passwords will be disabled, further training instigated and/or Trust disciplinary procedures followed.

4.4 MEDICO-LEGAL CONSIDERATIONS

4.4.1 The Professions Supplementary to Medicine Act 1960 requires Medical Laboratory scientists to be properly educated, qualified and trained in order to protect patients. This underlying principle should apply to all staff performing Point of Care Testing.

4.4.2 Responsibility

- The operator and the Clinical Unit are responsible for using the device properly, carrying out the tests and evaluating the results.
- The operator has full responsibility for ensuring that their user password/barcode remains confidential.
- The relevant pathology department is responsible for ensuring that the device is installed correctly, that quality assurance procedures are in place, that appropriate arrangements have been made for user training and certification and that appropriate standard operating procedures have been prepared and are maintained.
- The Trust provides indemnity for staff provided they follow formal standard operating procedures and are trained and certified to operate the device.

4.4.3 The provisions of the Data Protection Act must be incorporated into the practices and procedures of POCT.

4.4.4 For medico-legal reasons, adequate and appropriate data must be recorded to ensure the chronological relationship between test results, quality control results, device status and training is retained. The data must be recorded either in a logbook or electronically on the instrument / remote computer, MDA SN 9616 June 1996, MDA DB2002(03).

4.4.5 The providers of a Pathology service from a CPA accredited laboratory have a duty to ensure that the service is carried out within the recommended national and local quality assurance schemes. POCT falls within this duty.

4.5 HEALTH & SAFETY

4.5.2 Staff performing POCT must be aware of the microbiological hazards of the patient samples, the chemical hazards of reagents and the physical/electrical hazards of devices.

4.5.3 Staff must observe the precautions for safe working practices.

4.5.4 Risk assessment following Trust guidelines should be carried out before devices are commissioned. The infection control physician / medical microbiologist must be involved in decisions on the placement and safe maintenance of devices.

4.5.5 Standard operating procedures must include protocols for routine decontamination of devices, safe disposal of biological materials and safe handling of all specimens and spillages. A certificate, providing evidence of appropriate decontamination, must be issued by the Link Person or Technical Lead Healthcare Scientist before service or repair of equipment.

4.5.6 Devices should be sited to prevent unauthorised use and ensure that safety regulations are not contravened. The location must allow access to laboratory staff for maintenance.

4.5.7 All spillages or leaks of specimens should be dealt with in accordance with the local Infection Control Policy and detailed in SOPs.

4.5.8 All accidents or incidents with POCT devices must be reported to senior staff on the Clinical Unit (including the Link Person) and to the relevant pathology department concerned. An Incident Report form must be completed by staff on the Clinical Unit following Trust Policy & Procedures and copied to the POCT Team. Incidents involving user error or a device malfunction must all be reported.

4.5.9 The relevant pathology department must immediately inform the POCT Committee of any incidents for the Chairperson to report to the Adverse Incident Centre at the MHRA.

4.5.10 Reports of device malfunction should be confirmed by the relevant pathology department and also reported to the pathology Quality Management Group.

4.6 TRAINING

Much of the success of POCT depends on the effectiveness of the training of non-laboratory staff.

4.6.1 The designated trainer is responsible for the routine training of all staff required to use the device.

4.6.2 A comprehensive training manual should be prepared by the relevant departmental laboratory Lead Healthcare Scientist that describes the process and content of training and the arrangements for testing, re-testing and certification for all POCT devices. A central source of training records should be held by the POC team.

4.6.3 The training programme should include:
• awareness of pre-analytical factors, e.g. obtaining the correct specimen, the importance of clinical contraindications, sample handling, stability of sample and reagents. Patient preparation is an important factor to be considered.
• assessment of the skills necessary to use the device, perform quality control checks and record relevant data.
• decontamination and troubleshooting procedures, including guidance available from the laboratory.

4.6.4 All personnel will be certified on successful completion of their training module for the appropriate period of time and for any relevant conditions.

4.7 QUALITY ASSURANCE

4.7.1 All POCT users must be acquainted with the relevant Department of Health Medical Device Alerts (see appendices) and the requirement to comply with agreed QA procedures.

4.7.2 Internal Quality Control:

This is a means of validating results before they are issued. All QC results must be recorded and permanently retained.
The QC procedures will be device dependent but can include:
• use of material which mimics a patient sample to check that results fall within agreed limits
• use of an optical or electrical test system to check performance of measurement device.

4.7.3 External Quality Assessment:

This involves the analysis of samples received from the relevant pathology department, the manufacturer or external body.
• they should be distributed to the POCT site periodically by the relevant pathology department or external body, to whom results should be returned.
• the sample should be handled in a manner as similar as possible to that of a patient sample.
• the results must be recorded with date and time of analysis, device used and operator identification. The results must be reviewed by the laboratory at monthly QA meetings and where necessary appropriate action taken. Results must be retained for the lifetime of the instrument with a minimum of 2 calendar years.

4.7.4 Test results and device data:

Results from patients and controls should be recorded with specified device performance data to enable a full audit trail.
If the device Quality Control book is used, the records must include:-
• device name and identification number
• analytical range (if appropriate)
• patient ID name, hospital number and NHS number if available
• type of specimen
• date and time of analysis
• the results obtained
• the name of the operator
• calibration details if appropriate
• quality control results.
• batch number of reagents/cartridges when batch number has been changed.

Personal bar codes should be used whenever possible for data entry.
Devices with electronic audit trail facilities should be purchased if available as an option on a selected product.

4.7.5 Interpretation of results:

• Performance limits and clinical limitations must be established and documented in the SOP.
• If results are to be interpreted by staff other than the patient’s medical practitioner, guidelines for interpretation and advice should be described in the SOP and should be included in the training. This should cover abnormal results and referral guidelines.
• Criteria for referring results or enquiries and the procedure for seeking expert clinical or analytical advice should be agreed with the relevant diagnostic department in advance of the use of the device.

4.8 OPERATION AND MAINTENANCE

4.8.1 A Standard Operating Procedure (SOP) must be written by the relevant departmental laboratory Lead Healthcare Scientist for each POCT device, which must comply with CPA standards and be subject to regular revision. A controlled copy should be kept near the device (together with a Service Level Agreement) for ease of access, and in the Pathology Department.

4.8.2 The SOP should follow the standard Pathology format.

4.8.3 The SOP or SLA should include:-
• normal operating techniques
• contra-indications and limitations of the device and technique
• procedure required to perform routine maintenance and decontamination
• how to deal safely with specimens, spillages and accidents
• the safe disposal of biological materials
• a list of error messages and basic troubleshooting in case of instrument malfunction
• procedure for obtaining consumables including reagents, controls, calibrators, batteries etc
• the procedure for advice and guidance if a problem is unresolved, (contact telephone numbers must be included)
• a statement of who is responsible for removing a device from service if it is not being used properly or if it is not performing satisfactorily.
• alternative arrangements for analysis in the case of device failure.

4.8.4 A device maintenance log must be kept near to the device. It should contain:
• details of malfunctions
• details of problems encountered
• details of any maintenance procedures performed on the device.
Trained operators are required to complete the maintenance log as necessary.
4.8.5 The maintenance log will be periodically reviewed by the link person and any persistent issues brought to the attention of the laboratory.

4.9 PERIODIC AUDIT OF PERFORMANCE

4.9.1 The Clinical Unit Manager and the relevant pathology department will undertake a periodic audit of the performance of the use of the device at 12 monthly intervals. The audit will examine:

- quality control performance
- patient results record
- training record
- device maintenance record.

4.10 RESPONSIBILITIES

4.10.1 The Ashford and St Peter’s Hospitals NHS Trust is responsible for appointment of a POCT Committee.

4.10.2 The POCT Committee consists of a chairman drawn from the pathology senior staff, representatives of each pathology discipline and co-opted members who have specific responsibility for POCT. The chairperson is accountable through the Pathology Directorate to the Trust Management Board for the activities of the POCT Committee. In the absence of other committee members, the chairperson has the right to act in a discretionary capacity if immediate action is ever required, with the committee subsequently appraised of this action.

4.10.3 The POCT Committee is responsible for reviewing and monitoring the POCT Policy, for reviewing proposals to introduce new POCT devices and for reviewing the procedures and practices for the safe use and maintenance of the POCT devices.

4.10.4 Individual Clinical Directorates are responsible for demonstrating a clinical need for Point of Care Testing. Other individuals or departments, including Pathology, may identify the value to patients and to the institution of specific POCT devices or procedures.

4.10.5 The Business Manager/General Manager of the directorate in which the device is to be used is responsible for the preparation of the business case for the use of the POCT device.

4.10.6 The business case for the use of each POCT device will be examined by the POCT Committee, which will advise the pathology Directorate and the Trust executive of the merits of the case.

4.10.7 The Trust Chief Executive and relevant Clinical Director will be informed of any Clinical Units performing POCT which has not been approved by the POCT Committee.

4.10.8 Under the direction of the POCT Committee, a designated Healthcare Scientist and the Clinical Unit Manager are responsible for the appraisal and introduction of the device and for the establishment of quality assurance, Health & Safety and maintenance practices and procedures. They are responsible for formally identifying and recording who is responsible for ordering reagents, consumables and requesting maintenance.
4.10.9 A designated Clinical Unit Manager is responsible for ensuring the proper day to day use of each device and ensuring adherence to documented quality assurance practices and procedures. The POCT Team must be advised of any trained operators whose competency to use a device is in question. This may be managed through the Link Person.

4.10.10 A designated Link Person will be assigned to each device to oversee its day to day use, liaise with other users of the device (keeping up to date records of trained individuals) and with the laboratory.

4.10.11 Only named, trained and Certificated Operator(s) in the clinical unit should be authorised to use a device(s).

4.10.12 Certificated Operator(s) must comply with documented reporting and quality control procedures.

4.10.13 The Technical Lead in the appropriate pathology department is responsible for the maintenance of complex devices, quality assurance practices and procedures, and for monitoring the quality of the service. They are responsible for issuing a certificate prior to servicing or repair of equipment, once the device has been decontaminated.

4.10.14 All quality control practices and procedures should be in accordance with quality assurance practices and procedures prescribed by the POCT Committee. The Pathology Department and POCT Committee must have ready access to Quality Control data.

4.10.15 A named individual; the trainer, (Healthcare Scientist, specialist nurse, ward Link Person or a Nurse Educator) will be responsible for training users of new devices, for refreshing and recertificating existing users and for ensuring the register of certified users is updated.

4.10.16 Adverse incidents or concerns regarding POCT devices must be reported by the operator on Trust Incident Forms and copied to the secretary of the POCT group for logging and consideration at the next POCT group meeting.

4.11 REGISTER OF POCT EQUIPMENT

4.11.1 To effectively monitor the wide range and large number of POCT devices, the POCT Committee should keep a database of the location and function of all devices. This register should provide information on the range of tests and types of devices used within the Trust. The register should include 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)
   - Pathology Technical Lead

The register should facilitate device standardisation and therefore simplify staff training, reduce repair and maintenance costs and simplify back-up.
4.12 REVIEW AND AUDIT

A biennial review of the POCT policy will be undertaken by the POCT Committee and consideration given to the Trust’s policies, national guidelines, professional guidelines, Health & Safety policies and departmental business plans.

An annual audit of the POCT policy will be performed to ascertain its effectiveness and ensure that the Pathology Department is satisfying all requirements.

4.13 ARCHIVING ARRANGEMENTS

This is a Trust-wide document and archiving arrangements are managed by the Quality Department who can be contacted to request master/archived copies.

5.0 EQUALITY IMPACT ASSESSMENT

A baseline Equality Impact Assessment has been carried out on this policy and indicates that no further assessment is necessary. See appendix 4.

6.0 COST BENEFIT ANALYSIS

- There must be a clear definition of the problem that the device would solve so that a full examination of all possible solutions can be made.
- The pathology department must be involved in the production and evaluation of the cost benefit analysis.
- A full business case must be produced detailing all the financial consequences of the purchase. These will include the direct costs of running, maintenance, consumables, quality control, IT and service contract. The cost benefit analysis must include the full indirect costs for pathology involvement, including support, training and QC/QA monitoring, IT infrastructure as well as the inevitable cost of replacement.
- The cost benefit analysis must recognise the need for any device to be compatible with existing equipment, both in the laboratory and in other areas of the hospital. The pathology department must be consulted about the compatibility of all devices.
- Any device being considered must have a CE mark to ensure it is fit for the purpose and of suitable quality.

7.0 SUMMARY OF ACTIONS AND RESPONSIBILITIES

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### 8.0 CHECK LISTS

#### 8.1 LABORATORY EVALUATION OF PROPOSED DEVICE

Device
Manufacturer/supplier
Analytes measured
Instrument description: dimensions, accessories required, reagents
Calibration
Operation: QC patient samples
Data handling/IT links
Method comparison
Reagent batch comparison
Imprecision
Interferences
Sample volume dependency
Operator dependency
Health & safety implications
Costs
Conclusions
Recommendations (suitability for proposed purpose)

#### 8.2 INSTALLATION OF NEW DEVICE

Device
Clinical Unit
Unit manager
Link nurse
Trainer
Location of device: Health & safety risk assessment with completion of risk assessment form
Infection control inspection

Log book
QC record book
Register of users
SOP
Service Level Agreement
Training

8.3 TRAINING

Device
Designated trainer
Link Nurse
Training manual
SOP:
Pre-analytical considerations/sample collection
Contraindications
Reagent/sample stability
Operational procedures
Limitations of assay
Performance characteristics
Maintenance
Reference ranges
Health & safety/Hazard notices
Decontamination/cleaning procedures/spillages
QC/EQA
Recording data/data protection
Clinical significance of results/responsibilities/confirmatory testing
Requisitions/supplies
Contact names/numbers
Certificated user list
Arrangements for cascade/update training

9.0 APPENDICES

9.1 ASHFORD AND ST PETERS HOSPITALS NHS TRUST POCT COMMITTEE TERMS OF REFERENCE

9.2 PROFORMA FOR APPLICATION FOR PILOT STUDY OF A POCT DEVICE

9.3 PROFORMA FOR APPLICATION FOR ACQUISITION & IMPLEMENTATION OF POCT EQUIPMENT

9.4 EQUALITY IMPACT ASSESSMENT

REFERENCES
(Available from the Chairperson of the POCT Committee)

CURRENT
Clinical Pathology Accreditation (UK) Ltd: Standards for the Medical Laboratory. September 2007

Point of Care Testing. AACC Publication by Christopher Price & Jocelyn Hicks. 1999


HISTORICAL INTEREST


Guidelines on the control of near patient tests and procedures performed on patients by non-Pathology staff. Joint Working Group on Quality Assurance. JWGQA, Liverpool.

Professions Supplementary to Medicine Act 1960.


Jacobs E. Total quality management and point-of-care testing. Med Lab Observ 1993; 23(9S): 42-6


McQueen M J. The ethics and economics of out-of-laboratory testing. Can Med Assoc J 1993; 149: 1653-6

DEPARTMENT OF HEALTH/MEDICINES & HEALTHCARE PRODUCTS REGULATORY AGENCY PUBLICATIONS

www.doh.gov.uk
www.medical-devices.gov.uk
www.mhra.gov.uk


Near Patient Testing: Welsh Scientific Advisory Committee (Welsh Office) 1995


Extra-Laboratory Use of Blood Glucose Meters and Test Strips: Contra-Indications, Training and Advice to the Users. MDA Safety Notice 1996


The Interventional Procedures Programme HCS 2003/011 (Department of Health 2003)


Medical Device Alert: Blood glucose meters: LifeScan 1 Touch Ultra 2: Potential to misread results due to indistinct decimal point. MDA/2006/054 Issued 18 September 2006

Medical Device Alert: Lancing devices used in nursing homes and care homes: Devices implicated in transmission of hepatitis B. MDA/2006/066 Issued 6 December 2006


Medical Device Alert: Point of care and home-use blood glucose meters: Roche Accu-Chek and Glucotrend; Abbott Diabetes Care FreeStyle. Overestimation of glucose results with treatments containing maltose, xylose or galactose. MDA/2007/058 Issued 19 July 2007

Medical Device Alert: Point of care blood glucose measurement systems: HemoCue Glucose 201+ and HemoCue Glucose 201 RT. Ability to generate erroneous 0.0 mmol/l result. MDA/2007/059 Issued 2 August 2007

Medical Device Alert: Home use blood glucose meters: Boots brand blood glucose monitoring system. Display may be damaged if dropped. MDA/2007/077 Issued 15 October 2007
APPENDIX 1

ASHFORD AND ST PETER’S HOSPITALS NHS TRUST POCT COMMITTEE TERMS OF REFERENCE

STATUS

Sub group of the Pathology Management Team

CHAIR

Consultant Chemical Pathologist

MEMBERSHIP

Secretary & POCT Co-coordinator
Pathology Services Manager
Pathology Quality Manager
Pathology Training Manager
Biochemistry Representative
Haematology Representative
Microbiology Representative
Trust Clinical Risk Manager
Partnership Pathology Representative
PCT Representative

Others by invitation as appropriate, eg: Additional representative of diagnostic specialty, ICU, A/E, NICU, Nursing (diabetes, coagulation etc), Pharmacy, Infection Control, IT, Occupational Health, Trust Management.

FREQUENCY OF MEETINGS

Quarterly
Thursday lunchtimes.

QUORUM

Four, one of which must be the chairperson or POCT co-ordinator

1.1 REMIT

10.1.1 These terms of reference are drawn to comply with national guidelines (Management & Use of IVD Point of Care Test Devices, Device Bulletin March 2002, MDA
DB2002(03), Point of Care Testing – Requirements for Quality & Competence, British Standard BS EN ISO 22870:2006) and to adhere to the recommendations for best practice contained within them.

1.2 ACCOUNTABILITY

10.2.1 The POCT Committee is accountable to the Trust Management Board via the Pathology Directorate.

The POCT committee report to the Pathology Directorate biannually.

1.3 ORGANISATIONAL RELATIONSHIPS

10.3.1 The chair of the POCT Committee will be the Consultant Chemical Pathologist with responsibility for directing POCT activities. The POCT co-ordinator will represent the POCT Committee on the Medical Equipment Committee/Equipment Evaluation & Management Group.

1.3.2 The POCT Committee is responsible for the clinical risk management and clinical effectiveness of POCT across the Trust and local primary care sites covered by the POCT Service Level Agreement.

1.4 RESPONSIBILITIES

1.4.1 To manage the introduction and regulate the use of point of care testing devices across the Trust and local community, in accordance with the POCT Policy.

1.4.2 To inform the Trust Chief Executive and relevant Clinical Director/Clinical Governance Lead of any clinical units performing POCT which has not been approved by the POCT Committee.

1.4.3 To review practices and procedures for safe use and maintenance of POCT devices.

1.4.4 To maintain up to date records of all POCT devices currently in use.

1.4.5 To review recent publications/guidelines on POCT.

1.4.6 To address any POCT performance issues (including EQA performance).

1.4.7
To biennially review Trust POCT Policy
To annually review POCT SOPs
To annually audit Trust POCT Policy

POCT clinical protocols

1.4.8 To promote awareness of the POCT Policy across the Trust and Community based services served by the Trust.

1.4.9 To ensure any adverse incidents involving POCT devices are reported to the Adverse Incident Centre at the MHRA whenever indicated.

1.5 REPORTING ARRANGEMENTS
1.5.1 To produce an annual report and Action Plan to be submitted to the Director of Pathology and Pathology Management Team.

1.6 CONSTITUTION

1.6.1 Representatives of stake-holders may be nominated to the chairperson. The group may co-opt members with the approval of the chairperson and a majority vote at an appointed committee meeting.

1.6.2 The chairperson will be appointed by the Director of Pathology. The position may be reviewed by the Pathology Management Team.

1.6.3 Where an urgent decision is required on any POCT application, the chairperson, POCT co-ordinator and relevant Consultant Pathologist may make such a decision under delegated powers.

1.7 POCT COMMITTEE AGENDA

1.7.1 Standing Items
Equipment Register: maintain a record of all POCT instruments and kits covered by the Trust POCT policy (reviewed & circulated biennially)
Formal requests for use of POCT instrument and kits
Recent pertinent publications / MDA and Health Circulars pertinent to POCT
POCT Performance issues
EQAS Performance
Review POCT related incident report forms
Receive report from each Specialty
Any other business
PROFORMA FOR APPLICATION FOR PILOT STUDY OF A POCT DEVICE

Date:

To be submitted to the Point of Care Testing Committee, Ashford and St Peter’s Hospitals NHS Trust, for consideration at the next meeting.

Request from (clinical unit/hospital)...........................................................................................

Proposed POCT device................................................................................................................

Manufacturer/supplier of device...............................................................................................  

Analytes for consideration.........................................................................................................

Proposed location of device......................................................................................................

Grade/number of staff to use device........................................................................................

Clinical Unit Manager        (name)........................................................................................
  (signature)..................................................................................

Business/General Manager (name)..........................................................................................
  (signature)..................................................................................

Please ensure that a laboratory evaluation for the proposed device accompanies this request and that all details have been fully discussed with the relevant diagnostic department before submission.

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Approval for pilot study of POCT device         Date:

Request from (clinical unit/hospital)........................................................................................

Proposed POCT device................................................................................................................

Manufacturer/supplier of device...............................................................................................  

Analytes for consideration.........................................................................................................

The Point of Care Testing Committee has considered the above request and agrees to a pilot study being performed under the terms and conditions of the Trust POCT Policy.

Signature.................................................................................................................................
PROFORMA FOR APPLICATION FOR ACQUISITION & IMPLEMENTATION OF POCT EQUIPMENT
To be submitted to the Point of Care Testing Committee, Ashford and St Peter’s Hospitals NHS Trust, for consideration at the next meeting.

Request from (clinical unit/hospital)........................................................................................................
Type of POCT device required...................................................................................................................
Manufacturer(s)/supplier(s) for consideration..........................................................................................
...............................................................................................................................................................

Analytes for consideration.........................................................................................................................
...............................................................................................................................................................

Proposed location of device....................................................................................................................... 
Grade/number of staff to use device...........................................................................................................

European tender: Not required........... Required............

A full business case, cost benefit analysis and laboratory evaluation in support of this proposal is attached.
This proposal is submitted under the terms and conditions of the Trust POCT Policy.

Clinical Unit Manager (name)...................................................................................................................

 (signature)..............................................................................................................................................

Business/General Manager (name)...........................................................................................................

 (signature)..............................................................................................................................................

Date.........................................................................................................................................................
Please ensure that all details have been fully discussed with the relevant diagnostic department before submission.
## APPENDIX 4

### EQUALITY IMPACT ASSESSMENT TOOL

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

<table>
<thead>
<tr>
<th>1.</th>
<th>Does the policy/guidance affect one group less or more favourably than another on the basis of:</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Race and Ethnic origin (include gypsies and travellers) (consider communication, access to information on services and employment, and ease of access to services and employment)</td>
<td>No</td>
<td>For each category describe how you have involved stakeholders including service users and employees</td>
</tr>
<tr>
<td></td>
<td>Disability (consider communication issues, access to employment and services, whether individual care needs are being met and whether the policy promotes the involvement of disabled people)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gender (consider care needs and employment issues, identify and remove or justify terms which are gender specific)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Culture (consider dietary requirements and individual care needs)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Religion or belief (include dress, individual care needs and spiritual needs for consideration)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sexual orientation including lesbian, gay and bisexual people (consider whether the policy/service promotes a culture of openness and takes account of individual needs)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age (consider any barriers to accessing services or employment, identify and remove or justify terms which could be ageist)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Is there any evidence that some groups are affected differently?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>If you have identified potential discrimination, for example, less than equal access, are any exceptions valid, legal and/or justifiable, for example a genuine occupational qualification?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Is the impact of the policy/guidance likely to be negative?</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>
### Table

<table>
<thead>
<tr>
<th></th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. If so can the impact be avoided?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>6. What alternatives are there to achieving the policy/guidance without the impact?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>7. Can we reduce the impact by taking different action?</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

The options to be considered are as follows:-

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>No further action required</td>
<td>Yes</td>
</tr>
<tr>
<td>Further Impact Assessment</td>
<td>No</td>
</tr>
</tbody>
</table>

If the baseline equality impact assessment reveals that the specific policy is likely to have an adverse impact on some equality groups (e.g. racial groups) then there is a need to consider ways of dealing with the differential impact.

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>Any other action required</td>
<td>No</td>
</tr>
</tbody>
</table>

Please provide further details.

If further assessment is required please see the Integrated Single Equality Scheme.

For advice in respect of answering the above questions, please contact Maria Crosbie, HR Manager, on extension 2552.