Point of Care Testing (POCT) Policy

Department / Service :	Pathology
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Accountable Director :	Dr C Shetty (Laboratory Director)
Clinical Director :	Dr M Cornes (Consultant in Clinical Biochemistry)
Approved by :	Trust Management Committee
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Target Organisation(s) :	Worcestershire Acute Hospitals NHS Trust
Target Departments :	All Acute Trust departments
Target staff categories :	Acute Trust nursing staff and doctors

Policy Overview:

POCT is the performance of "pathology" tests in clinical areas, ie outside the central pathology laboratory, the potential advantage being the rapid availability of results that may be clinically useful. Because POCT tests directly affect patient care they should be as reliable as laboratory tests.

Key amendments to this Document:

Date	Amendment	By:
June 2011	Details of blood ketone meters and blood INR testing added to appendix 1	G Mascall
July 2011	Approved by chair of devices committee	Jane Smith
January 2014	Document reviewed and amended to latest Trust policy format	G Mascall
September 2016	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
December 2017	Document extended for 3 months as per TLG recommendation	TLG
March 2018	Document extended for 3 months as approved by TLG	TLG
June 2018	Document reviewed and updated	M Cornes
June 2019	Document reviewed, updated and approved	C Shetty

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1. Introduction

POCT is the performance of “pathology” tests in clinical areas, i.e. outside the central pathology laboratory, the potential advantage being the rapid availability of results that may be clinically useful. Because POCT tests directly affect patient care they should be as reliable as laboratory tests and follow the same stringent quality processes. However POCT is performed by staff without formal laboratory training, without the immediate reassurance of quality control and employing equipment that may not have been used with the greatest of care. These factors combine to make POCT a high-risk activity that must be addressed by implementing a management system that ensures high standards of performance and hence minimises risks to patients, staff and the Trust. In addition to these clinical risk concerns, POCT is more expensive than central laboratory testing so that cost effectiveness must be assessed when a new POCT device is being considered. This policy describes the management arrangements implemented to minimise this risk and ensure device appropriateness.

2. Scope of this document

The purpose of the POCT Policy is to ensure that all POCT procedures are performed to the same quality standards as laboratory-based tests uniformly across all sites covered by POCT. The policy only applies to devices procured via the POCT committee

3. Definitions

POCT = Point of Care Testing is the usual term employed and has replaced “Near Patient Testing” and “Extra-Laboratory Testing”.

4. Responsibility and Duties

The POCT committee sits under the Trust Medical Devices Committee and is responsible for establishing, implementing and monitoring POCT the policy. Medical devices meets two-monthly and is chaired by the Head of Facilities, PFI & Contracts. Membership includes the Trust Chief Medical Officer, Consultant Chemical Pathologist/Clinical Biochemist and representatives from Nursing and Midwifery, Infection Control, Training and Development, Clinical Governance and Primary Care.
The POCT committee meets a minimum of 6 times per year and is chaired by the Consultant Chemical Pathologist/Clinical Biochemist. In formulating policy this committee refers to national professional guidance and to appropriate legislation. Approval by the POCT committee is required before a new POCT test is introduced in the Trust (see Section 14). The POCT team and this policy, only covers devices procured with the engagement and approval of the POCT team.

Departmental Managers are responsible for ensuring all POCT undertaken in their wards/departments complies with Trust policy (see also Section 11.1).

5. Policy Statement.

Worcestershire Acute Hospitals NHS Trust recognises the importance and convenience of Point of Care Testing Devices. Therefore the Trust will ensure that consistent procedures are in place throughout the Trust in order to provide high quality of patient care through a safe, cost effective, and standardized POCT service.

6. Clinical Areas and Responsibilities.

6.1 Pathology

POCT on each hospital site is coordinated by the pathology department. The day-to-day involvement of pathology staff in POCT includes:

- Equipment maintenance, troubleshooting and liaising with manufacturers and suppliers when necessary.

- Coordination and/or delivery of training and refresher training of ward/departmental nursing staff, Specialist Nurses, Nurse Practitioners, Nursing and Midwifery students and medical staff. This is co-ordinated with Training and Development. Equipment suppliers may assist with this training. Training is recorded and monitored by the Pathology Department (section 12.4)
- Organization of internal quality control and external quality assessment schemes, including the supply of control specimens and the analysis and feedback of performance.
- Collaboration in clinical audit.
- Ensure Standard Operating Procedures (SOPs) are available for all POCT devices and that these are supplied to all clinical areas using the relevant POCT devices.

6.2 Clinical areas.

- The operation of POCT in clinical areas is the responsibility of the Departmental Managers who also determine the number and identity of staff who should deliver POCT (see Section 11.1).
- POCT activities (including managerial duties) should be addressed during annual appraisals.
- Training is coordinated with Training and Development and may be provided by the pathology laboratories (Section 11) or by nurses with POCT responsibilities. Nurses providing POCT training must receive their own training from pathology staff.
- Nursing and Midwifery students are able to access training via the Higher Educational Institute
- The grades of staff who can deliver POCT tests are determined by the Chief Nursing Officer or Designated Deputy in consultation with the POCT Committee (see Appendix 3).
- Departmental Managers should ensure all their devices are covered by internal and external quality controls. They should liaise with the laboratory to ensure appropriate cover (see Section 9.2).

6.3 Medical staff.

Medical staff, like all other staff, must be trained before undertaking POCT. Staff will not be able to access the POCT equipment without training.

7. POCT Equipment.

Disposable POCT devices including urine dipsticks are considered to be “equipment”.

7.1 Equipment procurement.

To procure a new POCT device the procedure in ‘Section 14: New POCT Tests’ must be followed**.** To obtain additional or replacement equipment refer to the appropriate section of Appendix 2**.** Only devices procured with the engagement of the POCT committee will be supported by the POCT team.

7.2 Equipment management.

Departmental Managers are responsible for ensuring equipment in their areas is used safely and efficiently according to relevant SOPs. Pathology staff will inform Departmental Managers of any deficiencies they become aware of.

7.3 Equipment support.

Equipment support in the event of breakdown should first be provided by nursing staff with POCT responsibilities.

Pathology staff will provide support during routine working hours:

Monday to Friday : 0900 - 1730 hrs
Saturday : 0800 - 1200 hrs

At all other hours, the Pathology staff may only be able to provide advisory support if needed.

Manufacturers/suppliers will provide further support during usual business hours, if the issue cannot be resolved on the ward.

Specific arrangements are described in the appropriate sections of Appendix 1.

7.4 Equipment operation.
Equipment must be used as instructed during training and as described in the Standard Operating Procedure (SOP) that is located alongside each item of equipment. In accordance with good document control practice, SOPs must not be copied. SOPs will be reviewed and updated by the local pathology department and significant changes communicated.

7.5 Log books.
Certain items of POCT equipment will have a logbook for recording information such as internal quality control results. Logbooks must be completed, as described during training and in the relevant SOP.

8. Health and Safety.

POCT performance must comply with the health and safety aspects of SOPs (e.g. specimen collection, disposal of clinical materials) and the Trust Health and Safety Policy and Procedures. All staff performing POCT testing must follow the appropriate precautions explained during training, and detailed in the relevant SOP's for each piece of equipment, including wearing of appropriate personal protective equipment including gloves.
Equipment should be cleaned in accordance with the Trust Decontamination Policy and Decontamination Certificates (see Infection Control Manual) must be completed before POCT equipment is repaired.

9. Quality and Audit.

9.1 Internal quality control (IQC)
Internal quality control material must be analysed at an appropriate interval (usually daily) and the results recorded and assessed as described in the appropriate SOP**.** If an internal quality control result falls outside specified limits the equipment must not be used until the problem has been resolved with the local pathology department.

9.2 External quality assessment (EQA).
External quality assessment schemes are administered by the appropriate local pathology department and provide objective retrospective information on the performance of both a piece of equipment. Arrangements for the distribution and analysis of control material will be agreed between the pathology department and Departmental Managers to ensure equipment and operators are assessed at appropriate intervals (see Appendix 1, EQA). The pathology department will provide feedback on performance and discuss with clinical users any action that might be required.

9.3 Clinical audit.
A collaborative audit programme should be agreed between the clinical users, the pathology department and the Clinical Governance department.

9.4 Pathology accreditation.
POCT is not currently within the scope of iso15189 accreditation by UKAS (United Kingdom Accreditation Service). The POCT service will become accredited to ISO22870 as soon as the team is in a position to do so.

9.5 Reporting to the Trust.
There will be six-monthly reports from the Medical Devices/POCT Committee to the Trust Safe Patient Group.

See also relevant Sections 7.4: Equipment operation, 7.5: Log books and 11: Training and Competencies**.**

10. Record Keeping and Security.

10.1 Passwords.
Wherever possible all POCT devices will be password protected. The advantages of this include:

- Ensures equipment is used only by staff that have been trained.
- The identity of the individual associated with the password and who has performed a test is recorded and forms a key part of the audit trail.
- Ensuring the appropriate use of passwords is essential for clinical governance purposes. Staff must only use passwords that have been allocated to them and must not allow their password to be used by others.

10.2 Test results.
Depending on the procedure (refer to the appropriate section of Appendix 1) test results may be recorded as:

- A written entry in the patient's notes.
- An instrument printout, inserted in the patient's notes.
- A written entry on a condition-specific (e.g. diabetes) chart.
- In the device manufacturers provided database
- An automatic entry in the ICE reporting system

In all instances the Trust's "Clinical Record Keeping – Policy and Guidelines" must be adhered to and the following information recorded, in addition to the test result:

- Patient identity.
- Time and date of test.
- Name of operator.

For instrument printouts the operator name is driven by the user password – operators must only use their own password - a record of the operator password and identity is also retained on the instrument.

10.3 Internal quality control results.
These are recorded as appropriate for the instrument (e.g. in the log book or on the instrument).

10.4 POCT training.
Staff must ensure they have been trained to use POCT equipment relevant to their role and should keep copies of their annual refresher training certificates and produce these when required, i.e. during their annual PDR.

11. POCT Staffing.

See Section 12 for further information on training.

11.1 Laboratory Staffing.
Within the Pathology laboratories, there will be a clinical lead for POCT and a POCT co-ordinator who is responsible for the day to day oversight of all POCT devices in use across the Trust. The

co-ordinator is responsible for organising training of staff, either directly, or through trainers from the equipment supplier. The co-ordinator is supported by other laboratory staff on two of the three sites in maintaining POCT devices and training.
The laboratory will maintain a database of all staff trained on POCT equipment.

11.2 Departmental Managers.
Managers are responsible for designating appropriate qualified staff within their clinical area to be Link Nurses/Practitioners for specified POCT equipment. Managers are responsible for ensuring no member of staff in their clinical area uses POCT equipment without the appropriate training.

11.3 Link Nurses.
Link Nurses/Practitioners are responsible for ensuring the day to day use of POCT equipment within their clinical area is performed according to the relevant SOP's by appropriately trained staff. Link Nurses/Practitioners may also be responsible, depending on the POCT equipment for annual refresher training for staff working in their clinical area, and ensuring that they and their staff all receive the required annual refresher training.

11.4 Registered Nursing Midwifery & AHP Staff.
Nursing, Midwifery & AHP staff using POCT equipment must only use equipment for which they have received the appropriate training/refresher training. They must keep their most recent certificate of training and produce this when requested during their annual PDR. They must not use barcodes from other members of staff

11.5 Nursing and midwifery students.
Nursing and midwifery students should only perform POCT testing as approved by the Trust Chief Nursing Officer (see appendix 3)

11.6 Health Care Support Workers.
Health Care Support Workers should only perform POCT testing as approved by the Trust Chief Nursing Officer (see 12.1). Trainee Nursing Assistants (registered and unregistered) should perform POCT testing as approved by the Trust chief nursing officer (see appendix 3)

11.7 Medical Staff.
Where required to perform POCT testing medical staff of all grades must be appropriately trained for the POCT equipment they are using.

For all grades of staff, use of any POCT equipment without appropriate training/refresher training is a breach of Trust policy.

12. Training and Competencies.

Staff can only perform a POCT procedure following successful completion of training. Biannual refresher training in the procedure must also be undertaken.

12.1 Competency for POCT.
The Chief Nursing Officer, in consultation with the Medical Devices/POCT Committee, determines the grades of non-medical staff that can be trained in POCT procedures for clinical service purposes. See Appendix 3.

12.2 Trained staff requirements.
The decision to train a non-medical member of staff is made by the Departmental Manager for the ward/unit/department. Although sufficient staff should be trained to provide an adequate level of cover in the clinical area, other factors to be considered include ensuring a sufficient workload

for individuals to maintain competency and the requirement to arrange quality control participation for all trained staff. Training is coordinated with Training and Development and may be provided by the pathology laboratories or by nurses with POCT responsibilities. (See Section 11: POCT Staffing).

12.3 Training responsibilities.
Training responsibilities for specific staff groups (including trainers) are described in Section 11: POCT Staffing.

12.4 Training records.
A record of staff training must be completed and sent to the Pathology department. Records of training are compiled by the Pathology Department and this information is made available to Training and Development. It is the responsibility of staff and students to ensure they obtain annual retraining.

12.5 Training for educational purposes.
Training may be provided for educational purposes, e.g. to pre-registration and other students and all results should be escalated to a registered member of staff

13. Established POCT Tests.

POCT tests that are currently approved for use in the Trust are described in Appendix 1.
Any other POCT test must be evaluated as described in Section 14: New POCT Tests, before it can be introduced.

14. New POCT Tests.

Before a new POCT test is introduced the following points must be considered. An application/business case should be made jointly with the appropriate pathology department to the Medical Devices/POCT Committee using the Trust pro forma (Appendix 2).

- What is the test and which group of patients would benefit from POCT?
- How is the service currently provided and does it adequately meet clinical needs?
- If clinical needs have not been met, what has been done to try to rectify the problem?
- Will POCT enable more effective diagnosis or treatment?
- Is there evidence that POCT will provide auditable clinical and/or economic benefits?
- Will POCT provide a cost-effective alternative to central pathology laboratory testing?

15. POCT Direction and Developments.

- There is a clear aim to standardise POCT equipment.
- There is a clear aim to integrate POCT results into the Trust results reporting system (ICE).
- Developments in IT (e.g. bar-coding of patient, operator and reagent identities) will be utilised to make POCT easier to use and to reduce risk.
- Pathology departments and clinical users should work together to ensure analytical services are provided in the most clinically and cost effective ways, including POCT where appropriate.
- The Trust Medical Devices/POCT Committee will collaborate whenever possible with the County CCGs and other healthcare agencies to provide consistent and integrated POCT services.
- Refresher training will be moved to an e-learning platform.

16. Implementation.

16.1 Plan for implementation

The policy will be uploaded to the Trust Intranet web site and a global email will be sent – it will also be publicised with a message on the Trust notice board. The policy will be discussed at all Induction sessions and during staff training sessions to ensure awareness of the policy.

16.2 Dissemination

The policy will be advertised in the daily Trust updates, and will be circulated to all relevant Departmental Managers, and the Clinical Divisions.

16.3 Training and awareness

See Section 12.

17. Monitoring and compliance

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.
7.	All POCT devices and testing sites must be registered and approved by the Trust POCT Committee.	Monitor requests for POCT devices and new sites	Twice a year	POCT lead	POCT Committee	Annually
6.1	All POCT devices must have a Standard Operating Procedure (SOP) which has been approved by the POCT committee and is subject to regular review.	SOPs to be registered with POCT committee	Annually	POCT Lead	POCT Committee	Annually
12.	All users of POCT devices must be authorised to do so by satisfactory completion of approved training and certification, reviewed as indicated in Appendix 1 for each POCT test/device.	All users registered on appropriate IT systems, with lockout if training/certification is not undertaken	Annually	POCT Lead	POCT Committee	Annually

18. Policy Review.

The policy will be reviewed two years after approval or sooner in the event of any significant changes in the Trust structure or processes that require amendment.

19. References.

19.1 Joint Working Group on Quality Assurance. Near to Patient or Point of Care Testing Guidelines. January 1999. Available from D. Kilshaw, Secretary, Joint Working Group on Quality Assurance, c/o Mast House, Derby Road, Liverpool L20 1EA.

19.2 Management and Use of IVD Point of Care Test Devices. Device Bulletin. Medicines and Healthcare Products Regulatory Agency, 2013

19.3 Guidelines on point-of care testing. The Royal College of Pathologists, 2004.

19.4 Additional Standards for Point of Care Testing (POCT) Facilities – United Kingdom Accreditation Services (UKAS) Version 1.01 November 2010.

19.5 Guidance Notes on Invitro Diagnostic Medical Devices Directive 98/79/EC. Medicines and Healthcare Products Regulatory Agency, 2006

20. Background.

20.1 Equality requirements

See 21.1

20.2 Financial Risk requirements

See 21.2

20.3 Consultation

Policy to be circulated to the staff identified below for comment prior to submission for Trust approval.

- Trust Chief Medical Officer
- Trust Chief Nursing Officer
- Trust Medical Devices Committee chairman (Head of Facilities, PFI & Contracts)
- Trust Director of Procurement
- Trust Divisional Director for Clinical Support
- Trust Divisional Director for Medicine
- Trust Divisional Director for Surgery
- Trust Divisional Director for Theatres, Ambulatory Care and Outpatients
- Trust Divisional Director for Women and Children

20.4 Approval process

Policy to be sent to group indicated in 20.3 for consultation.
Once comments received back, document to be amended if indicated, and presented to next Medical Devices Committee for approval.
Following approval here, to be sent for final approval and incorporation into list of active Trust policies.

21.1 - Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Age	No	
	• Disability	No	
	• Gender reassignment	No	
	• Marriage and civil partnership	No	
	• Pregnancy and maternity	No	
	• Race	No	
	• Religion or belief	No	
	• Sex	No	
	• Sexual orientation	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	N/a	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	N/a	
7.	**Can we reduce the impact by taking different action?**	N/a	

If you have identified a potential discriminatory impact of this key document, please refer it to Assistant Manager of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Assistant Manager of Human Resources.

21.2 - Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue?	No
3.	Does the implementation of this document require additional manpower?	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	Although all above are indicated as No, points 1,2 and 3, would require funding to be identified from the relevant clinical area for any new POCT equipment or tests.

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval

Appendix 1 – Approved POCT Equipment and Tests

1.1: Blood Glucose Meters.

1.1.1: Abbott Freestyle Precision Pro

Description of test/equipment/procedure
Measurement of blood glucose using networked Abbott Freestyle Precision Pro meter.

Reagents/consumables
This instrument **MUST** only be used with Abbott Freestyle Precision Pro test strips. Users obtain test strips from Pharmacy and lancets from Supplies. IQC material is provided by Clinical Biochemistry.

Locations
Agreed Acute Trust wards and departments (KH, AHR, WRH). Community wards and departments.

Procurement – replacements
By arrangement with the local Clinical Biochemistry department.

Procurement – additional
Discuss requirements with the local Clinical Biochemistry department.

Maintenance
The clinical user is responsible for basic cleaning.

Repair
Faulty instruments are returned to the local Clinical Biochemistry department and a temporary replacement is issued. The Clinical Biochemistry department will arrange a replacement with the supplier. (Also see section 7.3)

Users
Trained nurses, laboratory staff and doctors.
Nursing students
Midwifery students
Trainee Nursing Associates (registered and unregistered)
Health Care Associates (band 2 & 3)

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners) or by Clinical Biochemistry staff.
Training is also provided by the associated Higher Educational Institute for Nursing and Midwifery students.
Barcode issued on completion of successful training.
Bi-annual refresher training for staff mandatory.

Records of trained staff
Record of all staff kept electronically on server in biochemistry. If training expires, user barcode will indicate unable to perform testing when scanned.
These are maintained by Clinical Biochemistry Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
In the patient's notes or on a Diabetes Chart for the patient. Copy of result also electronically kept on server in Trust. Access to results via Clinical Biochemistry.

IQC
Busy areas test at two levels daily, less busy areas one level. The results are recorded in the instrument logbook. Instruments can only be used if IQC results fall within the defined limits.
Each member of staff should perform at least two IQC assays annually.

EQA
EQA material is distributed by the Clinical Biochemistry department and should be assayed quarterly for each instrument. Results are returned to Clinical Biochemistry who then issue reports on performance.

1.1.2: Abbott Freestyle NEO H

Description of test/equipment/procedure
Measurement of blood glucose using non-networked Abbott Freestyle NEO H meter.

Reagents/consumables
This instrument **MUST** only be used with Abbott Freestyle Optium NEO H test strips
Users obtain test strips from Pharmacy and lancets from Supplies.
IQC material is provided by Clinical Biochemistry.

Locations
Agreed Acute Trust wards and departments (KH, AHR, WRH). Community wards and departments.
(List of wards approved for this equipment held by POCT co-ordinator).

Procurement – replacements
By arrangement with the local Clinical Biochemistry department.

Procurement – additional
Discuss requirements with the local Clinical Biochemistry department.

Maintenance
The clinical user is responsible for basic cleaning.

Repair
Faulty instruments are returned to the local Clinical Biochemistry department and a temporary replacement is issued.
The Clinical Biochemistry department will arrange a replacement with the supplier. (Also see section 7.3)

Users
Trained nurses, laboratory staff and doctors.
Nursing students
Midwifery students
Trainee Nursing Associates (registered and unregistered)
Health Care Associates (band 2 & 3)

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners) or by Clinical Biochemistry staff.
Training is also provided by the associated Higher Educational Institute for Nursing and Midwifery students.
Barcode issued on completion of successful training.
Bi-annual refresher training for staff mandatory.

Records of trained staff
Record of all staff kept electronically on server in Biochemistry.
These are maintained by Clinical Biochemistry Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
In the patient's notes or on a Diabetes Chart for the patient.

IQC

Busy areas test at two levels daily, less busy areas one level. The results are recorded in the instrument logbook. Instruments can only be used if IQC results fall within the defined limits.
Each member of staff should perform at least two IQC assays annually.

EQA
EQA material is distributed by the Clinical Biochemistry department and should be assayed quarterly for each instrument.
Results are returned to Clinical Biochemistry who then issue reports on performance.

1.1.4: Nova StatStrip.

Description of test/equipment/procedure
Measurement of blood glucose using networked Nova StatStrip meter.

Reagents/consumables
This instrument MUST only be used with StatStrip Xpress Glucose strips
Users obtain test strips from Pharmacy and lancets from Supplies.
IQC material is provided by Clinical Biochemistry.
Locations
Neonatal unit, Transitional Care, Post-Natal and Delivery Suite WRH.

Procurement – replacements
By arrangement the local Clinical Biochemistry department.

Procurement – additional
Discuss requirements with the local Clinical Biochemistry department initially.

Maintenance
Cleaned daily by ward staff.

Repair
The Clinical Biochemistry department will attempt to repair the instrument. If this is unsuccessful it will be returned to Nova via Siemens/local Clinical Biochemistry department. (Also see section 7.3)

Users
Trained nurses, laboratory staff and doctors.
Nursing students
Midwifery students
Trainee Nursing Associates (registered and unregistered)
Health Care Associates (band 2 & 3)

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners) or by Clinical Biochemistry staff.
Training is also provided by the associated Higher Educational Institute for Nursing and Midwifery students.
Barcode issued on completion of successful training
Bi-annual refresher training for staff mandatory.

Records of trained staff
These are maintained by Clinical Biochemistry Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
In the patient's notes or on a chart.

IQC
Performed daily by Clinical Biochemistry. The results are recorded in the instrument logbook. Instruments can only be used if IQC results fall within the defined limits.

EQA
EQA material is distributed by the Clinical Biochemistry department and should be assayed quarterly for each instrument.
Each member of staff should perform at least two EQA assays annually.
Results are returned to Clinical Biochemistry who then issue reports on performance.

1.2: Blood Ketone Meters

1.2.1: Abbott Freestyle Precision Pro

Description of test/equipment/procedure
Measurement of blood ketone using networked Abbott Freestyle Precision Pro meter.

Reagents/consumables
This instrument **MUST** only be used with Abbott FreestylePrecision Pro Blood Ketone Test Strips.
Users obtain test strips from Pharmacy and lancets from Supplies. IQC material is provided by Clinical Biochemistry.

Locations
Agreed Acute Trust wards and departments (KH, AHR, WRH).
(List of wards approved for this test and equipment held by POCT co-ordinator).

Procurement – replacements
By arrangement with the local Clinical Biochemistry department.

Procurement – additional
Discuss requirements with the local Clinical Biochemistry department.

Maintenance
The clinical user is responsible for basic cleaning.

Repair
Faulty instruments are returned to the local Clinical Biochemistry department and a temporary replacement is issued. The Clinical Biochemistry department will arrange a replacement with the supplier. (Also see section 7.3)

Users
Trained nurses, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners) or by Clinical Biochemistry staff. Barcode issued on completion of successful training.
Bi-annual refresher training for staff mandatory.

Records of trained staff
Record of all staff kept electronically on server in Trust, if training expired, user barcode will indicate unable to perform testing when scanned.
These are maintained by Clinical Biochemistry Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
In the patient's notes or on a Diabetes Chart for the patient. Copy of result also electronically kept on server in Trust. Access to results via Clinical Biochemistry.

IQC
Busy areas test at two levels daily, less busy areas one level. The results are recorded in the instrument logbook. Instruments can only be used if IQC results fall within the defined limits.
Each member of staff should perform at least two IQC assays annually.

EQA
EQA material is distributed by the Clinical Biochemistry department and should be assayed quarterly for each instrument. Results are returned to Clinical Biochemistry who then issue reports on performance.

1.2.2: Abbott Freestyle NEO H

Description of test/equipment/procedure
Measurement of blood ketone using non-networked Abbott Freesytle NEOH meter.

Reagents/consumables
This instrument **MUST** only be used with Abbott Freestyle Optium H β Ketone test strips.
Users obtain test strips from Pharmacy and lancets from Supplies.
IQC material is provided by Clinical Biochemistry.

Locations
Agreed Acute Trust wards and departments (KH, AHR, WRH).
(List of wards approved for this test and equipment held by POCT co-ordinator).

Procurement – replacements
By arrangement with the local Clinical Biochemistry department.

Procurement – additional
Discuss requirements with the local Clinical Biochemistry department.

Maintenance
The clinical user is responsible for basic cleaning.

Repair
Faulty instruments are returned to the local Clinical Biochemistry department and a temporary replacement is issued.
The Clinical Biochemistry department will arrange a replacement with the supplier. (Also see section 7.3)

Users
Trained nurses, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners) or by Clinical Biochemistry staff. Barcode issued on completion of successful training.
Bi-annual refresher training for staff mandatory.

Records of trained staff
Record of all staff kept electronically on server in Trust.
These are maintained by Clinical Biochemistry Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
In the patient's notes or on a Diabetes Chart for the patient.

IQC
Busy areas test at two levels daily, less busy areas one level. The results are recorded in the instrument logbook. Instruments can only be used if IQC results fall within the defined limits.
Each member of staff should perform at least two IQC assays annually.

EQA
EQA material is distributed by the Clinical Biochemistry department and should be assayed quarterly for each instrument.
Results are returned to Clinical Biochemistry who then issue reports on performance.

1.3: Blood Gas Analysers

1.3.1: Instrumentation Laboratory GEM 4000

Description of test/equipment/procedure
Instrumentation Laboratory GEM 4000 blood gas analysers.

Reagents/consumables
Ordering and stock control by Clinical Biochemistry.

Location
Wards at all three sites as agreed with Clinical Biochemistry.

Procurement – replacements
Through Siemens (WRH), Pathology Directorate and Trust Investment Committees.

Procurement – additional
Joint bid with clinical department/directorate, through Pathology Directorate and Trust Investment Committees.

Maintenance
Maintenance undertaken by Clinical Biochemistry.

Repair
See section 7.3 for staff timings.
Simple repairs by Clinical Biochemistry, otherwise Instrumentation Laboratory.

Users
Doctors, nurses, Nursing students, Midwifery students, Trainee Nursing Associates, Health Care Associates and pathology staff
.

Training
By pathology staff, Instrumentation Laboratory and “trained trainers” in clinical areas.
Mandatory bi-annual refresher training for staff.

Records of trained staff
These are maintained by Clinical Biochemistry Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
Each instrument retains records. Instrument printouts or written results may be entered in the patient’s notes.

IQC
Instruments continually monitor the performance of the assays and automatically mask off assay if unsatisfactory performance detected

EQA
Performed by Clinical Biochemistry staff.

1.3.2 Radiometer ABL 77.

Description of test/equipment/procedure
Radiometer ABL 77 blood gas analyser.

Reagents/consumables
Stock ordered by respiratory department, AHR

Location
Respiratory outpatients AHR

Procurement – replacements
Trust Investment Committees.

Procurement – additional
N/A

Maintenance
Performed by Respiratory Dept or Radiometer

Repair
Radiometer engineer attends. (Also see section 7.3)

Users
Respiratory Unit staff, AHR

Training
Training provided by Radiometer
Mandatory bi-annual refresher training for staff.

Records of trained staff
These are maintained by Clinical Biochemistry Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
Either handwritten in patient medical record, or instrument printout fixed into notes.

IQC
Supervised by Respiratory dept staff,

EQA
Performed by Respiratory staff

1.4: Blood INR.

Description of test/equipment/procedure
Roche Coaguchek XS plus.

Reagents/consumables
This instrument **MUST** only be used with Roche Coaguchek XS plus test strips
Users obtain test strips from Antioaculant Specialist Nurses through Haematology Department, lancets from Supplies.
IQC material is provided by Haematology.

Locations
Anticoagulation clinics and other clinics as agreed by POCT Committee on all three sites

Procurement – replacements
By arrangement with the local Haematology department.

Procurement – additional
Discuss requirements with the local Haematology department.

Maintenance
The clinical user is responsible for basic cleaning.

Repair
Faulty instruments are returned to the local Haematology department and a temporary replacement is issued. The Haematology department will arrange a replacement with the supplier. (Also see section 7.3)

Users
Trained nurses, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers or by Haematology staff.
Mandatory bi-annual refresher training for staff.

Records of trained staff
These are maintained by Haematology Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
In the patient's notes or on the vital parameters monitoring charts for the patient.

IQC
Busy areas test at two levels daily, less busy areas one level. The results are recorded in the instrument logbook. Instruments can only be used if IQC results fall within the defined limits.
Each member of staff should perform at least two IQC assays annually.

EQA
EQA material is distributed by the Haematology department and should be assayed quarterly for each instrument.
Results are returned to Haematology who then issue reports on performance.

1.5: Hemocue Hb Meter.

Description of test/equipment/procedure
Measurement of haemoglobin using networked Hemocue Hb 201+ DM meter.

Reagents/consumables
Cuvettes ordered by users from Hemocue/Radiometer

Locations
Theatres at all three sites

Procurement – replacements
By arrangement the local Clinical Biochemistry department.

Procurement – additional
Discuss requirements with the local Clinical Biochemistry department initially.

Maintenance
Cleaned daily by ward staff.

Repair
The Clinical Biochemistry department will attempt to repair the instrument. If this is unsuccessful it will be returned to Hemocue via Siemens/local Clinical Biochemistry department. (Also see section 7.3)

Users
Trained nurses, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners) Radiometer or by Clinical Biochemistry staff. Mandatory bi-annual refresher training for staff.

Records of trained staff
These are maintained by Clinical Biochemistry Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
In the patient's notes or on a chart.

IQC
Performed when required for use by ward/dept users. The results are recorded in the instrument logbook. Instruments can only be used if IQC results fall within the defined limits.

EQA
.None

1.6: Blood HBA1C.

Description of test/equipment/procedure
Siemens DCA Vantage

Reagents/consumables
This instrument **MUST** only be used with cartridges provided by the instrument supplier Siemens.
Test cartridges purchased directly from Siemens by Paediatric Outpatient department.
IQC material is provided by Siemens.

Locations
Paediatric Outpatients (AHR, WRH, KTC).

Procurement – replacements
Directly with Siemens.

Procurement – additional
Directly with Siemens.

Maintenance
The clinical user is responsible for basic cleaning.

Repair
Faulty instruments, Siemens to be notified directly to arrange repair or replacement. (Also see section 7.3)

Users
Trained nurses.

Training
Training is provided by Nurse Trainers or Siemens staff.
Mandatory bi-annual refresher training for staff.

Records of trained staff
These are maintained by Paediatric Outpatient departments and made available to Training and Development, from information provided by the trainers.

Reporting of results
In the patient's clinical notes and recorded onto Accu-Check 360 database currently in use in the Paediatric Diabetes Clinics.

IQC
IQC performed at 2 levels at each clinic when the analyser is used. Results to be recorded into record book kept alongside instrument..

EQA
EQA material is distributed by the Clinical Biochemistry department and should be assayed or each instrument. Results are returned to Clinical Biochemistry who then issue reports on performance.

1.7: Urine Stick Testing.

Description of test/equipment/procedure
Siemens (Bayer) Multistix for “routine” urine testing.

Reagents/consumables
Obtained from Pharmacy.

Location
Clinical areas throughout the Trust.

Procurement – replacements
N/A – disposable.

Procurement – additional
N/A disposable.

Maintenance
Sticks must be stored and used in accordance with the manufacturer’s instructions (e.g. within expiry dates and using correct timings).

Repair
N/A – disposable.

Users
Nurses, Nursing students, Midwifery students, Trainee Nursing Associates, HCAs anddoctors.

Training
Staff may only use sticks following appropriate training by nominated staff within the clinical area. (Ward managers/Sisters are responsible for ensuring only appropriately trained staff perform these tests).
Mandatory bi-annual refresher training for staff.
Records of trained staff
These are maintained by trainer for the clinical area.

Reporting of results
Results must be written in the patient’s notes according to the Trust’s “Clinical Record Keeping – Policy and Guidelines”. Abnormal results must be drawn to the attention of more senior staff.

IQC
None

EQA
None

1.8: Invitech Pregnancy Test Dipstick

Description of test/equipment/procedure
Qualitative measurement of urine HCG using the Invitech pregnancy dipstick test.

Reagents/consumables
Invitech Pregnancy Tests Urine 10mIU/mL dipsticks obtained from Pharmacy.

Locations
Wards and Out-patient clinics.

Procurement – replacements
By arrangement with the local Clinical Biochemistry department.

Procurement – additional
Discuss requirements with the local Clinical Biochemistry department initially.

Maintenance
None

Repair
The Clinical Biochemistry department will investigate any concerns that users may have with the performance of the strips, box should be returned to Clinical Biochemistry department. (Also see section 7.3)

Users
Trained nurses, student nurses, trainee nursing associates, HCAs, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners), Invitech staff or by Clinical Biochemistry staff. Mandatory bi-annual refresher training for staff.
Records of trained staff
These are maintained by Clinical Biochemistry Department and made available to Training and Development, from information provided by the trainers.

Reporting of results
Results should be reported onto Pregnancy Test Report forms (obtained from Clinical Biochemistry) and then this form should be put into the patients notes.

IQC
Currently there is no IQC material available.

EQA
Currently users are not asked to perform EQA.

1.9: Fetal Fibronectin in Cervicovaginal Secretions.

Description of test/equipment/procedure
Test used for ? premature rupture of membranes in weeks 24 – 34
Adeza Biomedical QuickCheck fFN

Reagents/consumables
Obtained by clinical areas from supplier: Mast Group, Bootle, Merseyside

Locations
Labour wards and Day Assessment Units at WRH.

Procurement – replacements
N/A – disposable

Procurement – additional
N/A – disposable

Maintenance
Slides and other materials must be used in accordance with the manufacturers instructions, e.g. within expiry dates and using correct timings

Repair
N/A – disposable

Users
Midwives and other health care professionals, as approved by the Obstetrics and Gynaecology (O&G) directorate

Training
Provided by the supplier (MastGroup) or trained members of staff.
Mandatory bi-annual refresher training for staff.
Records of trained staff
These are maintained by the Obstetrics and Gynaecology (O&G) directorate

Reporting of results
Handwritten in patients' notes

IQC
None

EQA
None

Note
The significance of the absence of QA procedures for this test was discussed with the Clinical Director (CD) for O&G. The CD explained that this test has been widely adopted in routine clinical practice and that its use was necessary to maintain a clinically acceptable standard of practice. The Trust POCT Strategy Committee (since succeeded by the Medical Devices/POCT committee) agreed in November 2005 that, on balance, the test should be used in the Trust despite the scientific misgivings. The representative from the supplier (Mast Group) undertook to alert the US manufacturers to concerns that a test lacking external QA and appropriate internal QC procedures would not normally be considered "fit for purpose". Performance of this test and adherence to Trust policy is the responsibility of the O&G Directorate.

Appendix 2 - Procedure for the Introduction of a New POCT Test

Proposals to introduce a new POCT procedure must be sponsored by a clinical department/directorate who will be major users of the test and also by the most appropriate pathology department. The information requested below should be submitted to the Trust Medical Devices/POCT Committee.

Before undertaking a detailed assessment of a new POCT test it is strongly recommended that provisional approval is obtained from the Medical Devices/POCT Committee by completion the first 2 pages where possible (Please discuss with the relevant Pathology department who will be able to assist in the completion of this paperwork).

Please describe the test/procedure/equipment:

Name/position of sponsor, clinical department:

Name/position of sponsor, pathology department:

Does this proposal have the support of the appropriate clinical department(s) and/or directorate(s)? Please describe:

Does this proposal have the support of the appropriate pathology department(s)? Please describe:

Please list any documentation relevant to the above (e.g. letters, minutes) which should be attached to this proposal:

Is the test currently available in the Trust (non-POCT or POCT)? If so, please describe:

If this is a new test, why can it not be provided from the pathology department?

If it is an existing test why do current arrangements not fulfil clinical need? Please describe clinical audit results that demonstrate this and steps that have been taken to modify the current service to attempt to meet this need:

If equipment is required how will it be funded?

Are there any estate or service (eg power, drainage) requirements for the installation of this equipment?

How will equipment support and maintenance costs be funded?

How will consumables be funded?

Do clinical staff have the time to undertake this test (including time for training and participation in quality control)?

What resources will be required by the pathology department to support this test? How will these be funded?

What clinical benefits are anticipated from the introduction of this POCT procedure?

How will these be demonstrated?

Please describe the analytical system:

Is the pathology department satisfied with its performance characteristics?

If a test for the analyte is also provided by the pathology department, how do results compare and what steps will be taken to accommodate any differences and minimise clinical risk?

Please:

Describe procedures and responsibilities for results recording:

Describe training requirements and responsibilities:

Describe procedures and responsibilities for the support of test procedures/equipment:

Outline internal quality control procedures and responsibilities:

Outline arrangements for external quality assessment:

Describe health and safety issues and the outcome of discussions with Infection Control staff:

Outline audit plans to demonstrate improvements in clinical care:

Appendix 3 - Training and Competencies for POCT Service Provision

Staff must undergo approved training before carrying out POCT tests. Trained status is valid for a year, at which time retraining must be undertaken.

Grade of staff for whom POCT training and service performance is appropriate.

Student nurses and midwives, trainee nursing associates and HCAs, specified by the Chief Nursing Officer or Designated Deputy and Midwifery and subsequently endorsed by the Trust POCT Strategy Committee (since succeeded by the Medical Devices/POCT committee).

Criteria for training an individual member of staff.

The member of staff must be of an appropriate grade (see above) and the clinical manager must be satisfied that:

- The individual is suitable to assume the necessary responsibilities.
- There is a service need to train an additional member of staff.
- Workload will be sufficient to maintain expertise.

POCT/Link Nurse trainers

- POCT trainers must be registered healthcare professionals.
- Training and Development will coordinate the training and approval of POCT trainers, usually in collaboration with the local pathology laboratory.