Trust Policy	Worcestershire Acute Hospitals NHS Trust

Point of Care Testing Policy

Department / Service:	Pathology
Originator:	G. Mascall (Consultant in Clinical Biochemistry)
Accountable Director:	M. Crowther
Approved by:	Trust Management Committee
Date of approval:	18th June 2014
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Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	All Acute Trust departments
Target staff categories	Acute Trusts 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

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1. Introduction

POCT has been identified as a high risk activity. This policy describes the management arrangements implemented to minimise this risk.
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. 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 procedure is being considered.

2. Scope of this document

The purpose of the POCT Policy is to ensure that all POCT procedures are performed to uniformly high standards across the Trust, and also on those sites outside the Trust for which the Trust has POCT responsibilities.

3. Definitions

"Point of Care Testing" (POCT) is the usual term employed and has replaced "Near Patient Testing" and "Extra-Laboratory Testing".

4. Responsibility and Duties

The Trust Medical Devices/POCT Committee is responsible for establishing, implementing and monitoring POCT policy and reports to The Safe Patient Group. It 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. In formulating policy this committee refers to national professional guidance and to appropriate legislation. Approval by this committee is required before a new POCT test is introduced in the Trust (see Section 14).

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 laboratories.

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

- Equipment maintenance and troubleshooting and liaising with manufacturers and suppliers when necessary.
- Training and retraining of ward/departmental nursing staff, Specialist Nurses, Nurse Practitioners and medical staff 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 undertake 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.
- The grades of staff for whom POCT is appropriate are determined by the Chief Nursing Officer or Designated Deputy in consultation with the Medical Devices/POCT Committee (see Appendix 3).
- Departmental Managers should discuss their requirements for external quality assessment specimens with the appropriate pathology laboratory (see Section 9.2).
- Other non-medical staff who may undertake POCT include Specialist Nurses and Nurse Practitioners who should discuss their training with their Departmental Managers.
- Medical staff, like all other staff, must be trained before undertaking POCT. Medical staff's most frequent direct involvement in POCT is blood gas testing and training for this will be provided by the local Clinical Biochemistry department. Most blood gas analysers are password-protected and staff must only use their own password, which will have been allocated following training.

6.3 Medical staff.

Medical staff, like all other staff, must be trained before undertaking POCT. Medical staff's most frequent direct involvement in POCT is blood gas testing and training for this will be provided by the local Clinical Biochemistry department. Most blood gas analysers are password-protected and staff must only use their own password, which will have been allocated following training.

7. POCT Equipment.

Disposable POCT devices (e.g. as used for pregnancy testing) are considered to be "equipment".

7.1 Equipment procurement.

To procure equipment for a new POCT procedure see Section 14: New POCT Tests**.** To obtain additional or replacement equipment for existing procedures, refer to the appropriate section of Appendix 1**.**

7.2 Equipment management.

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

7.3 Equipment support.

Equipment support may be provided by nursing staff with POCT responsibilities where appropriate, pathology staff or manufacturers/suppliers. 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.

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 will 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 when handling body fluids..
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 (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 information on the performance of both a piece of equipment and its operator. 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.

The aspects of POCT that are the responsibilities of the local pathology departments are included in the accreditation procedures (e.g. inspection and approval by CPA (Clinical Pathology Accreditation) UK Ltd) applying to those departments.

9.5 Reporting to the Trust.

There will be a six-monthly report 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.

There is a clear trend towards POCT equipment being password-protected.

- This helps to ensure equipment is used only by staff who 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 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 for blood glucose meters or on the instrument for blood gas analysers).

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 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 all three sites in maintaining POCT devices and training.
The laboratory will maintain a record 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 working correctly, and being used, 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.

11.5 Health Care Support Workers.
Health Care Support Workers should only perform POCT testing as approved by the Trust Chief Nursing Officer (see 12.1).

11.6 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 retraining 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 who 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.

For Blood Glucose monitoring equipment, Blood Gas Analysers and Urine Pregnancy testing devices, trainers must make a record of staff they have trained. 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 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. Such training does not qualify the member of staff to independently perform POCT for service purposes in a specific clinical area, the criteria for which are stated in 10.2 above. However, previous educational training would be expected to facilitate service training.

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 proforma (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 pathology IT system.
- 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.

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 Standard Operating Procedure (SOP) which has been approved by the POCT committee and is subject to regular review.	SOP's 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 one year after approval or sooner in the event of any significant changes in the Trust structure or processes that require amendment.

19. References.

19.1 Guidelines for Near Patient / Point of Care Testing.
Joint Working Group on Quality Assurance, 1999.

19.2 Management and Use of IVD Point of Care Test Devices.
Device Bulletin.
Medical Devices Agency, 2002.

19.3 Guidelines on point-of care testing.
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.

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 20.5 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:**		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	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 Xceed Pro

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

Reagents/consumables
This instrument **MUST** only be used with Abbott Precision Xceed 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.

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.

1.1.2: Abbott Freestyle Optium H

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

Reagents/consumables
This instrument **MUST** only be used with Abbott Optium 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 POOCT 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.

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.

1.1.3: Hemocue

Description of test/equipment/procedure
Measurement of blood glucose using non-networked Hemocue Glucose 201+ meter.

Reagents/consumables
Ordered and stocked by Clinical Biochemistry, AH.
Hemocue Glucose cuvettes

Locations
Neonatal units, AH.

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 the local Clinical Biochemistry department.

Users
Trained nurses, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners) or by Clinical Biochemistry staff.
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.

1.1.4: Nova StatStrip.

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

Reagents/consumables
Ordered and stocked by Clinical Biochemistry, WRH.
Nova StatStrip

Locations
Neonatal unit, 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.

Users
Trained nurses, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners) or by Clinical Biochemistry staff.
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 Xceed Pro

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

Reagents/consumables
This instrument **MUST** only be used with Abbott Precision Xceed 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.

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 Optium H

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

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

Locations
Paediatric Inpatient wards (AHR, WRH)

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.

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: Radiometer ABL 700 Series

Description of test/equipment/procedure
Radiometer ABL 700 series blood gas analysers.

Reagents/consumables
Ordering and stock control by Clinical Biochemistry.

Location
Acute wards AHR and WRH 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
Daily, weekly and monthly maintenance undertaken by Clinical Biochemistry.
Six-monthly maintenance by Radiometer.

Repair
Simple repairs by Clinical Biochemistry, otherwise Radiometer.

Users
Doctors, nurses, pathology staff.

Training
By pathology staff, Radiometer and “trained trainers” in clinical areas.
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
Each instrument retains records. Instrument printouts or written results may be entered in the patient’s notes.

IQC
Instruments automatically assay one level daily (out of four) and unsatisfactory results are flagged.

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 and stored by Clinical Biochemistry.

Location
Clinical Investigation Units at WRH & KH.

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

Procurement – additional
N/A

Maintenance
Performed by Clinical Biochemistry staff.

Repair
Biochemistry staff attempt repair. If unsuccessful, Radiometer engineer attends.

Users
Mainly Clinical Investigation Unit staff, trained by Biochemistry.

Training
Training provided by Biochemistry staff.
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
Either handwritten in patient medical record, or instrument printout fixed into notes.

IQC
Supervised by Clinical Biochemistry staff, varies according to site / model.

EQA
Performed by Clinical Biochemistry 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 (AHR, WRH).

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.

Users
Trained nurses, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers or by Haematology staff.
Bi-annual refresher training for staff mandatory.

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 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 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 non-networked Hemocue Hb meter.

Reagents/consumables
Cuvettes ordered by users from Hemocue

Locations
Theatres at WRH and AHR

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.

Users
Trained nurses, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners) or by Clinical Biochemistry staff.
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 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
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.

1.6: 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 form 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.

Users
Trained nurses.

Training
Training is provided by Nurse Trainers or Siemens staff.
Bi-annual refresher training for staff mandatory.

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
Dip-sticks 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, HCAs, doctors.

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).
Bi-annual refresher training for staff mandatory.

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.

Users
Trained nurses, laboratory staff and doctors.

Training
Training is provided by Nurse Trainers (Link Nurses/Practitioners), Invitech staff or by Clinical Biochemistry staff. 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
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. However, EQA samples are analysed monthly using these test strips within the Clinical Biochemistry department.

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 AHR and 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.
Bi-annual refresher training for staff mandatory.

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.

NVQ level 2 and above, 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.