DEPARTMENT OF PATHOLOGY

POINT OF CARE TESTING QUALITY MANUAL
1. Introduction

This manual describes the policies and the quality management system in use for point of care (POCT) testing activities at the RUH. These activities are included in the scope of the Clinical Pathology Accreditation (CPA) scheme for Biochemistry and Haematology. There are additional CPA standards for POCT and the way in which these additional standards are included within the Quality Management System (QMS) is described in this manual.

This manual should be read in conjunction with the RUH Pathology Quality Manual and relevant policies that are referred to below.

2. Policies and Objectives

The Pathology Quality Policy in the Quality Manual defines the scope of our services including POCT and also our intention to provide a high quality service and our commitment to good professional practice, protection of health and safety and compliance with legislation and accreditation standards.

The RUH Point of Care Testing Policy (ref. 772/2013) covers a number of aspects of POCT that are relevant to the QMS for POCT. These include roles and responsibilities, procurement, training, operation, standard operating procedures, recording of results, quality control and quality assessment. This Manual should be read in conjunction with this Policy. There are other RUH policies that are relevant to POCT and these are listed in Appendix 1.

The long term quality objectives for POCT are as defined in the RUH Pathology Quality Manual and these are reviewed at the time of Annual Quality Review. Short term quality objectives for POCT are set and reviewed within the POCT Sub-group to the Medical Equipment Committee. The minutes of this group’s meetings provide relevant records.

3. Scope of Point of Care Testing Activities

The scope of this manual is point of care testing of blood or urine that comes under the scope of the Pathology department and is defined as below:

Haemoglobin testing using Hemocue machines. This takes place in RUH Theatres.

INR testing using Coaguchek device. Coaguchek tests for INRs are carried out by nursing staff on the Eye ward and trained staff at two GP surgeries.

Blood gas analysers and co-oximeters using Roche Cobas and other makes of equipment in a small number of RUH Wards.

Glucose testing using Abbott PXP hand-held devices. These are used by a large number of RUH Wards. One Ward also tests for ketones.

Glucose testing using Abbott Optium XC devices in a number of GP Practices using GP staff.

Pregnancy testing using One Step Pregnancy Test. These are used in a number of RUH Wards and areas.
Urine dipsticks by Meditest, some of these used with Uryxxon readers. These are used in a number of Wards.

A record of equipment in use is maintained on QPulse using the Equipment module.

4. Organisation and Management

The overall responsibility for POCT within the Trust lies with the Medical Equipment Committee (MEC). This committee is chaired by the Director of Pathology and is made up of healthcare professionals. There is also a POCT multidisciplinary subgroup of the MEC that has a delegated role in the establishing and monitoring of the operational aspects of POCT. In conjunction with the MEC, this subgroup, which meets every quarter, ensures that:

• the responsibilities, authority and interrelationships of all personnel involved in POCT are specified and communicated within the organisation;
• staff performing POCT receive appropriate training, supervision and competence testing;
• all proposals to introduce any product, device, or system for POCT are evaluated for their clinical effectiveness and cost efficiency the selection of POCT devices and systems includes their practicability and the comparability of their results with those obtained in the laboratory;
• the selection of POCT devices and systems includes their practicability and the comparability of their results with those obtained in the laboratory;
• the reports of the POCT quality assurance programme(s) are reviewed by the group’s members and advice on improvement is provided and implemented.

Person Responsible for Managing POCT Services

This role consists of the following:

• Ensuring that POCT is carried out in accordance with clinical need and based on technical feasibility.
• The risks associated with POCT are kept under regular review.
• Action is taken on significant issues concerning the conduct of POCT.
• Ensuring that incidents associated with POCT are reviewed and appropriate investigation, root cause analysis and corrective action are taken.

POCT Co-ordinators

This role consists of the following:

• Taking part in the specification and the trials of new equipment for use in POCT.
• Ensuring that suitable POCT SOPs are developed and kept up to date.
• Ensuring that training is provided for staff that use POCT, including link nurses / persons so that they in turn are able to train POCT users.
• Ensuring that audits of POCT practice are carried out within Pathology and within the Hospital (in conjunction with link nurses / persons in latter case).
• Arranging for POCT EQA to be carried out and monitoring the outcomes.
• Providing support in the case of device performance issues.
• Investigating POCT failures & incidents as required.
POCT Quality Manager

This role consists of the following:

- Developing a suitable quality management system to provide a safe and effective POCT service and meet accreditation requirements.
- Maintaining the POCT quality management system in the light of changes in policy, requirements and experience.
- Providing a mechanism for reporting and managing weaknesses, failures and incidents in relation to POCT.
- Organising and providing information for regular POCT reviews.

Structure of POCT-related Committees and Groups

There is more information about the roles of the above groups in the RUH POCT policy. This reflects the clinical governance and reporting structure for POCT.

5. Quality Management System for Point of Care Testing

This Pathology Quality Management System includes POCT within its policies and procedures. This section highlights aspects of the QMS that are specific to POCT and references the relevant CPA standards.
A ORGANISATION AND QUALITY MANAGEMENT SYSTEM
A1 Organisation and management

A1.6 The management of Pathology ensures that POCT operates according to the requirements of the CPA Standards for the Medical Laboratory and the Additional Standards for POCT Facilities though a detailed understanding of the requirements of these standards, through incorporating them into the Pathology Quality System and through internal audit of the various POCT activities.

A1.7 Senior management of Pathology and the Trust ensure through the persons that have designated responsibilities in the POCT area that there are suitable procedures in place that monitor the quality of the service provided. The main quality indicators for POCT are performance in External Quality Assurance and the results of internal quality audit. These are discussed in the meetings of the POCT Subgroup of the Medical Equipment Committee.

A1.8 The Medical Equipment Committee is a healthcare professional grouping that looks at the evaluation, selection, purchasing, the introduction into use and the disposal of medical equipment.

A1.9 A multidisciplinary POCT group has been appointed to implement the Trust POCT policy in the relevant areas of the organisation. This includes ensuring that the roles of the various personnel involved in POCT are understood and also ensuring that training, supervision and competency assessments are carried out. New devices and systems are evaluated before being put into use to confirm that the expected results can be achieved and that suitable performance under operational conditions is achieved and that results are comparable with results from the laboratory. Reports from the POCT QA programme such as EQA performance, internal audits, failures and incidents are reviewed and improvements put into place where these are needed.

A2 Needs and requirements of users

A2.5 In the case of other organisations to whom the RUH provides POCT services such as EQA provision, there are written agreements that define the role of each party and who has the ultimate responsibility for the results of POCT testing. The current POCT services to other organisations consist of an INR measurement service to Sirona Care & Health CIC and EQA for glucose meters to a number of GP Practices.

A4 Quality management system

A4.4 The Pathology Quality Management system has been designed so that its scope includes the management and conduct of POCT. There is an overall procedure for POCT and POCT activities have been included in the relevant system procedures and there are also specific documents for POCT such as POCT SOPs and forms.
A7 Quality manager

A7.4 The Pathology Quality Manager has the responsibility for ensuring that the Quality System for POCT is implemented and properly maintained.

A8 Document control

A8.4 Manuals and instructions for POCT are under document control and are readily available for users.

A11 Management review

A11.4 There is a separate review of POCT that is carried out on an annual basis within the POCT Subgroup. This review covers the clinical need and effectiveness of POCT as well as its cost effectiveness. A Summary of this review is provided to the Pathology Annual Quality Review.

B PERSONNEL

B1 Laboratory director

B1.6 A POCT Subgroup of the Medical Equipment Committee has been appointed. This is a multidisciplinary group that oversees the use of POCT devices in the Hospital.

B1.7 There is an annual review of POCT. This review includes an ongoing evaluation of the effectiveness of POCT and identifies opportunities for improvement.
B2 Staffing

B2.4 The POCT subgroup ensures that there are suitable staffing levels in order to implement the POCT quality management system and to train the staff carrying out POCT.

B6 Staff records

B6.3 Staff carrying out POCT are designated and records are maintained of their competency to carry out this work.

B9 Staff training and education

B9.7 Staff carrying out POCT are trained to carry out the test according to instructions and SOPs. There are also a number of other aspects that are covered during the training. See the POCT testing procedure (QSP/26) for more information.

B9.8 Competency of staff to perform tests is assessed after training and at intervals after that. There may be re-training if required. Records of these assessments are kept. See the POCT testing procedure (QSP/26) for more information.

C Premises and Environment

C1 Premises and environment

C1.5 The premises in which POCT is conducted are provided based on the environment, space, storage, safety and other requirements of the particular test being conducted.

E Pre-examination Process

E3 Specimen collection and handling

E3.4 Inability to be able to process specimens is recorded in the relevant log book.

F Examination Process

F3 Ensuring the quality of examinations

F3.6 Where results are obtained by both POCT and the laboratory, the results will be compared and both results made available to the relevant clinician.

G The Post Examination Phase

G2 The report

G2.6 POCT testing reports are recorded in the patient’s medical record and they are separate from laboratory test results. The name of the person carrying out the test is also recorded. See the POCT testing procedure (QSP/26) for more information.
H EVALUATION AND QUALITY ASSURANCE

H5.5 The RUH participates in a number of EQA schemes for POCT testing. More information on the schemes is provided in the POCT testing procedure (QSP/26). Where there is no scheme available, samples are circulated to other similar analysers and results compared.
## Appendix 1 RUH Policies Relevant to POCT

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Equipment Policy</td>
<td>713 / 2011</td>
</tr>
<tr>
<td>Point of Care Testing Policy</td>
<td>772 / 2013</td>
</tr>
<tr>
<td>Information Governance</td>
<td>316 / 2009</td>
</tr>
<tr>
<td>Records Management, Health</td>
<td>323 / 2012</td>
</tr>
<tr>
<td>Decontamination Policy</td>
<td>618 / 2011</td>
</tr>
<tr>
<td>Incident Reporting and Management</td>
<td>213 / 2013</td>
</tr>
<tr>
<td>Product Control Group</td>
<td>217 / 2007</td>
</tr>
</tbody>
</table>