

**DEPARTMENT OF PATHOLOGY**

**Point of Care Testing (POCT) Quality Manual**



## 1. Introduction

This manual describes the policies and the Quality Management System (QMS) in use for point of care testing (POCT) activities at the RUH. These activities will be included in the scope of the UKAS scheme for Blood Sciences POCT services as soon as they are in a suitable position to apply for accreditation. These are additional UKAS standards for POCT. This manual should be read in conjunction with the RUH Pathology Quality Manual (MAN/1) 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. 772/2018) 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. Other RUH policies that are relevant to POCT are listed in Appendix 1.

The long term quality objectives for POCT are as defined in the RUH Pathology Quality Manual. Longer term objectives are reviewed and recorded at the Annual Quality Review. Further, shorter term quality objectives for POCT are set and reviewed within the POCT Committee. The minutes of this group's meetings provide relevant records and are available on the POCT section of the RUH intranet.

## 3. Scope of Point of Care Testing Activities

Point of care testing of blood or urine under the scope of the Pathology department and is defined as below:

Instrument	Analyte/s	Location
Hemocue	Haemoglobin	RUH Theatres
CoaguChek	INR	RUH Wards & GP Surgeries
Blood Gas Analysers – Cobas BXXX, etc	Blood gases, co-oximetry, glucose, lactate etc	RUH Wards & other areas
Abbott FPP Analyser	Glucose and Ketones	RUH Wards
Siemens DCA Vantage	HbA1c	Paediatric Diabetes OPD
One Step Pregnancy Test	hCG	RUH Wards
Meditest	Urine dipstick	RUH Wards

Note: Glucose testing on GP held devices are currently not quality managed by the RUH POCT organisation (Oct 2018). This will be reviewed as the management of POCT within the RUH becomes more established and is supported by an appropriate staff structure.

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 Head of Clinical Engineering.

The chair of the POCT committee attends the MEC meetings to report on POCT issues and changes relating to POCT equipment and associated processes.

The POCT committee itself is made up of healthcare professionals from Pathology and other clinical areas. In conjunction with the MEC, this committee, 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 (POCT Coordinator)

This role consists of the following:

- Ensuring that POCT is carried out in accordance with clinical need, in line with best practice and includes consideration of 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.
- Taking part in the specification and the trials of new equipment for use in POCT alongside ward or clinical staff in the area of use.
- 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 QMS to provide a safe and effective POCT service and meet accreditation requirements.
- Maintaining the POCT QMS 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.

## QMS for POCT:

The Pathology QMS includes POCT within its policies and procedures. This section highlights aspects of the QMS that are specific to POCT and references the relevant UKAS standards. (ISO15189:2012 & ISO22870:2006)

### ORGANISATION AND QUALITY MANAGEMENT SYSTEM (4)

#### Organisation and management (4.1)

The management of Pathology ensures that POCT operates according to the requirements of the UKAS Standards for the Medical Laboratory and the Additional Standards for POCT facilities through 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. (ISO 15189:2012 & ISO 22870:2006).

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.

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.

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.

**Needs and requirements of users (4.1.2.2)**

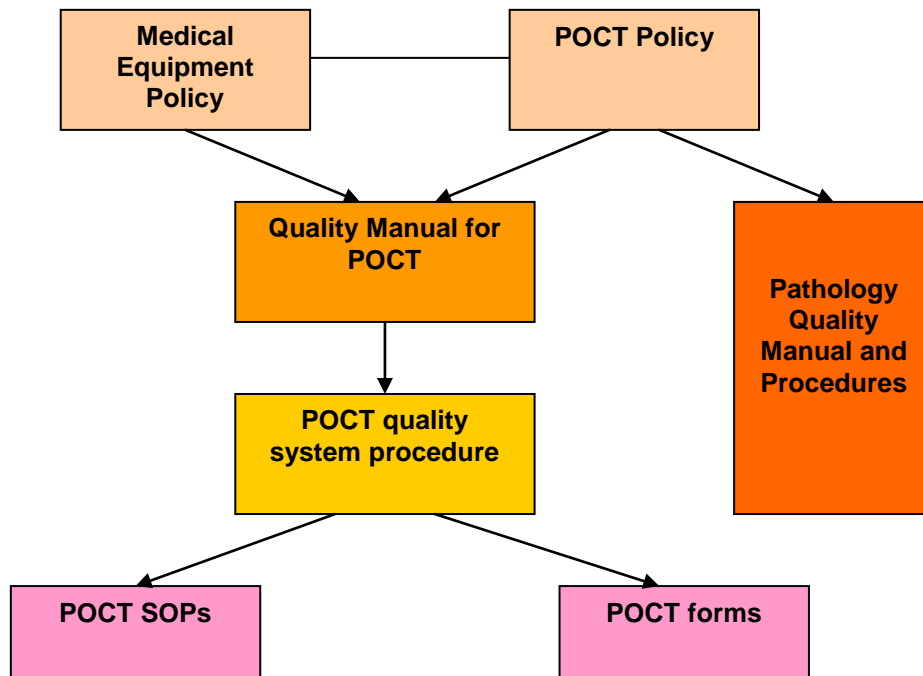
Laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services meet the needs of the patients and those using the laboratory services.

**Quality Policy (4.1.2.3)**

**See QPulse (MAN/1)**

The Pathology Quality Management system has been designed so that its scope includes the management and conduct of POCT.

**Diagram of QMS for POCT**



**Quality manager (4.1.2.7)**

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

**Document control (4.3)**

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

**Laboratory director has the delegated responsibility and competence to direct the services provided. (4.1.1.4)**

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

There is an annual review of POCT. This review includes an ongoing evaluation of the effectiveness of POCT and identifies opportunities for improvement (Annual Quality Review)

**Staffing (5.1)**

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.

**Staff records**

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

**Staff training and education**

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.

5.1.7 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.

**PREMISES AND ENVIRONMENT (5.2)**

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.

**PRE-EXAMINATION PROCESS (5.4)**

**Specimen collection and handling**

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

**EXAMINATION PROCESS (5.5)**

**Ensuring the quality of examinations (5.6)**

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

**THE POST EXAMINATION PHASE (5.7)****The report (5.8)**

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.

**EVALUATION AND QUALITY ASSURANCE (4.14)****External quality assessment**

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**

<b>Policy Title</b>	<b>Ref.</b>
Medical Equipment Policy	713 / 2018
Point of Care Testing Policy	772 / 2018
Information Governance	331 / 2018
Records Management, Health	323 / 2017
Decontamination Policy	618 / 2016
Incident Reporting and Management	213 / 2016