# POINT OF CARE TESTING POLICY (POCT)

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**Responsible Directorate:** Medical and Governance

**Replaces (if appropriate):** United Hospitals Trust Policy for Point of Care Testing (Implemented 2006)

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**NHSCT MISSION STATEMENT**

*To provide for all the quality of services we would expect for our families and ourselves*
**1.0 INTRODUCTION**

1.1 Point of Care Testing (POCT), also known as near patient, bedside or extra-laboratory testing, refers to the analysis of patients’ samples outside the conventional laboratory setting. POCT is usually performed by non-pathology healthcare professionals using devices ranging from a simple ‘dip-stick’ to highly sophisticated analytical instrumentation.

1.2 Advancing technology has markedly expanded the potential for POCT by increasing the range and reliability of devices and reducing the vulnerability to operator error. However, POCT carries additional risk and is generally more expensive than the laboratory alternative, so introduction of a new service requires careful consideration and a clear view of the benefits to be gained. Clinical Governance has been identified as an essential part of any POCT service.

1.3 Guidelines on POCT have been published by a number of organisations and most recently by the Medical Devices Agency. It is essential that POCT applications are subject to clinical effectiveness studies and the associated risks managed to the standards published. This document outlines the principles of good practice and aims to promote a unified approach to POCT in the Province; ensure that consistent procedures are in place and that high quality cost effective POCT services are provided.

**2.0 PLANNING A POCT SERVICE**

2.1 The local Pathology Laboratory should establish a multidisciplinary POCT committee to represent all interests and oversee the planning, implementation and co-ordination of POCT activities in the hospital and community.

2.2 At the outset, the POCT committee should establish that the perceived need is valid and that a POCT solution will be clinically and operationally effective.

2.3 The Pathology laboratory will advise on the suitability of equipment and co-ordinate the assessment and evaluation of candidate devices.

2.4 Any decision to proceed with a POCT application should be subject to a business case detailing the clinical and operational benefits to be gained and the likely economic impact. The cost/benefit analysis must include both direct costs and the full indirect costs of pathology involvement.

**3.0 ORGANISATION and MANAGEMENT**

3.1 Managers should be aware of their responsibility for clinical governance and of the medico legal implications of an erroneous result. Liability under the consumer
protection act (1987) will only remain with the manufacturer or supplier if the user can demonstrate that POCT equipment has been used in strict accordance with the manufacturer’s instructions.

3.2 The local Pathology laboratory, through the POCT committee, will undertake to support POCT and co-ordinate management and Quality Assurance activities in liaison with designated healthcare staff in the clinical unit concerned. Accountability for the following areas should be explicit.

3.3 **Accreditation**

POCT should be organised and managed to the standards required by Clinical Pathology Accreditation (UK) Ltd., or an equivalent accreditation organisation, and be subject to inspection and assessment as part of the accreditation of the local Pathology Service.

3.4 **Training**

Only staff whose training and competence has been established and recorded should be permitted to carry out POCT. The local Pathology laboratory must specify and approve training in collaboration with the manufacturer or supplier. This should cover the elements essential to the safe and reliable application of the POCT device. A list of trained and authorised users should be maintained with each device and update training arranged as appropriate.

3.5 **Standard Operating Procedure (SOP)**

The POCT committee should ensure that an SOP, written to Clinical Pathology Accreditation (UK) Ltd., or an equivalent accreditation organisation standard, is in place for each device. This shall include the manufacturer’s instructions, exactly reproduced, and all information required to operate the device safely, produce reliable results (interpretation of results, error messages, quality control procedures and basic maintenance), record keeping and who to contact for advice. Mechanisms should be in place to ensure that SOPs are regularly reviewed and updated.

3.6 **Maintenance**

The POCT committee will designate responsibility for preventative and routine maintenance of specific devices and the authority to call out a service engineer. It will be the responsibility of users to report any problem, defect or failure as soon as possible and inform the local pathology laboratory if a back-up service is required.

3.7 **Health and Safety**

The potential hazards associated with the siting of the POCT device, handling, storage and disposal of reagents, waste body fluids and sharps etc. in clinical areas must be recognised and due account taken of current Health and Safety legislation and the need for an effective infection control policy.
3.8 Quality Assurance (QA)

Quality assurance encompasses all measures taken to ensure that investigations are reliable and will include Internal Quality Control (IQC) procedures and External Quality Assessment (EQA). Responsibility for compliance with QA policy lies with the management of the clinical unit concerned; however, the local Pathology laboratory will oversee IQC and EQA performance and exercise the authority to remove any device from service with immediate effect on the basis of poor performance including instances of unauthorised or incorrect use. The Pathology Laboratory shall also provide an appropriate back up in the event of loss of service.

3.9 Record Keeping

It is essential that appropriate records are maintained by the user. This will include recording of patients’ results (unequivocal patient identification, date and time of analysis and operator ID), and ensuring the continuity of patients’ records. A record of all IQC, reagent batch numbers and the maintenance log should be maintained for the lifetime of the device. EQA data should be stored for a minimum of 2 years.

3.10 Adverse Incident Reporting

Healthcare managers are required to follow Trust Policy on Incident and Near Miss Reporting. Adverse incidents involving medical devices, including POCT devices, are reported to the Medical Devices Agency for investigation. Any errors arising out of failure to adhere to operating systems must be reported and monitored through the relevant quality management systems. Where serious errors occur these will be reported to the Clinical Governance and Point of Care committees.

3.11 Audit

Regular audit of the reliability and effectiveness of POCT devices and the arrangements for management of the service should be carried out.

3.12 Budgetary Arrangements

Responsibility for all revenue consequences, including a maintenance contract, device interfacing, repairs, consumables including Quality Control materials and all other parts required must be agreed with the local POCT committee.

3.13 Agreement

Arrangements between the local Pathology Laboratory and users for the management of a POCT service must be agreed in detail before any device is commissioned. The agreement should be in the form of a written contract signed by relevant Consultant Staff.
REFERENCES


