Point of Care Testing Policy

V2.0

December 2014
1. **Introduction**

1.1. Point of Care Testing (POCT) is the performance of analytical tests on patient specimens outside of the laboratory by non-laboratory staff.

1.2. POCT is an established part of clinical practice and offers rapid provision of test results which carry the same weight in patient management as results obtained in the Laboratory.

1.3. It is a significant Risk Management Issue for the Trust as incorrect results have the same medico-legal implications regardless of who performed the test.

1.4. This version supersedes any previous versions of this document.

2. **Purpose of this Policy/Procedure**

2.1. The purpose of this policy is to ensure that consistent procedures are in place throughout the Royal Cornwall Hospitals NHS Trust to reduce to a minimum the risk to patients and staff from errors that may occur from the use of these devices.

2.2. This policy is designed to ensure that the POCT systems used within RCHT are managed in accordance with national guidelines and accreditation standards. It is also designed to ensure that the introduction of new POCT technology is appropriate and consistent across the Trust.

2.3. The policy has been produced using

- Management and Use of IVD Point of Care Test Devices: Medicines and Healthcare Products Regulatory Agency (MHRA), MDA DB2002(3)

3. **Scope**

3.1. This policy applies to all healthcare professionals undertaking POCT at RCHT.

3.2. It also applies to those Trusts who have service level agreements with RCHT for the provision of a POCT service.

3.3. This policy applies to both new and existing POCT devices.

4. **Definitions / Glossary**

- POCT: the performance of analytical tests on patient specimens outside the laboratory by non-laboratory staff.
- POCT device: any analyser, dipstick or other instrument used to obtain results on patient specimens outside the laboratory.
- User: any individual using a POCT device.
5. Ownership and Responsibilities

5.1. The **POCT Committee** are responsible for reviewing and monitoring:

- The POCT policy
- Proposals to introduce new POCT
- Procedures and practices for the safe use and maintenance of POCT devices

5.2. **Laboratory POCT Staff** are responsible for:

- Routine maintenance and troubleshooting of POCT devices, as defined by the SLA
- Arranging appropriate training
- Liaising with Key Trainers
- Monitoring quality control and quality assurance
- Ensuring that operating procedures are available
- Selection and evaluation of equipment to ensure that POCT is adopted only where is has proven clinical value
- Providing a back-up service in the event of POCT device failure
- Reporting to the Trust’s POCT Committee
- Reporting technical performance problems to the MHRA
- Distributing MHRA alerts to the Trust’s in-house safety alerts team
- Expert advice and liaison with users.

5.3. **Managers of Areas using POCT** are responsible for:

- Ensuring staff are aware of their personal responsibilities with regard to training and the use of POCT devices
- Ensuring that staff are trained and competent to use POCT devices
- Keeping records of training and competency
- Ensure that all users carry out quality control and quality assurance as advised
- Nominating a Key person to assist training new users and oversee day to day operation of POCT within their area

5.4. **Individual POCT Users** will ensure that:

- They only use POCT equipment after adequate training and if personally confident in their competence to do so
- Their training and competency records are kept up to date
- Standard operating procedures are followed, including sample handling, running quality checks, recording results.
- Abnormal or unusual patient results are reported to the person responsible, without delay
- Problems with a device, or any part of a procedure are reported as soon as possible to the person in charge or the POCT Laboratory Team
- Sharps and consumables are disposed of immediately and in accordance with Trust Waste Disposal Policy
- Equipment and workstations are kept clean in accordance with Trust Control of Infection policy
6. Standards and Practice

6.1. Table of Trust Approved POCT Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Parameters</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiometer ABL90</td>
<td>pH, pCO2, pO2, Na+, K+, Ca++, lac, glu, tHb, sO2, coHb, metHb, tBil</td>
<td>ED, Critical Care, NNU, Urgent Care Centre (WCH), MAU, Main Theatre, Polkerris</td>
</tr>
<tr>
<td>Radiometer ABL830</td>
<td>pH, pCO2, pO2, tHb, sO2, coHb, metHb, tBil</td>
<td>Delivery Suite</td>
</tr>
<tr>
<td>Nova Statstrip</td>
<td>Glucose and/or Ketone</td>
<td>All</td>
</tr>
<tr>
<td>SureScreen Pregnancy Test</td>
<td>hCG</td>
<td>All</td>
</tr>
<tr>
<td>Roche Combur7 urine test strips</td>
<td>pH, protein, glucose, ketone, leu, nit, blood</td>
<td>All</td>
</tr>
<tr>
<td>Radiometer AQT</td>
<td>DDimer, CRP, TnT</td>
<td>Urgent Care Centre (WCH)</td>
</tr>
<tr>
<td>Hologic meter</td>
<td>fFN</td>
<td>Delivery Suite</td>
</tr>
<tr>
<td>Seimens DCA Vantage</td>
<td>HbA1c</td>
<td>Paediatric Diabetes OPDs</td>
</tr>
<tr>
<td>Sysmex 1000-i</td>
<td>FBC 5-part diff</td>
<td>Urgent Care Centre (WCH)</td>
</tr>
<tr>
<td>Abbott i-stat</td>
<td>Urea, creatinine</td>
<td>Urgent Care Centre (WCH)</td>
</tr>
<tr>
<td>HemoCue</td>
<td>tHB</td>
<td>West Cornwall Theatre St Michael’s Theatre Delivery Suite Theatre – General/Trauma</td>
</tr>
<tr>
<td>Roche Coaguchek</td>
<td>INR</td>
<td>ED / DVT Clinic</td>
</tr>
<tr>
<td>Haemacon</td>
<td>INR</td>
<td>Cardiology</td>
</tr>
</tbody>
</table>

6.2. Implementing new POCT

6.2.1. The MHRA state that before deciding whether to implement POCT it is essential to:

- establish a clinical need
- consider the benefit to patients of introducing POCT
- conduct cost benefit analysis with full examination of alternative solutions

6.2.2. Due to the risks involved, the use of POCT devices should be limited to those circumstances where they are the only or best solution to obtaining test results when compared with the central laboratory.

Point of Care Testing Policy
6.2.3. All applications for new POCT systems must be made via the Trust's POCT Committee and all new POCT devices or systems must undergo a rigorous evaluation prior to their introduction.

6.2.4. A Service Level agreement must be established which encompasses all aspects of the proposed services

6.3. Training and Competence

6.3.1. The success of POCT depends crucially on the effectiveness of the training of non-laboratory staff.

6.3.2. Staff are not permitted to use POCT devices until they have received training from an approved Key Trainer, the Manufacturer, or a member of the Laboratory POCT team. Users must demonstrate satisfactory levels of competence to be able to use POCT devices.

6.3.3. All staff have a personal responsibility not to use POCT devices if they are not competent to do so, unless adequately supervised. The reason for this is to protect the patient, and ensure the quality of the service is appropriate to the clinical setting

6.3.4. From a clinical governance perspective, users of POCT should have a sound understanding of the relevant analytical principles, and of issues such as quality assurance (QA), interpretation of test results, limitations to use and liability issues.

6.3.5. All training programs should therefore include:

- Awareness of pre-analytical factors such as contra-indications, correct sample type and stability
- Assessment of competence, practical assessment where possible and/or a short learning test
- Technical limitations of the device
- What to do if results fall outside of defined limits
- Processing internal quality control and external quality assessment sample
- The importance of the audit trail from personal log-on to recording patient results

6.3.6. Staff training records will be held appropriately.

6.4. Standard Operating Procedure

6.4.1. Standard Operating Procedures (SOPS) must be available to and followed by all users of the device. SOPs for all devices should be available via the Trust's intranet and Pathology Laboratory.
The document will include: instructions for the use of the device, simple troubleshooting, the interpretation of error messages, normal ranges and action to be taken when a result is obtained (normal or abnormal), the recording of data, the relevant quality control procedures (IQC and EQA); decontamination procedures and training update frequency.

6.5. Recording Results

6.5.1. Patient results must be securely filed in their Health Record and if possible as an electronic patient record. Results obtained using a POCT device must be distinguishable from those obtained from the laboratory.

6.5.2. The following information must be clearly recorded to enable an audit trail

- Unequivocal patient identity
- Date and time of POC test
- The identity of the operator
- Lot number (for devices that do not automatically record this information)

6.5.3. Personal bar codes or PINs must be used whenever possible for data entry. Operator ID barcodes and passwords must never be shared or given out to any other member of staff.

6.5.4. Electronic results must confirm to the HL7 v2.3 ORU R01 result message specification.

6.5.5. POCT devices should support Positive Patient Identification by reading either the 1d or 2d barcode on patient wristbands. When available this must include the ability to use version control on the wristbands.

6.6. Quality

6.6.1. There are two components of quality assurance, internal quality control (IQC) and external quality assessment (EQA) that can help to ensure reliable results are obtained.

6.6.2. Clinical Pathology Accreditation (CPA) and MHRA require that all Pathology Departments participate in IQC and EQA schemes for POCT Devices where possible

6.6.3. Internal Quality Control (IQC):
This is the analysis of a control material performed by the user before patient testing to ensure the instrument is providing accurate results. The results obtained must be within a stated range. Where possible, analysers will be programmed to lock out failed parameters so that incorrect results cannot be obtained.

6.6.4. External Quality Assessment (EQA):
EQA involves the analysis of samples with unknown values from an external source.
EQA samples are distributed by the Pathology Department to all POCT devices for which there is an EQA Scheme available, to assess analysis techniques as well as instrument performance. Results are then subject to peer group assessment and statistical analysis to compare performance across different sites locally, within the Trust, and also on a national scale.

6.7. Health and Safety

6.7.1. All POCT should be undertaken in a way that does not put the patient or any member of the Trust’s staff at additional risk.

6.7.2. All users of POCT equipment must comply with all the current Trust Health and Safety Policies.

6.7.3. The standard operating procedure for each device should identify all specific health and safety precautions that must be taken to protect both patients and staff.

6.7.4. Any health and safety incidents must be reported on Datix and discussed by the Trust POCT Committee.

6.8. Infection Control

6.8.1. POCT users must recognise the potential hazards of handling and disposing of body fluids and sharps outside of the laboratory setting and be reminded of the importance of:

- Universal infection control precautions
- The wearing of gloves and other protective clothing
- Prevention of cross infection with blood-borne viruses
- Safe handling and disposal of healthcare waste, including sharps
- Safe medical device use, including decontamination of reusable devices.

6.8.2. In line with the Trust Decontamination Policy each device must receive appropriate decontamination before being transferred between patients, departments, or laboratory. Any equipment that has been decontaminated must be labelled as such.

6.9. Adverse Incident Reporting

6.9.1. In the POCT environment, an adverse incident such as an incorrect result could lead to a delay in treatment, exacerbation of a life-threatening illness, cause serious deterioration in health or even death.

6.9.2. Any adverse incidents involving POCT devices e.g. instrument failure, health and safety issue or clinical incident must be reported in accordance with the Trust’s incident reporting policy.
6.9.3. The Medical Devices Agency (MDA) is responsible for investigating adverse incidents associated with all medical devices. Safety Notices and Product Alerts are issued by the MHRA, circulated and disseminated by the Trust’s Safety Alerts Team.

7. Governance

7.1. The Point of Care committee meeting will be held biannually. Any Governance issues will be escalated through the Trust as per the flow chart below.

Flow Chart of POCT Governance arrangements

8. Dissemination and Implementation

8.1. This policy will be published on the Trust Document Library following authorisation by the Executive Director. Pathology POCT will highlight the publication across the Trust via the Daily Bulletin.

8.2. Implementation of this policy will be supported through departmental visits and training as required

9. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Dr Anthea Patterson, Consultant Biochemist</td>
</tr>
<tr>
<td>Tool</td>
<td>The Pathology Laboratory subscribes to National Quality Assurance Schemes for every parameter available</td>
</tr>
<tr>
<td>Frequency</td>
<td>Frequency of individual schemes vary from fortnightly to three monthly.</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>EQA results are discussed at POCT Team meetings every month.</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>An annual report is compiled by the POCT Committee and submitted to the Pathology Annual Management Review. The Leads for ensuring actions are completed are Helen Hobba, Senior Biomedical Scientist, and Dr Anthea Patterson.</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Poor EQA performance is fed back directly to staff in charge of clinical areas (and the Matron’s Group if required)</td>
</tr>
</tbody>
</table>

10. **Updating and Review**

10.1. This policy will normally be reviewed no less than every three years unless an earlier review is required.

11. **Equality and Diversity**

11.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Diversity & Human Rights Policy’ or the Equality and Diversity website.

11.2. The Initial Equality Impact Assessment Screening Form is at Appendix 3.
Appendix 1. Point-of-Care Testing (POCT) Committee Terms of Reference

**Purpose of the Group:**
This group has been established to undertake the management of all aspects of point-of-care testing in accordance with recognised guidelines (Clinical Pathology Accreditation, MHRA, CQC). It will endeavour to ensure the delivery of a high quality, cost effective POCT service that is relevant to local needs.

**Membership of the Group:**
This group is a multidisciplinary forum comprising of members from pathology, nursing and/or clinical support teams from each of the clinical directorates which undertake POCT. Pharmacy, Health and Safety, Clinical Governance, Infection Control, IT, Finance, Training and Education Departments are also represented.

When representatives are unable to attend meetings, a deputy can be nominated to attend in their absence. The Group will invite other relevant staff to attend as appropriate to the agenda.

**Role of the Group:**
The Group will:
- Advise the Director of Pathology, on the introduction of POCT schemes, after having compiled a business case with the relevant directorate.
- Conduct overall risk assessments of current POCT sites against defined quality standards.
- Keep an inventory of all equipment used for POCT and ensure that equipment maintenance logs are kept.
- Ensure that all POCT activity complies with local and national guidelines, best practice and legal requirements, in order to ensure that high quality results are obtained by trained operators in a safe environment.
- Define the organisation and content of staff training and maintain a register of authorised users.
- Be responsible for the preparation of procedures and forms and agree on their suitability before issue
- Make clear the lines of responsibility for clinical action taken on the basis of POCT results
- Regularly discuss QC & QA performance.
- Investigate promptly any adverse incidents involving POCT equipment or procedures
- Conduct an annual audit of each POCT site activity.
- Keep users updated with new guidelines, changes in procedure, changes in legislation, new technologies, MHRA bulletins and any other information relevant to POCT.
- Have the authority to withdraw a POCT device if the agreed standards of operation are not met.

**Meeting Arrangements:**
The group will meet on a 6 monthly basis or more often, as specific sub-groups, if required.

**Accountability:**
The POCT WG will report into the Governance structure of the Trust through the Divisional Quality Group.
### Appendix 2. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Point of Care Testing Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>December 2014</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>December 2014</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>December 2017</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Clinical Chemistry, Pathology, CSSC Division (Dr Anthea Patterson, Consultant Biochemist Helen Hobba, Senior Biomedical Scientist)</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252546</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>To ensure that the POCT systems used within RCHT are managed in accordance with national guidelines and accreditation standards. It is also designed to ensure that the introduction of new POCT technology is appropriate and consistent across the Trust</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Point of care testing, POCT</td>
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<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>June 2014</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>Point of Care Testing Policy v1.0 (not published on Docs Library)</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>POCT Committee (12.06.14) CSSC Governance DMB (16.12.14)</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td>Sally Rowe, Divisional Director</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Janet Gardner, Governance Lead CSSC Division</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>[Original Copy Signed]</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet</td>
</tr>
<tr>
<td>Document Library Folder/Sub Folder</td>
<td>Clinical / Pathology</td>
</tr>
<tr>
<td>Links to key external standards</td>
<td>MHRA Publications Management and use of IVD point of care test devices - DB2010(02) 2010</td>
</tr>
</tbody>
</table>
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http://www.mhra.gov.uk

MHRA. DB2011(01) 'Reporting adverse incidents and disseminating Medical Device Alerts'. 2011

http://www.mhra.gov.uk

**British and European Standards**

CPA Standards – Standards for accreditation of Medical Laboratories 2009

http://www.cpa-uk.co.uk/

Additional Standards for Point of Care (POCT) Facilities CPA - 2010.

http://www.cpa-uk.co.uk/

BS EN ISO 22870:2006 Point of Care Testing (POCT) - Requirements for quality and competence.

http://www.iso.org/iso/catalogue_detail.htm?csnumber=35173

BS EN ISO 15189:2012 Annex D(Normative) – Point of Care Testing (POCT)

http://www.iso.org/iso/catalogue_detail?csnumber=42641

**Related Documents:**

- POCT Committee Terms of Reference
- POCT Application Document

**Training Need Identified?**

No

**Version Control Table**

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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<tbody>
<tr>
<td></td>
<td>V1.0</td>
<td>Initial Issue (not published on Documents Library)</td>
<td></td>
</tr>
<tr>
<td>12 Jun 14</td>
<td>V2.0</td>
<td>Complete revision of policy to meet RCHT Documents Library criteria</td>
<td>Anthea Patterson, Consultant Biochemist Helen Hobba, Senior Biomedical Scientist</td>
</tr>
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**All or part of this document can be released under the Freedom of Information Act 2000**

**This document is to be retained for 10 years from the date of expiry.**

**This document is only valid on the day of printing**

**Controlled Document**

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

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## Appendix 3. Initial Equality Impact Assessment Form

<table>
<thead>
<tr>
<th>Name of the policy: <strong>Point of Care Testing Policy</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Directorate and service area: Clinical Chemistry, Pathology, CSSC</td>
</tr>
<tr>
<td>Name of individual completing assessment: Anthea Patterson</td>
</tr>
</tbody>
</table>

### 1. Policy Aim*
Who is the strategy / policy / proposal / service function aimed at?

- All healthcare professionals undertaking POCT at RCHT

### 2. Policy Objectives*

- To ensure that the POCT systems used within RCHT are managed in accordance with national guidelines and accreditation standards. It is also designed to ensure that the introduction of new POCT technology is appropriate and consistent across the Trust

### 3. Policy – intended Outcomes*

- Minimum risk to patients and staff from errors that may occur from the use of POCT devices

### 4. *How will you measure the outcome?*

- The Pathology Laboratory subscribes to National Quality Assurance Schemes for every parameter available.

### 5. Who is intended to benefit from the policy?

- Patients and staff

### 6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?

- No

### 6b) If yes, have these *groups been consulted?

### 6c) Please list any groups who have been consulted about this procedure.

### 7. The Impact

Please complete the following table.

Are there concerns that the policy **could** have differential impact on:

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

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You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation - this excludes any policies which have been identified as not requiring consultation. or
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.  

9. If you are not recommending a Full Impact assessment please explain why.

No potential differential impact identified

Signature of policy developer / lead manager / director  
Date of completion and submission

Names and signatures of members carrying out the Screening Assessment  
1. Anthea Patterson  
2. Helen Hobba

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead,  
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa,  
Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed ____________________  
Date ____________________

Point of Care Testing Policy