

## Management of Point Of Care Testing (POCT) Devices Policy

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<b>Trust Lead:</b>	Dr Prashanth Patel (Consultant Metabolic Physician/ Chemical Pathologist)
<b>Board Director Lead:</b>	Dr Andrew Furlong (Medical Director)
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### **REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW**

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August 2018 – review of V2, The policy has been completely rewritten to reflect current practice.

August 2021 – review of V3, The removal of UHL Committee POCT Terms of reference, application process for new or replacement POCT Devices, application form for new or replacement POCT devices and list of POCT devices used at UHL. Guidance will sit on Sharepoint.

### **KEY WORDS**

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Point of Care Testing (POCT)

Near Patient Testing (NPT)

Medical Devices

Medical Equipment Management Service (MEMS)

## 1 INTRODUCTION AND OVERVIEW

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- 1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for the management of Point of Care Testing (POCT) devices.
- 1.2 POCT devices are used widely across UHL for diagnosis, monitoring and treatment. The aim of this policy is to ensure that POCT devices are subject to well governed processes to maximise benefits to the patients and minimise risks.
- 1.3 The Trust staff must comply with this policy and standards for the management of POCT devices.
- 1.4 This document provides a working directive for all areas that use POCT in their clinical management of patients thereby reducing the risk to patients and staff. This document sits in line with directives as outlined by the Medicines & Healthcare products Regulatory Agency (MHRA) and ISO Standards 15189 and 22870 and must be adhered to protect users and patients.

## 2 POLICY SCOPE –WHO THE POLICY APPLIES TO AND ANY SPECIFIC EXCLUSIONS

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- 2.1 This policy applies to all staff users employed across UHL including bank staff and agency staff that are involved in the use and management of POCT devices and have received the appropriate training and assessed as competent to undertake this role.
- 2.2 This policy applies to all managers within their responsible clinical areas to ensure there is a governance process in place to monitor and audit compliance against this policy.
- 2.3 All staff using any any Point of Care device within UHL must be trained and competent to use them, and the evidence must be held by the Clinical/ ward Manager in the clinical area.
- 2.4 This policy does not include any POCT Systems in primary care or in the community, although there may be scope to include these in the future.
- 2.5 This policy does not cover equipment for patient or patients' relative self-monitoring POCT devices or any patients "own personal" POCT devices.

## 3 DEFINITIONS AND ABBREVIATIONS

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- a) A **medical device** is defined under EC directive 2007/47/ec as: "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software intended by its manufacture to be used for human beings."
- b) **Point of care testing device** or "Near-patient testing" device is defined by Medicines and Healthcare products Regulatory Agency (MHRA) as: "any analytical test performed by a healthcare profession or non-medical individual outside the conventional laboratory setting."
- c) **Single use device** is the term used to describe any medical device intended to be used on an individual patient during a single procedure and then discarded. Items labelled or recommended by the manufacturer as single use must not be reprocessed and used on another patient.

- d) **Medical Equipment Management Services (MEMS)** provide comprehensive technical support for medical equipment.
- e) Medicines and Healthcare products Regulatory Agency (**MHRA**) is the governing body that advises the safe and correct use of POCT devices.
- f) United Kingdom Accreditation Service (**UKAS**) is the accreditation body which assesses all Pathology departments to ensure adherence to the international standard ISO 15189:2012<sup>1</sup>. They also outline POCT terms (ISO 22870:2016)<sup>2</sup>.
- g) **Whole Life Costs** is the term used to describe all the costs associated with owning a piece of medical equipment; e.g. maintenance, consumables, training, as well as initial procurement of the actual device.
- h) Internal Quality Control (**IQC**) is a method using control material of a known measure and concentration to test if a POCT device is operationally sound. These are ideally done on a daily basis or at least prior to the use of a device.
- i) External Quality Assurance (**EQA**) is sent out by the POCT Team usually on a monthly or bi-monthly and it determines the safe operation of a POCT Device from operator to result. It also compares the result to other users across the UK.

## **4 ROLES – WHO DOES WHAT**

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### **4.1 Executive Team**

- a) The **Medical Director** is responsible at Board Level for the management of medical devices throughout the Trust. The Medical Director acts in the role of Executive Lead for CQC and the Medical Equipment Executive (MEE) Committee.
- b) The **Executive Team** will take responsibility for POCT devices in this policy. Issues relating to POCT will be reported to the executive team via the Executive Quality Board (EQB).

### **4.2 UHL Committee (Medical Equipment Executive) is responsible for:**

- a) Providing assurance to the Trust that CQC Standards and MHRA guidelines relating to medical devices are being achieved. The Medical Equipment Executive is chaired by a senior clinician, with delegated authority from the Medical Director.
- b) Identifying risks associated with the use of medical devices reported by the POCT Committee.
- c) Supporting POCT Committee with issues relating to POCT devices and where required informing the Executive team of issues requiring their support.

### **4.3 UHL POCT Committee (Point Of Care Testing) is responsible for:**

- a) Providing assurance to the Medical Equipment Executive that CQC standards and MHRA guidelines relating to POCT devices are being achieved. The POCT Committee is chaired by a senior clinician, with delegated authority from the Medical Director.
- b) Identifying risks associated with the use of POCT devices (e.g. near miss date)
- c) Referring all issues relating to infection, prevention and control to the Infection Prevention Committee structure.
- d) Advising the Trust on the device selection, procurement, maintenance, quality control (QC) and external quality assurance (EQA).

- e) The periodic review of the POCT policy and the POCT Committee terms of reference.
- f) Ensuring that the POCT policy is adhered to and followed when devices are being requisitioned and to ensure that POCT adds to the patient pathway by ensuring clinical effectiveness.
- g) Overseeing the POCT working group to ensure all aspects of POCT within the organisation are included and to ensure compliance with external standards, with this group reporting to the POCT Committee and MEE.
- h) Ensuring no POCT equipment is purchased or procured without the agreement of the POCT committee.
- i) Removing any POCT device that have not been approved or managed by the POCT Committee following the event of an untoward incident involving that device. will be captured on the Datix system. The POCT Committee will have the authority and support of the Medical Director. Relevant risk assessment will be carried out before this action and will be discussed with CMG Directors and Heads of Nursing.
- j) On discovery on the POCT device is not approved or managed correctly, a risk assessment must be carried out for devices to be approved by the POCT Committee. In the event of untoward incident reported as per Datix policy.

**4.4 POCT Clinical Lead and POCT Manager** is responsible for:

- a) Liaising with users and manufacturers in the purchasing of new POCT devices.
- b) Taking the lead for training of users (initial and competency).
- c) Implementing, enrolling and managing of POCT EQA programmes.
- d) Reviewing performance of IQC and EQA for POCT devices.
- e) Organising and managing corrective and preventative actions as required to ensure optimum analytical performance of POCT devices
- f) Managing and control documentation and its review and update.
- g) Managing procurement and selection of POCT devices.
- h) Linking with the Clinical Management Group (CMG) Quality and Safety Board meetings.

**4.5 Clinical Management Group (CMG) Clinical Directors, Heads of Operations and Heads of Nursing** are responsible for ensuring the requirements of this policy are met and that staffs within their teams comply at all times. CMG senior managers are responsible for:

- a) Ensuring equipment is procured in accordance with the Trust's purchasing policy and procedures and is selected following approval by the POCT Committee for clinical suitability, quality and safety, and "whole life" costs.
- b) Ensuring POCT devices intended for use on more than one patient must be decontaminated in line with the UHL Cleaning and Decontamination Policy B5/2006.
- c) Ensuring POCT devices are used only by staff that have trained and been assessed as competent.
- d) Ensuring copies of staff training records are sent to the POCT Team who must hold a central bank for all those trained.

- e) Ensuring that there is appropriate focus within their CMG division and as advised by the MHRA, have a nominated individual within each CMG as a POCT Champion.
- f) Ensuring safety information, adverse incidents, faulty products, recalls and MHRA alerts and bulletins are actioned and communicated to all relevant staff and acted upon in a timely manner.
- g) Ensuring action is taken to address adverse incidents involving POCT devices in line with the UHL Policy for Management of Patient and Staff Safety A10/2002.
- h) Ensuring faulty re-usable POCT devices are cleaned and decontaminated as set out in Cleaning and Decontamination for Infection Control UHL Policy B5/2006 and sent for repair to the medical equipment management service (MEMS) or POCT Team with a completed decontamination certificate that includes all relevant information to enable identification of the fault.
- i) Ensuring the POCT device is CE marked and consumables are compliant with current health and safety legislation.
- j) Ensuring that training records for service users are kept in the Ward Managers Office to evidence which staff are trained to use POCT devices. The folders will be provided by the POCT Team. This will be risk assessed and discussed with speciality Head of Service / CMG Clinical Director before the device is removed.

4.6 **Line Managers** are responsible for:

- a) Arranging technical support from the Supplier or MEMS and ensure maintenance checks are being monitored where appropriate.
- b) Ensuring all staff that use POCT devices are trained. (also see section 6)
- c) Ensuring that training records are available and up to date evidencing that staff are trained to use POCT devices.(also see section 6)
- d) Ensuring all trained staff is competency assessed every three years in line with the Core Training Policy For Statutory, mandatory and Essential to Job role Training (B21/2005).

4.7 **Clinical and Non-Clinical POCT Staff Users** are responsible for:

- a) Ensuring they are appropriately trained and assessed as competent in the use of POCT devices. Staff must not use a POCT device if they are not competent to do so.
- b) Ensuring POCT Devices are appropriately stored when not in use to avoid any damage to the equipment.
- c) Ensuring they follow the Trust's decontamination procedures after use, between patients and prior to equipment being returned for repair or calibration.
- d) Reporting any problems or issues with POCT devices to the MEMS or POCT Team.
- e) Ensuring personal passwords or individual POCT barcodes are not shared with other staff and understanding their responsibility for adhering to this principle.
- f) Ensuring procedures for POCT devices are followed as described in the Standard Operating Procedure (SOP) and Quick Guides.

- g) Ensuring all generated patient results and quality control results are documented appropriately in the notes or logbooks.
- h) Ensuring the responsible clinician or test requestor is notified of the test result.
- i) Ensuring all adverse incidents is reported into the Datix incident reporting system and informing the line manager who will escalate to the POCT Team.

4.8 **Medical Physics** are responsible for:

- a) Administering the asset inventory management system (AIMS).
- d) Ensuring renewal for maintenance contracts relating to POCT devices.
- e) For training and assessing competency for blood gas analysers.

**BLOOD GAS ANALYSERS ONLY**

- b) Delivering first line support for the blood gas analysers during normal working hours.
- c) Ensuring on-call support for specific blood gas analysers, out of hours.
- d) Performance of Monthly EQA samples for all blood gas analysers
- e) Management of the day to day running of the instruments

4.9 **Pharmacy** is responsible for:

- a) Overseeing the ordering, handling and distribution of some POCT reagents and consumables.
- b) Liaising with users regarding the ordering and distribution of specific POCT reagents and consumables.
- c) Liaising with the POCT Team for acceptance testing of reagents where appropriate.

4.10 **Information Technology (IT)** is responsible for:

- a) Providing support for the use of IT systems used within Pathology and POCT Including POCT Middleware systems and Interfaces with Trust LIMS systems.
- b) Upholding the service level agreement between Pathology and Trust IT.

## **5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS**

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### **5.1 The Point of Care Team**

The POCT Team will provide a full support service for the users of, and potential user of POCT devices. As part of the service the team will:

- a) Review the clinical need for POCT at the site
- b) Advise in the selection of appropriate equipment including whether the equipment is fit for purpose
- c) Select a suitable environment for placing the equipment
- d) Perform validation and verification for the point of care analytical methods with the traditional laboratory method where one exists. Where there is no comparable method the equipment will be assessed for safe use.
- e) Liaise with

Procurement in the purchase of new equipment to include tender processes and development of equipment specifications

- f) Liaise with the Suppliers and arrange installation and installation.
- g) Provide technical support and perform maintenance where appropriate
- h) Organise and/or perform training for POCT users and clinical educators.
- i) Ensure trained staff are competency assessed on a regular basis
- j) Keep up to date records for staff training and competency
- k) Monitor Internal Quality Control (IQC)
- l) Provide External Quality Assurance (EQA), monitor performance and ensure compliance in our own departments.
- m) Provide feedback and act on poor performance. Repeated poor performance will be reported to the responsible person of the clinical area and could result in the removal of POCT device
- n) Work with procurement and materials management for the management for the provision of consumables..
- o) Provide all documentation required for point of care testing including Standard Operating Procedure (SOPs), training records and, database management, competency assessment, patient results record sheets, reagent log sheets, quality control log sheets, patient results log sheets, quick guides etc.
- p) Perform audit of point of care processes

## **5.2 Supporting Information**

- a) For further POCT information visit the Trust POCT webpage. Navigate as follows:

Open internet explorer > Click on > Click on the ' ... ' tab> Click on 'Pathology' > Select the Pathology Point of Care Testing link.

All documentation available at this location is valid only on the day of printing. The version accessed at this location is the current version authorised by the POCT Team. No other versions are permitted for use. POCT Team will provide printed quick guides for use with devices where required and these will be document controlled as per the Pathology Quality Management System, Qpulse.

## **5.3 Connectivity**

- a) The introduction of connectivity solutions within the Trust is a necessity for the POCT Team to effectively monitor equipment and to provide a timely response for analyser support. It also offers greater functionality in terms of:
  - Long term data storage
  - Remote technical support of equipment
  - Managed user barcode access
- b) It also enables remote monitoring of:
  - Patient results
  - Quality control
  - Calibration status



- Consumable management
  - Supporting Audit
- c) All Point of Care devices across the Trust must be networked where possible so that the benefits of connectivity solutions can be realised. The cost of connectivity will be borne by the point of care area and should form part of the original business case.

#### **5.4 The Introduction of New POCT activities**

- a) Before introducing new POCT device/activity the clinical need should be established by evaluating:
- critical nature of the result
  - potential for improving patient care
  - assessment of the laboratories ability to provide satisfactory turn-around-times currently or through improvement
  - demonstration that reliable technology exists
  - cost/benefit outcome

A business case should then be drawn up and presented to the POCT Committee for approval using the POCT Application Form provided by the POCT team.

- b) A proposal form for any new POCT device will need to be completed by the requester (see Appendix 3) and then submitted with any supporting documentation to the POCT Team for Committee approval. The final decision for approval may include other groups such as Trusts Revenue and Capital Investment Committees.

#### **5.5 POCT Device Selection**

- a) The POCT must be consulted when clinical areas are considering providing any point of care test. All POCT devices must be evaluated by the POCT team with regard to:
- Risk to patient care optimisation
  - appropriateness for clinical purpose
  - analytical proficiency
  - technical limits
  - ease of use
  - correlation of results with those of main Pathology laboratory or current POCT device
  - cost effectiveness
  - training requirements

#### **5.6 POCT Procedures**

- a) A standard operational procedure (SOP), compliant with ISO 15189/22870 standard requirements must be in place for each POCT performed, and will reference the following
- clinical background
  - analytical principle

- manufacturer instructions
  - health and safety information
  - pre-analytical considerations
  - equipment
  - reagents, standards, controls and quality assurance
  - test procedure
  - maintenance and calibration
  - record-keeping
  - references
- b) SOPs will be developed by the POCT team and countersigned by the clinical lead for their suitability in the intended clinical setting.

## 5.7 Personnel Considerations

- a) All users of POCT must be trained and certified in the use of any POCT Devices and deemed as competent. (Also see section 6) Training should cover pre-analytical, analytical and post-analytical factors and include:
- specimen requirements
  - operational factors
  - quality assurance and quality control
  - health and safety
  - appropriate action on obtaining results
- b) On completion of training users all training will be recorded on HELM learning management system.
- c) Users will also be required to complete and sign the POCT training form for evidence that training was delivered, received and accepted. The competency will be undertaken by the POCT Team, or Line Manager.
- d) The POCT database of trained and authorised users will be maintained in a clearly identifiable folder located in the ward managers office. Any update training will be arranged as deemed appropriate from which competency will then be assessed.

## 5.8 Standards/Key Performance Indicators

- a) **Internal Quality Control (IQC)** - Performance of IQC is essential to ensure the quality of the results produced is acceptable for patient management.
- b) **External Quality Assurance (EQA)** - Participation in external quality assurance is mandatory.. Records of results and performance will be stored in the scheme web portals, accessible at any time by the Point of Care team. The cost of EQA material and the monitoring of EQA will be borne by point of care site and communicated to the user on a regular basis.
- c) **Poor Performance-** The POCT team will monitor the quality of point of care processes and investigate incidences of poor performance. In the event that poor performance occurs the POCT team will identify the cause, whether process based, equipment error or user error, and act accordingly to restore acceptable performance.

If in the event that poor performance remains, due to inappropriate use of equipment or continual poor technique following official training, the POCT team may advise the removal of the point of care device from the clinical site.

- d) **Device Audit-** All incidences of poor performance or adverse events will be recorded by the POCT team for audit purposes and corrective action. Datix reports shall be raised in line with Trust incident reporting guidance. Minor incidents shall be recorded by the POCT team and where non-conformance is identified this will be logged on Qpulse, pathology quality management system.

## 5.9 Maintenance and Repair of POCT Equipment

- a) Clinical engineering (MEMS) are involved in the upkeep of POCT devices such as blood gas analysers. In the event the MEMS team are contacted about POCT devices there needs to be engagement with the POC team.
- b) Users of POCT must follow the manufacturer's recommendation for maintenance as started in the SOP and quick guides for that device, and written records of maintenance programmes will be kept by the point of care team for audit purposes. The POCT Team may be responsible for maintenance of equipment, arranging service contracts, coordinating service visits, storing service reports and requesting engineer assistance.
- c) The POCT team will coordinate periodic supplier maintenance visits in line with the service contract.
- d) If a point of care device has developed a fault which cannot be addressed by the POCT team, the manufacturer or distributor will be contacted by the POCT team to log the fault.
- e) Depending on whether a service contract has been purchased the fault will be rectified in one of the following ways:
- An engineer visit will be arranged who will restore functionality
  - The equipment will be returned to the manufacturer for repair
  - The manufacturer will provide an alternative device on loan until the fault has been fixed
  - The POCT team will make other arrangements to limit the impact of the device not being available, including access to devices of the same type within the organisation.

### 5.11 POCT Equipment Inventory

- a) An inventory of all Trust equipment will be kept electronically by the POCT team. This is in the form of spreadsheets, equipment asset database on Qpulse and AIMS. These are updated as and when serial numbers or model types are changed or acquired.
- b) All asset numbers, where available and appropriate, are recorded in the spreadsheets along with their location.

## 5.11 POCT Results

- a) Any POCT result produced should be acted upon appropriately as stated in local SOP or guidelines and documented into the patient health record.
- b) The user must follow written SOP procedures and Trust Policy for the Management of Diagnostic Testing Procedures (Trust reference B7/2013) for the reporting of results which should include:
  - reference range of measurement
  - definition of critical values and limits
  - clear definition of action to be taken when abnormal results are obtained.
  - appropriate documentation with regard to confidentiality and permanency.
- c) The UHL POCT service is not fully connected due to the capability of some devices in use.
  - Devices connected to middleware and interfaced will send results directly to the hospital network IT system (ICE) and be available to clinical staff for review and action.
  - Some non-connected devices will produce a result print out which are recorded in the patient notes and bedside charts.
  - Some test are interpretative and ready by eye. These results are recorded in patient notes or result log books provided by the POCT team.
- c) All analyses must be recorded in the patient health record, POCT result logbook or on POCT middleware or electronic patient record. This includes a full range of results obtained regardless of whether the result is normal or abnormal.
- d) Production, handling and storage of patient results are subject to the Trust Information Policy B4/2004. Inappropriate use of or access to patient data is a clear breach of Trust policy and the contract of employment.

## 6 EDUCATION AND TRAINING REQUIREMENTS

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- a) Only users who are trained and competent will be permitted to use the relevant POCT device.
- b) Device training is therefore mandatory for staff that are identified as users of the POCT device. To ensure safety and quality, the training records must be kept by the line manager and be readily available within the clinical area that the POCT device is to be used. The POCT Team will keep copies of the completed training forms.
- c) A central training register for each clinical location and POCT device must be kept valid and available for inspection at any time. This will be kept in the POCT office in pathology.
- d) The Line Manager for each clinical area with POCT device(s) must take responsibility for ensuring staff using the device are trained and maintain competency with competency re-assessment dates established.

- e) Discussion and identification of any training and competency assessments required for POCT users will be included in their annual appraisal.
- f) Training requirements will form part of the standard POCT application process and will be integrated in the tender process for procuring any new POCT devices.

## **7 PROCESS FOR MONITORING COMPLIANCE**

### **7.1 Monitoring**

The POCT Committee is responsible for monitoring compliance with this policy. The procurement team are responsible for ensuring that no new devices are procured without the formal approval of the POCT Committee. Once a new service is in place the POCT Team are responsible for the quality management of the service and compliance with the POCT Policy.

### **7.2 Audit**

The POCT Team with the assistance from the Pathology Service are responsible for the auditing of the POCT Service. An internal audit programme is scheduled throughout the year using the Pathology document management system Q-Pulse.

### **7.3 Feedback**

- a) Audit results are reported to the POCT Committee through their bi-monthly meetings. Small non-compliances are managed by the POCT Committee who is responsible for drawing up an action plan to address these and report them to the Medical Equipment Executive Board (MEE) if urgent action is required.
- b) The results from the monitoring and audit will be presented to the MEE Board in a quarterly report. The report will include details of current monitoring and audit results, any identified areas of good practice, improvements and any deficiencies. It will include the suggested recommendations and an action plan, any deficiencies identified, with named staff leads and timescales.

<b>Element to be monitored</b>	<b>Lead</b>	<b>Tool</b>	<b>Frequency</b>	<b>Reporting arrangements Who or what committee will the completed report go to.</b>
All devices to be recorded on Medical Physics equipment AIMS database and Qpulse Asset Module. (additions, disposals and transfers)	POCT Team / Medical Physics	AIMS (electronic system) Qpulse (electronic system)	Monthly	POCT Lead / Team to work with Assigned leads for each clinical area. List to be updated monthly.
No new POCT device to be purchased without going through POCT process	POCT Team / Medical Physics / Procurement	Procurement system	Bi-Monthly	POCT Lead / Team to work with leads for each clinical area New POCT devices
Reduction in the number of incident /serious untoward incidents relating to POCT device results	POCT Committee Chairperson / all device users	Incident database (DATIX)	On-going / six monthly review	Any patient safety issues or clinical governance issues to be discussed at POCT Committee and communicated to EQB via MEE.
Local Audits on POCT Devices	POCT Team Pathology	Q-Pulse system	Quarterly	Audit results are reported to the POCT Committee to

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements Who or what committee will the completed report go to.
	Services			develop an action plan to address any non-compliance. Any urgent action required to be communicated to MEE.
Training and Competency to be monitored.	POCT Team	HELM Qpulse (electronic system)	Quarterly	POCT Team to work with Ward Managers on keeping records of training and feedback on progress.

## 8 EQUALITY IMPACT ASSESSMENT

- a) The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
- b) As part of its development, this policy and its impact on equality has been reviewed and no detriment was identified.

## 9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

Medical Devices Directive. (1993) 93/42/EEC, Official Journal EC, 36, L169 The Medical Devices Regulations, SI 2002 No. 618. Consumer Protection (2002).

Medicines and Healthcare products Regulatory Agency; Device Bulletin: Management and Use of IVD Point of Care Test Devices; DB2010 (02); February 2010.

[www.mhra.gov.uk/home/groups/dtsbi/documents/publication/con071105.pdf](http://www.mhra.gov.uk/home/groups/dtsbi/documents/publication/con071105.pdf)

[www.mhra.gov.uk/Publications/Postersandleaflets/CON008382](http://www.mhra.gov.uk/Publications/Postersandleaflets/CON008382)

Clinical Governance: Implications for point of care testing: D B Freedman, Ann. Clin. Biochem. Vol. 139, No. 5, Sep. 2002, 421 – 423.

Point of Care Testing (Near Patient Testing) Guidance on the Involvement of the Clinical Laboratory. IBMS guidance from IBMS website.

The Royal College of Pathologists: Guideline on point of care testing April 2004. Additional Standards for Point of Care Testing (POCT) Facilities from CPA (UK) Ltd. From [www.cpa-uk.co.uk](http://www.cpa-uk.co.uk)

A practical Guide to Point of Care Testing from NHS Improvement Website.

UHL Medical Devices Policy (Trust Ref B26/2005)

UHL Risk Management Policy (Trust Ref A12/2002)

Information Governance UHL Policy (Trust Ref B4/2004)

UHL Cleaning and Decontamination for Infection Control Policy (Trust Ref B5/2006).

UHL Policy for Management of Patient and Staff Safety (Trust Ref A10/2002).

Additional Standards for Point-of-Care Testing (POCT) Facilities;

Clinical Pathology Accreditation (UK) Ltd v1.01 Nov 2010

Assortment of Point of Care Testing Policies from various NHS Trusts from UK, including Management of POCT devices policy V6 2020 from Nottingham University Hospitals (NUH) and Point of Care Testing Policy 2017 Plymouth Hospitals NHS Trust.

## **10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW**

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- a) This rewritten new policy will be reviewed in 18 months following approval or in response to any clinical risks identified to and by the POCT Committee.
- b) The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system.
- c) Previous electronic versions are archived on 'Sharepoint'. Staffs working at the local level are responsible for destroying paper copies of previous iterations of this policy.