

**Reference Number:** UHB 062  
**Version Number:** 2

**Date of Next Review:** 12 Sep 2020  
**Previous Trust/LHB Reference Number:** T233

## POINT-OF-CARE TESTING (POCT) POLICY

### Policy Statement

To ensure the Health Board delivers its aims, objectives, responsibilities and legal requirements transparently and consistently we will have an evidence based, consistent approach in the use and management of Point of Care Testing (POCT).

The Health Board will comply with the relevant guidelines on POCT: the Welsh Government Policy on the Management of Point of Care Testing: What, when and how? (WSAC) 2017 and the relevant clauses relating to POCT (*Standard 3.1, 5.1, 2.9, 2.1, 3.4, 3.5*), Health and Care Standards for Wales, 2015.

### Policy Commitment

POCT is usually carried out in a busy environment with little or no 'thinking-time' before a change in patient management is instigated. Adequate checks and balances must therefore be in place to prevent medical errors and reduce risks. In considering the medico-legal status, under clinical governance and controls assurance directives and standards, NHS organisations are subject to both legal and statutory requirements relating to the "Duty of Care." This requires the UHB to ensure that staff and patients do not suffer any unreasonable harm or loss; that staff are competent, that the organisation provides safe working practices and that equipment, facilities and environmental conditions are safe. The UHB has a legal obligation under the Health and Safety at Work etc Act 1974 and under various regulations to provide training to its employees in the use of work equipment in cases where lack of training will increase the risk of harm to employees or other persons including patients. The Health and Safety Executive has stated that it would expect to be able to see evidence of the effectiveness of training, hence the need for training to be assessed and recorded.

We are committed to ensuring that there are appropriate arrangements in place to provide guidance on the selection and procurement of devices, that all staff undertaking POCT are trained and competent, that quality assurance procedures are in place and that there are systems in place to ensure the effective collection, sharing and reporting of high quality data and information within a sound information governance framework.

- POCT devices must only be purchased after a case for clinical need and a detailed implementation plan has been approved by the POCT Group.
- The POCT Team will take responsibility for providing advice on the purchase of devices, training, maintaining and monitoring the quality of these services. Clinical Directors have a responsibility to ensure that there is a clinical requirement for POCT and the integration of POCT devices into care pathways is clinically effective. They

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must also ensure that the infrastructure and working environment is appropriate to undertake diagnostic testing and that operators have the necessary skills and competence to undertake these tasks.

- There must be close liaison between Directorates undertaking POCT and the POCT team on all issues relating to POCT. An agreement which satisfies the site requirement and defines the Directorate, Operator and POCT team obligations, is mandatory. This must be incorporated into a Service Level Agreement (SLA)
- All staff who use POCT devices must complete the UHB approved training and competence assessment and have obtained a valid certificate of competence for that device before carrying out tests on patients.
- Where possible POCT devices that allow connectivity to the All Wales POCT Information System must be used.
- POCT which fails to meet the requirements of this policy will be suspended by the UHB until compliance can be demonstrated.

### **Supporting Procedures and Written Control Documents**

This Policy and the supporting document Management of Point of care procedure describe the process in regards to Point of Care testing.

**Other supporting documents are:**

### **Legislation and guidance**

1. Welsh Government, WHC (2017) 034 Policy on the Management of Point of Care Testing (POCT) : What, When and How?  
<http://gov.wales/topics/health/nhswales/circulars/performance-delivery/?lang=en>
2. Management and use of IVD point of care test devices - DB2010(02). MHRA  
<http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON071082>
3. Health and Care Standards for Wales, Welsh Assembly Government, Apr 2015.  
[http://www.wales.nhs.uk/sitesplus/documents/1064/24729\\_Health%20Standards%20Framework\\_2015\\_E1.pdf](http://www.wales.nhs.uk/sitesplus/documents/1064/24729_Health%20Standards%20Framework_2015_E1.pdf)
4. BS EN ISO 22870:2006 Point of Care Testing (POCT) – Requirement for quality and competence Available from BSI: <http://www.bsigroup.co.uk>
5. The Management of Health & Safety at Work Regulations 1999.
6. The Provision and Use of Work Equipment Regulations 1998.
7. The Workplace (Health, Safety and Welfare) Regulations 1992.
8. The Medical Devices Directive 93/42/EEC June 1993.
9. NCCLS Point-of-Care Connectivity; Approved Standard. NCCLS document POCT1-

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A (ISBN 1-56238-450-3). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001

### References

1. Point of Care Testing: Needs opportunity and Innovation, 3<sup>rd</sup> Ed, Edited by C. P. Price, A. St. John and L.L Kricka.
2. Internal Quality Control in Point of Care Testing: Where's the Evidence?; J. Holt, D. Freedman ; Annals of Clinical Biochem 2015, Vol. 52(5)

### Scope

This policy applies to all healthcare staff employed or contracted by the UHB to undertake diagnostic testing on patients. This includes those on honorary contracts, students working within the UHB, persons employed by Cardiff University, Public Health Wales, and independent contractors commissioned by the UHB to undertake testing.

The Policy also applies to primary care services such as - community dental services, community nursing services, family planning clinics and GP out of hours services.

GP contractors are not mandated to follow this policy as they are ultimately responsible for developing their own governance processes, policies and procedures for the quality and safety of POCT. However, it provides a framework for good practice with particular relevance to quality assurance and training, complementing existing guidance WHC (2017) 034, relevant within that setting.

<b>Health Impact Assessment</b>	An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be a positive impact. Key actions have been identified and incorporated within this policy and procedure.
<b>Policy Approved by</b>	Quality Safety and Experience Committee
<b>Group with authority to approve procedures written to explain how this policy will be implemented</b>	Point of Care Testing Group
<b>Accountable Executive or Clinical Board Director</b>	Medical Director

### Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the [Governance Directorate](#).

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<b>Summary of reviews/amendments</b>			
<b>Version Number</b>	<b>Date Review Approved</b>	<b>Date Published</b>	<b>Summary of Amendments</b>
1	14/06/15	19/07/15	New Policy
2	12/09/17	22/09/17	Revised document – Policy split into separate Policy and Procedure documents. 1. Reviewed in line with WHC (2017) 034 POCT 2. Reviewed in line with Policy and Health and Care Standards 2015.