



EPBS' Policy Statement on Point of Care Testing (POCT)

Point of care testing (POCT) involves collecting specimens and performing analyses near the patient. Patient safety and quality assurance are best addressed by virtue of a multi-disciplinary governance system.

Point of care testing is performed in the following “near-patient” areas:

- **Within hospitals;** in emergency units, in acute departments, e.g. anaesthesia and intensive care units, other hospital departments and outpatients' departments.
- **Outside hospitals;** in institutions, in nursing and care units, in community treatment centres, at clinics in primary health care, in physician's offices and in patients' homes.
- As part of the ambulance services or other mobile facilities.
- Patients' self-testing.

Point of care testing has an important role to play in the delivery of an efficient healthcare service because of its ability to provide a rapid test result, in a timely manner, close to the patient. This may lead to increased clinical effectiveness and improved outcome for patients.

It is important that where POCT is delivered there is a clearly defined and well structured approach and robust clinical governance framework, in order to ensure that it is performed in a safe and effective manner.

All POCT should comply with the requirements of the International Organization for Standardization (ISO)

ISO 22870 Point-of-care testing (POCT) – Requirements for quality and competence.

ISO 15189 Medical laboratories – Particular requirements for quality and competence.

ISO 15190 Medical laboratories – Requirements for safety.

Biomedical Scientists within the European Association for Professions in Biomedical Science (EPBS), have the necessary expertise and competence to take a lead role in ensuring safe and effective governance of POCT. This includes the responsibility for areas such as selection and validation of equipment, education and training of users, internal and external quality assurance, maintenance, record keeping of quality and patient data, incident reporting, risk management and clinical audit, advice and interpretation.

It is important to bear in mind that patients depend on accurate and reliable results from POCT devices to allow for effective diagnosis and monitoring of treatment. Operator competence is essential for optimal POCT performance.



Potential advantages of POCT include:

- Improved turn-around time.
- Enhanced clinical management.
- Better patient compliance with results of analytical tests.
- Savings in cost and time for patients.

Potential disadvantages of POCT include:

- Inappropriate testing leading to increased costs with no benefits to the patient.
- Inaccurate results, leading to less than optimal health outcomes for the patient with additional testing and treatment.
- Possible health damages to the patient.
- Possible increased consultation and waiting times.
- Analytical results from POCT possibly not being reported as part of the patient chart or electronic health record (EHR)

Questions to consider before introducing POCT in Health Care

- Is the use of POCT providing a faster result to effect clinical treatment?
- Is it good patient safety to perform POCT?
- Is the effectiveness of POCT at least as good as for the same clinical laboratory analysis?
- Is it the same or more cost-effective to perform POCT compared with clinical laboratory analysis?
- How will POCT be financed?
- Are there differences between POCT environments, such as rural or urban settings, and target populations?
- How will laws and regulations apply to implementation of POCT?
- Possible microbiological, chemical and environmental hazards.

Glossary and abbreviations

Several terms and abbreviations are used to describe Point of care testing:

Point of care testing – POCT

Near-patient testing – NPT

Bedside testing – BT

Patient self testing – PST

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Bibliography:

1. ISO 22870 Point-of-care testing (POCT) - Requirements for quality and competence.
2. ISO 15189 Medical laboratories - Particular requirements for quality and competence.
3. ISO 15190 Medical laboratories – Requirements for safety.
4. Guidelines for Safe and Effective Management and Use of Point of Care Testing. Approved by the Academy of Medical Laboratory Science, Association of Clinical Biochemists in Ireland, Irish Medicines Board and RCPI Faculty of Pathology. November 28, 2007. Ireland
5. NHS Guides and evaluations on Point of care and self testing, United Kingdom:
<http://www.pasa.nhs.uk/PASA/Templates/Content.aspx?NRMODE=Published&NRNODEGUID=%7BD41FABCF-73FC-4D96-974E-EB457B152037%7D&NRORIGINALURL=/PASAWeb/NHSprocurement/CEP+old/outputs/Labmed.htm&NRCACHEHINT=NoModifyGuest#POC>
6. Point-of-Care Testing (Near-Patient Testing). Guidance on the Involvement of the Clinical Laboratory. Institute of Biomedical Science, United Kingdom
7. Management and Use of IVD Point of Care Test Devices:
<http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON007333> The Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom.
8. Point of care testing - top 10 tips:
www.mhra.gov.uk/Publications/Postersandleaflets/CON008382. The Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom.
9. Point of Care Testing. NITO The Norwegian Institute of Biomedical Science. 2. edition, revised 2008.
10. Near patient testing activities - a development of the health care process. Vårdförbundet (The Swedish Association of Health Professionals) and IBL (The Swedish Institute of Biomedical Laboratory Science), April 2005.
11. SIMeL-POCT Position Paper 2009. Available at <http://www.simel.it/notizie>
12. Umgang mit Point-of-Care-Testing – labmed-Empfehlungen:
http://www.labmed.ch/doc/doc_download.cfm?uuid=11F2BEBDD9D9424C46B2DA91FAB1EB25&&IRACER_AUTOLINK&&. Labmed Schweiz Suisse Svizzera.
13. Australia: Point of Care Testing trial. PoCT in general practice. May 7th, 2009.
<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pathology-poctt-index.htm>.
14. Briedigkeit L, Müller-Plathe O, Schlebusch H, Ziems J. Recommendations of the German Working Group on Medical Laboratory Testing (AML) on the introduction and quality assurance of procedures for Point-Of-Care Testing (POCT) in hospitals. Clin Chem Lab Med, 1999, 37: 919-925.
15. Clinical Laboratory Improvement Amendments (CLIA) Equivalent Quality Control Procedure. Brochure n. 4. Available at <http://www.cms.hhs.gov/clia>
16. Clinical and Laboratory Standards Institute, CLSI: www.clsi.org
17. International Organization for Standardization, ISO: www.iso.org
18. College of American Pathologists, CAP: www.cap.org
19. United Kingdom National External Quality Assessment Service, UK NEQAS:
<http://www.ukneqas.org.uk>
20. Scandinavian evaluation of laboratory equipment for primary health care, SKUP:
<http://www.skup.nu/>
21. Point of Care: The Journal of Near-Patient Testing & Technology:
<http://journals.lww.com/poctjournal>