AUSTRALASIAN ASSOCIATION OF CLINICAL BIOCHEMISTS INC

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# Position Statement

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| Title | **Point of Care Testing** |
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## Background

Healthcare is under increasing pressure due to rising costs and increased community expectations. These pressures are changing how care is provided, particularly through the increasing use of same-day procedures and community alternatives to hospital care.

Pathology has a key role in medical decision-making and is often regarded as rate-limiting and resulting in delayed clinical management decisions. Point of care testing (PoCT) is now widely recognised as contributing to better healthcare by significantly reducing turnaround time for pathology testing. As more robust point of care tests become available, interest in running this type of testing is expanding.

Members of the Australasian Association of Clinical Biochemists (AACB) have expertise in PoCT and believe that this application of diagnostic pathology can make significant and positive medical, economic and social contributions to the health of the community when used appropriately. The AACB believes it has a responsibility to make this knowledge and expertise available to ensure such technology is used safely and effectively.

**The AACB is of the view that all PoCT should be accessed and conducted within formal quality frameworks to ensure such testing is conducted to professional standards that assure fitness for medical purpose.**

## Terminology

PoCT already covers a broad range of both pathology and non-pathology testing, and although the expertise of the AACB is primarily concerned with PoCT as it relates to clinical biochemistry testing, many of the views expressed here are also relevant to other pathology disciplines.

## Principles for the conduct of Point of Care Testing

### Use

PoCT contributes to improved patient care across a broad range of professional healthcare settings where timely access to appropriate pathology testing cannot be adequately met by a centralised diagnostic laboratory. In the community, there is increasing demand to be informed and for individuals to actively participate in their own healthcare and management. Thus PoCT can increasingly contribute to patient care and well-being in the community setting.

PoCT encompasses a broad range of use, from networked bench-top multi-analyte instruments dispersed in hospital patient care areas, to INR testing devices and simple hand-held glucose meters used by diabetic patients in their homes. This policy statement focuses on the broad principles that will provide for the appropriate, safe and effective use of PoCT.

### Users

PoCT is undertaken by diagnostic laboratory personnel, non-laboratory trained healthcare professionals and individuals for personal or commercial purposes. All users of PoCT should receive formal training in the operation of devices to ensure that they understand the quality of results which are required for the clinical purposes of the test.

### Quality of PoCT

The term 'quality' encompasses both the accuracy and reproducibility of test results, and the reliability of devices to produce test results that meet expected performance specifications.

Quality assurance is a comprehensive set of policies, procedures and practices used to monitor the entire testing process and ensure that the results are reliable. Collectively these are often referred to as a quality framework.

The quality of a test performed by a PoCT device should be appropriate for the medical purpose for which the test was conducted. The fitness for purpose is the immediate responsibility of the individual or organisation accountable for the care of the person tested. Depending on circumstance, responsible entities may be pathology laboratories, general practitioners, medical specialists, hospitals, pharmacies or the individuals tested. Where testing is partly or fully funded or rebated by the Commonwealth or State Governments, responsibility for testing quality is exercised through the legislated requirement that the testing is only conducted by entities accredited for such testing by the NATA/RCPA accreditation scheme.

Where PoCT is conducted outside this formal quality framework (eg. in the circumstance of a self-testing person, or an individual purchasing a test(s) from a third party), it is presently the responsibility of the individual to ensure that the quality of testing is sufficient for their medical or health purpose. In this circumstance, it is strongly recommended that expert advice be sought from appropriate professional bodies such as the APPN or AACB.

The AACB committee recommends familiarity and understanding of the NPAAC PoCT guidelines

before commencing PoCT testing

**Selection of PoCT Devices**

The in-principle decision to employ PoCT should be based on demonstrable benefits, which will generally derive from clinical, economic, logistic or personal considerations.

There are several factors to be considered when selecting PoCT devices;

- Analytical quality of the device in relation to its intended clinical purpose
- Training/education requirements for users of the device
- Service and/or maintenance requirements
- Quality management materials/programs available
- Supplier support e.g. installation of device, training materials/services, ongoing support
- Storage/portability of system
- Connectivity/data integration of device

Selection of a PoCT device should be determined by the suitability of the analytical quality of the device for the intended clinical purpose It is strongly recommended that non-laboratory individuals seek independent clinical, scientific and technical advice from sources such as the APPN, AACB, RCPA, accredited medical testing laboratories, or relevant medical and professional associations.

**Implementation**

Successful implementation of PoCT requires possession of a functional device, appropriate operator training, and education in device use and clinical application(s) of test results. Formal investigations to verify that the testing device performs to the required analytical and other specifications, must be undertaken and the findings recorded and retained. A literature search for independent 3rd party evaluations may be undertaken using resources such as SKUP, the Point of Care Journal, or other reputable scientific publications. Other necessary steps include arrangements for appropriate location and storage of the device and any consumables, security from unauthorised use of devices and associated consumables, and for record keeping. Depending on the nature and usage of devices, it may be appropriate to document procedures for the routine use of devices and have these easily accessible to authorised operators.

Training in the conduct of PoCT and the application of results to health care is a critical element in ensuring the quality use of such testing. Training should be performed by an appropriately qualified person who has been working with PoCT for at least 5 years. Training should follow the recommendations in the NPACC PoCT Guidelines.

It is recommended that non-laboratory users of PoCT seek advice from NATA/RCPA accredited medical testing laboratories, or from a relevant professional body such as the APPN or AACB if confirmation of, or further technical information is required.

**Routine Use of PoCT**

On-going use of PoCT devices requires upkeep of required operator competency (skills and knowledge), maintenance of the device, appropriate use of quality control and quality assurance materials and use of appropriately stored, unexpired consumables. Regular objective evidence that test results meet the clinical and technical specifications specified at implementation is essential. Appropriate record-keeping is a critical element in ensuring that PoCT devices produce quality results.

**Quality Control of PoCT**

The measurement of quality control material at regular intervals is used to ensure that a device is meeting the clinical and technical specifications required for a particular test. This is considered an essential requirement for all devices that are generating results on which a clinical decision may be made.

The design of QC procedures for PoCT devices must accommodate the diversity of analytical systems available and the variety of locations where PoCT is performed. Suitable quality control material can generally be obtained from the suppliers of the PoCT devices. If this is not available, appropriate advice can be obtained from NATA/RCPA accredited medical testing laboratories, and from relevant scientific and medical associations.

The following are considered as minimum quality control requirements for a PoCT device:

- A quality control sample must be analysed with every new shipment or lot number of consumables.
- One quality control sample per month must be analysed.
- It is recommended that if only one quality control sample is analysed it is in the pathological range. If two levels of quality control material are being analysed, both a normal and an abnormal sample should be analysed.
- If no suitable quality control material is available, patient specimens must be substituted and results compared with those from a local accredited pathology laboratory.
- All quality control results should be recorded.

**External Quality Assurance of PoCT**

There are a number of external quality assurance schemes available for PoCT. Although it may be highly desirable to be enrolled in such a scheme, participation is only a requirement if reimbursement for the testing is being sought via the Medical Benefits Schedule.

**Further Information**

Enquiries may be made to: Australasian Association of Clinical Biochemists.

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**Abbreviations**

AACB: Australasian Association of Clinical Biochemists

NATA; National Association of Testing Authorities

RCPA: Royal College of Pathologists of Australasia

PoCT: Point of Care Testing.

APPN: Australian Point-of-Care Practitioner Network

**Reference**

NPAAC PoCT Guidelines:

https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-poctguid