

Position Statement

Subject: **Point of Care Testing**
Approval Date: March 2002, Revised June 2006, March 2009, August 2013,
February 2016, January 2020, December 2020
Review Date: January 2024
Review By: BPPQ
Number: 1/2002

Introduction

Point of Care Testing (POCT) as an approach to diagnostic pathology is not new, however the range of testing available and interest in deploying this approach has been rapidly increasing. The following statement outlines the position of the Royal College of Pathologists of Australasia (RCPA) on this issue.

Definition

POCT is defined as pathology testing performed in close proximity to a patient by a healthcare worker and usually outside the precincts of a traditional laboratory. This is usually undertaken at the time of and for use during a consultation or episode of care.

Use of POCT

POCT devices used for a medical purpose in Australia are required to comply with the Therapeutic Goods Administration “*in vitro* diagnostic device” (IVD) regulatory framework, and in New Zealand with the Medicines Act 1981 and its associated Regulations. Regulatory requirements for IVD use may also be present in other countries.

Numerous factors can impact the accuracy and reliability of results obtained from POCT devices and compromise patient safety. The following describes the proper use of POCT within a healthcare facility or practice.

This Position Statement is not intended to apply to patient self-testing or Home testing.

General Principles

1. The results of POCT either must be equivalent in quality and accuracy to those from an accredited pathology laboratory, or show a demonstrable benefit to patient care that exceeds the risks of any inaccuracy or lowering of quality standards. Where there is doubt regarding the reliability of a result generated through POCT that may impact on patient care, confirmatory laboratory testing should/MUST be undertaken. The wellbeing of patients must be the primary consideration.
2. POCT must be restricted to those tests and circumstances in which:
 - the immediacy of results will have a significant beneficial impact on clinical decision making and patient outcomes (e.g. changing drug doses); or
 - the test is one that is appropriately used as an opportunistic screening test (e.g. pregnancy, HIV in some circumstances); and

- the quality of test is equivalent to an accredited laboratory, or the benefit to patient care exceeds the risks of any inaccuracy or lowering of quality standards.
3. There must be a documented quality system¹ to direct, control and evaluate the quality of POCT performed and a nominated person responsible for ensuring that the requirements of the quality system are adhered to at all times. The quality system must address pre analytical, analytical and post analytical aspects of the testing processes as well as responsibilities and procedures to ensure safe reliable testing.
 4. Documented participation in appropriate quality control and quality assurance activities must be included as part of the quality system.
 5. There must be effective systems in place to ensure accurate patient identity, specimen integrity and traceability of specimen and results.
 6. Participation in external proficiency testing programs must occur, where such programs are available, and acceptable performance must be achieved. It is recommended that some patient samples are exchanged and tested at an accredited laboratory service as one component of external proficiency testing (quality assurance).
 7. POCT must be conducted under appropriate supervision¹ and in a safe, secure working environment which takes into account appropriate storage of reagents, consumables, specimens and records as well as safe disposal of waste.
 8. POCT must only be conducted by appropriately trained staff for whom documented records of ongoing competency with the relevant POCT instrumentation are available.
 9. POCT should not be used to replace routine non-urgent tests when access to pathology laboratory testing is readily available, unless patient access and/or cost benefit and quality equivalence or superiority is demonstrated
 10. POCT services must have a system that ensures all results of testing are properly recorded in the patient record and communicated with the usual demographic details, date, time of collection, units and reference intervals.
 11. POCT must be conducted in compliance with privacy and other legislation.
 12. POCT adverse incidents and corrective actions taken must be documented and auditable. The POCT service must participate in an external program for POCT Incident Monitoring where available.

Measures to support adequacy of setting

- When starting a POCT testing service, it is recommended that there be consultation with an accredited laboratory regarding advice about selection of devices and essential elements of the quality assurance framework.
- A POCT service must have adequate governance arrangements.

¹ As per NPAAC Best Practice Guidelines – “Guidelines for Point of Care Testing” (First Edition 2015)₂

Reference to specific POCT

Measurement of Haemoglobin A1c (HbA1c)

At this stage, POCT testing for HbA1c does not appear to be sufficiently robust for diagnostic purposes with the performance of the POCT measurement of HbA1c varying considerably. Randomised controlled studies did not reveal any outcome or cost benefit associated with POCT measurement of HbA1C in a primary care setting⁶, nor was it associated with increased patient or health professional satisfaction.

Measure of international normalised ratio (INR)

POCT INR is an effective adjunct for making timely clinical decisions. However, POCT is lower for INR values above 4 and as such, all results > 4.0 should be repeated by the laboratory. If this isn't possible, a repeat PoCT INR test should be performed and a check that quality control results have been within the target range. For PoCT INR > 8.0, a venous sample should be sent to the lab for verification but appropriate treatment should be commenced (after repeat PoCT test confirms >8.0).⁷

COVID-19 IgG/IgM Antibody tests

COVID-19 IgG/IgM rapid POCT have no role to play in the acute diagnosis of COVID 19 virus infection. See [RCPA Position Statement - COVID19 IgG/IgM RAPID POCT TESTS](#)

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