

National Pathology Accreditation Advisory Council (NPAAC) Guidance for Point of Care Testing

It is noted that there is widespread interest in the implementation of point of care tests for COVID-19 and that testing may be made available in a range of healthcare settings, including hospitals and outside of accredited pathology laboratories. The quality and safety of point of care testing (PoCT) is critical, particularly during this time.

NPAAC advice and quality standards for pathology testing are risk based and require the assessment of risks to patients or operators and mitigating those risks.

To support the increase in testing demand for COVID-19, the primary aim of this advice is to provide guidance on the use of PoCT with the aim of reducing the risk to a patient of a poor health outcome from poor performance tests or an inappropriate test for the intended purpose (e.g. serology test for acute diagnosis). Risk can occur because of poor training of the operator, poor patient preparation before the test, the PoCT device not operating to produce an accurate result, poor housekeeping with the use of out of date device consumables, misidentifying the patient or reporting the wrong result, not keeping the result in the patient medical records or misinterpreting the result. The risk applies in all settings where PoCT services are provided.

For the proper implementation of PoCT, there should be a quality framework that addresses support systems for the performance of testing, which may include a training program, advice on clinical utility or selection of device, External Quality Assurance and online support systems to provide advice to PoCT operators.

Key considerations that apply to the use of PoCT used in all healthcare settings are as follows:

1. Regardless of an organisation's structure, the clinical governance process **must** demonstrate clear accountability and responsibility for supervising PoCT and the delivery of results.
2. PoCT operators **must** be appropriately trained and competent to perform PoCT in the healthcare setting. It is critical that staff have the necessary training and skills to perform such testing and to be able to understand the test result.
3. Specimen collection **must** be in accordance with the instructions for use provided with the PoCT device.
4. The patient or client **must** be accurately identified during specimen collection and throughout the testing and reporting process to ensure traceability of the specimen through to the results report or electronic medical record.

5. Quality control (QC) procedures must be used for all testing provided and criteria for accepting QC results **must** be documented. Any action to be taken when QC results are unacceptable **must** be documented.
6. There **must** be active enrolment and participation in an External Quality Assurance (EQA) Program. The EQA program will identify any issues with the testing program, such as issues of concern with test results or tests, or operator of the test.
7. Breakdown in the communication of information, particularly relating to test results, is a major preventable cause of patient harm. Where possible, PoCT devices **should** be connected to electronic information systems to minimise post-testing errors. For example, whether the test result for the correct patient has been delivered to the treating practitioner for action.
8. A safe, secure working environment **must** be provided to ensure PoCT testing is safely and effectively performed.

Further guidance on minimum practice standards for PoCT can be found on the NPAAC webpage - <https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm>

An implementation flowchart has also been provided for reference.

IMPLEMENTING POINT OF CARE TESTING (PoCT) INTO YOUR ORGANISATION – FLOWCHART

DETERMINE THE NEED FOR PoCT IN YOUR ORGANISATION

If YES

SELECT THE APPROPRIATE PoCT DEVICE FOR YOUR ORGANISATION

Select your device

IMPLEMENT PoCT SERVICE

QUALITY ASSURANCE (QA)
QUALITY CONTROL (QC)

RECORDS
(e.g. test results; instrument event log; quality control log; maintenance record)

TRAINING/COMPETENCY
(e.g. training materials/resources)

ONGOING PROFESSIONAL SUPPORT

- Manufacturer
- PoCT network service providers
- Accredited pathology laboratory
- Professional organisations