

# Horizon Scanning Series

## The Future of Precision Medicine in Australia

### *Point of Care Testing*

*This input paper was prepared by Professor Catriona McLean (Alfred Health)  
and Professor Robyn Ward (The University of Queensland)*

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# Point of care testing

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## 1. Summary of Point of Care testing in Australia

The use of Point of Care testing (PoCT) in Australia is increasing and will continue to increase into the next decade. Publications on PoCT on Pubmed have increased 800% in the last decade. PoCT is performed near the individual and leads to immediate results that may inform decision making. The National Pathology Accreditation Advisory Council (NPAAC) of Australia has issued a set of guidelines for the use of PoCT with guidance on; governance, quality systems, staff training, safety, environmental issues, specimen and result integrity issues related to the use of PoCT. Specific PoCT require certification, for instance PoCT HbA1c requires National Glycohemoglobin Standardisation Program (NGSP) certification. PoCT is available for use in; pathology laboratories, hospital networks (to allow critical testing to be performed at the bedside or in a clinic), specialist medical retrieval medicine, General Practitioner (GP) practices, Aboriginal and Torres Strait Islander medical services, specialist community health services, and in other situations or community settings, such as pharmacies, sporting venues and law enforcement. In Australia, all *in vitro* diagnostic medical devices (IVDs) that are used for a therapeutic purpose are subject to regulation under the *Therapeutic Goods Act 1989*. Applicable to most PoCT, a new regulatory framework for IVDs was implemented on 1 July 2010, following amendments made to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) to include IVDs as a subset of medical devices. Before PoCT is implemented, the analytical performance requirements for the intended purpose must be defined **in comparison** to the performance of a laboratory test. The performance characteristics (estimates of error, or accuracy) should be should report trueness and precision of the test. Implementation of an accreditation framework for Quality Control and Quality Assurance is essential to ensuring the PoCT are suitable for use in clinical practice. For any PoCT the allowable limits of performance, the method of implementation and maintenance of the PoCT need to be well evaluated prior to adoption of the technique<sup>1-5</sup>. For use of the PoCT, the selection of the test system should be based on intended clinical use and usually falls into two categories; 1) low complexity and 2) medium complexity. Examples of PoCTs in regular use, in specific circumstances, include glucose and HbA1c analysis. Two recent Australian examples analysing troponin levels and viral load referenced, highlight sensitivity and specificity of PoCT in the diagnosis of myocardial infarction<sup>6</sup> and venepuncture versus finger-prick blood for Hepatitis C viral loads<sup>7</sup>. High complexity testing requiring laboratory analysers are not within the scope of PoCT. The value of PoCT in health care also depends on how many tests are required at the point of contact. For instance, a PoCT HbA1c has little value if the patient needs a suite of other tests which are not available at PoCT. A recent study has shown that PoCT is more expensive per test than laboratory based tests and is less precise than laboratory analytical testing. Pre-analytical and post-analytical errors may also be present. Finally, interpretation needs to be done in the correct clinical context as with all laboratory tests. Use of PoCT is likely to increase into the future, particularly in some areas, but testing should be done in the appropriate clinical setting and within in an Australian quality framework.

## References

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