



Assuring quality of POCT in Australia

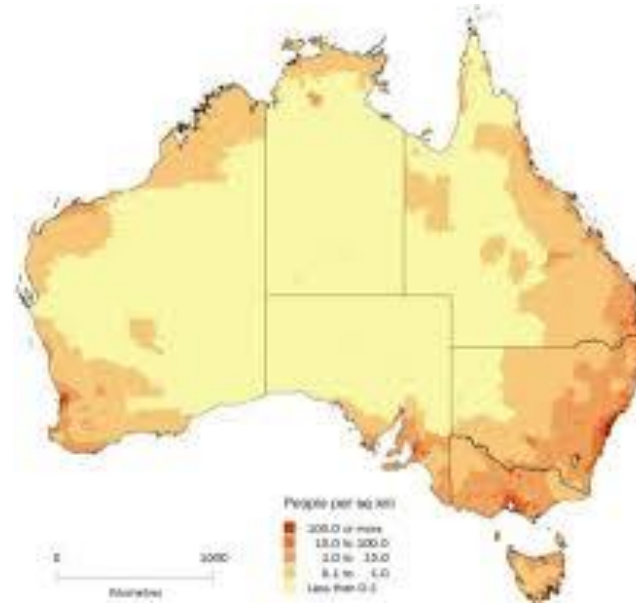
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This presentation provides a snapshot of POC testing in Australia. It does not attempt to be comprehensive.



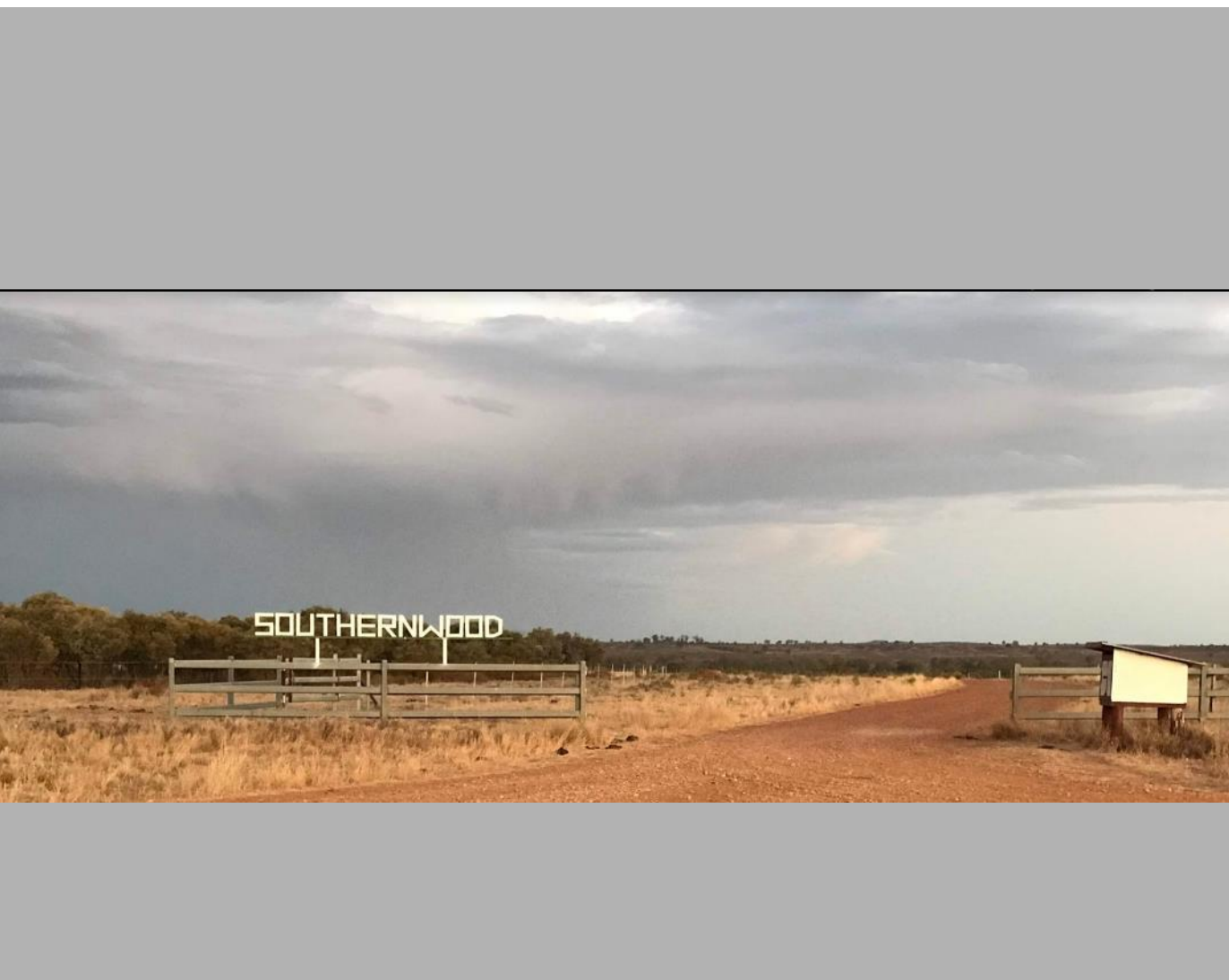
- In 1770 James Cook claimed the east coast of Australia. It was officially made a British colony.
- Australia is the 6th largest country by land mass
- In 2019, it is the 54th biggest country in the world by population
- Population density 3/km² - one of the lowest in the world!
- Aboriginal and Torres Strait Islander Population = 649,171*

*2016 Census



Australian Population 2019

25 Million



- > A 2014 report from the Australian Institute of Health Welfare estimated that a third of Australians live outside the major cities and noted that mortality rates and rates of preventable hospitalisations increase with remoteness.

Funding of pathology services in Australia

- > Free access to public hospital care, including pathology testing, for public patients is funded jointly by the Australian, State and Territory governments
- > The Australian Government subsidises the costs of general practice and medical specialist services (including to pathology) to private patients in the community and private patients in hospitals

Safety & Quality

- > Pathology laboratories in Australia vary in their complexity, the numbers and types of tests they can perform, the professionals who staff them and the technology they have available.
- > In Australia, laboratory accreditation is recognised as an essential means of promoting high quality pathology service provision to patients, their requesting doctors and to the community, and maintaining public confidence.
- > Since 1986, Commonwealth legislation (*Health Insurance Act 1973*) has required that private pathology laboratories must be accredited for access to the government subsidies.
- > Now all public pathology providers are covered by the pathology laboratory accreditation arrangements.

Regulation of IVDs

- > Until 2010, only HIV and HCV assays (and a small number of other IVDs) were subject to regulation by the Therapeutic Goods Administration
- > Until that date, no self-tests were permitted to be supplied in Australia
- > After 2010, the GHTF regulatory model was adopted and all IVDs are now subject to regulation, following a risk-based approach to regulatory control.
- > The Australian regulatory scheme is based on recognition and reliance mechanisms with the exception of a limited number of higher risk devices.
- > The regulation allows for restrictions of supply of certain types of devices.
- > IVDs must be included on the Australian Register of Therapeutic Goods (ARTG) as a basis for legal supply

Regulation of IVDs

- > IVDs intended for self-testing are tests that are used in the home or a similar environment and are not carried out under the supervision of a health care provider. Certain types of self-testing IVDs will be prohibited from supply. These include:
 - IVDs used to test for pathogens or diagnose notifiable infectious diseases;
 - tests to determine genetic traits;
 - IVDs used to test for serious disorders, for example cancer or myocardial infarction.

- > <https://www.tga.gov.au/overview-regulatory-framework-vitro-diagnostic-medical-devices> (2011)

Regulation of IVDs

- > The ban on the supply of HIV self-tests in Australia was lifted in July 2014.
- > The effect of this is that HIV self-tests can now be included in the ARTG and legally supplied in Australia, subject to satisfying the applicable regulatory requirements.

Definition

For the Australian government, PoCT is defined as pathology testing performed at the point or time of care that helps healthcare practitioners make immediate and informed decisions about a patient's management.

Expectations of Australian patients

- > At the most elementary level, patients as consumers of health care expect that the quality of care provided be synonymous with freedom from medical error.
- > This includes freedom from errors in laboratory and POC testing.
- > For patient safety to be achieved within the current context (of laboratory and POC testing), quality goals for both analytical and clinical management must be given an appropriately high priority.

Medical errors in diagnostic testing

- > Medical errors are mainly failures in testing procedures or failure to complete planned actions.
- > These are generally described as pre-analytical errors, analytical errors or post-analytical errors.
- > In order to achieve appropriate test results which are fit for purpose, all aspects of the testing process must be addressed in an efficient and reliable manner.
- > To achieve this goal, operational standards, rules and guidelines must be applied.
- > These same rules apply whether the objective is central laboratory testing or POCT.

How difficult is POCT?

- > “Although the overall impact of POCT errors on patient care was considered low, with 51.8% of all reported errors considered to have no impact, 48.2% of errors were considered to have some impact on patient care”.²

² O’Kane MJ, McManus P, McGowan N, Lynch PLM. Quality error rates in point-of-care testing. Clin Chem 2011;57:1267-1271.

Error types

- > Principal reasons for pre-analytical errors in laboratory testing have been identified as
 - haemolysed specimen (54% of all pre-analytical errors),
 - insufficient specimen (21% of all pre-analytical errors), and
 - incorrect specimen (13% of all pre-analytical errors).³
- > In a traditional laboratory these types of error are relatively easy to detect. In a POCT situation, this type of error may well pass undetected with a compromised patient result being produced.
- > In addition to pre-analytical errors, POCT in particular is prone to “native interferences” which alter the reactivity of the analytical process to produce errors which may largely go undetected i.e. analytical specificity

³ Bonini P, et al. Errors in laboratory medicine. Clin Chem 2002; 48: 691.

How difficult is POCT?

- > “Although POCT appears to be deceptively simple, if incorrectly performed it may present a risk to patient care and, if used inappropriately or overused can lead to significant increases in the cost of patient care.
- > To ensure results obtained are comparable to the traditional pathology laboratory, POCT should be implemented within a framework of quality standards.
- > This quality framework should include: operator education, training and competency, quality control, proficiency testing and accreditation.”¹

¹ Tirimacco R. Design, implementation and outcomes for POCT: cost implications. POC 2008; 7 (3): 128.

Australian Government overarching principles

- > Standards and guidelines developed for POCT using evidence-based procedures are designed to assist with the implementation, management, operation and on-going quality assessment of the selected technology.
- > With adherence to appropriate standards and guidelines, POCT provides significant benefits for both patients and healthcare providers.

Standard setting and guidelines bodies for POCT in Australia

> Standards Australia

- development of national standards or promulgating standards developed by ISO.

> NPAAC

- Advises the Commonwealth, state and territory health ministers on matters relating to the accreditation of pathology laboratories.
- Responsible for the development and maintenance of standards and guidelines which help define the quality procedures for the practice of pathology and is the principal Australian provider of standards for pathology
- AS 4633 / ISO 15189 has been confirmed by NPAAC as the principal standard which is used as the basis for accreditation of pathology laboratories in Australia.
- Other NPAAC standards are developed to cover specific areas as required or to provide more detailed information not specifically available in AS 4633 / ISO 15189.

Standard setting and guidelines bodies for POCT in Australia

- > Royal Australian College of General Practitioners in association with the Department of Health and Ageing general practice trials' technical advisory committee.
 - *Standards for point-of-care testing*
 - improve the quality and safety of point-of-care testing (PoCT) performed by health services
 - help services identify and address any gaps they have in their systems and processes.
- > Australasian Association of Clinical Biochemists (AACB)
- > Royal College of Pathologists of Australasia (RCPA)
- > Aust Govt Medical Services Advisory Committee

Standard setting and guidelines bodies for POCT : State level



Policy Directive



Managed Point of Care Testing (PoCT) Service

Summary This Policy Directive provides guidance for the safe and effective management and use of PoCT, used by competent individuals using devices that are fit for their intended purpose on the correct patient, giving results which become part of the patient record.

Document type Policy Directive

Document number PD2018_028

Publication date 19 July 2018

Author branch NSW Health Pathology

Branch contact (02) 4924 6714

Replaces PD2015_028

Review date 19 July 2023

Policy manual Not applicable

File number H13/79028

Status Active

Functional group Clinical/Patient Services - Pathology

Applies to Ministry of Health, Public Health Units, Local Health Districts, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, NSW Health Pathology, Government Medical Officers, Community Health Centres, NSW Ambulance Service, Public Hospitals, Private Hospitals and day Procedure Centres



Standards for point-of-care testing

5th edition



Why have standards for POCT?

The sophistication and reliability of PoCT systems and instruments has improved markedly in recent years, making PoCT more accessible for general practices.

Fit-for-purpose standards will help general practices ensure the quality of their PoCT services.

Standards were developed by the RACGP in consultation with general practitioners (GPs), practice managers, nurses, consumers, technical experts and other stakeholders.



What POC assays can be used in Australia?

- > The Standards for PoCT assume that an Australian general practice's PoCT devices or systems, including but not limited to consumables, reagents, controls and software, are listed on the ARTG.

The screenshot shows the Australian Government Department of Health Therapeutic Goods Administration (TGA) website. The page is titled 'Medical devices & IVDs' and provides information about the regulation of medical devices and in vitro diagnostic medical devices (IVDs) in Australia. The page includes a navigation menu, a search bar, and a list of quick links.

Australian Government
Department of Health
Therapeutic Goods Administration

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 - Medical devices reforms
 - Regulatory decisions and notices
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- ▶ Blood and blood components

Home > Industry

Medical devices & IVDs

Medical devices include a wide range of products such as medical gloves, bandages, syringes, condoms, contact lenses, in vitro diagnostic medical devices, disinfectants, X-ray equipment, surgical lasers, pacemakers, dialysis equipment, baby incubators, heart valves.

- [Medical devices regulation basics](#)
General information about how medical devices are regulated in Australia
- [IVD medical devices regulation basics](#)
General information about how in vitro diagnostic medical devices (IVDs) are regulated in Australia
- [Standards, guidelines & publications \(medical devices & IVDs\)](#)
Standards, guidelines and publications about the regulation of medical devices and in vitro diagnostic medical devices
- [Forms for medical device & IVD sponsors](#)
Links to forms for sponsors of medical devices and in vitro diagnostic medical devices
- [Medical devices reforms](#)
The TGA has begun work on a series of reforms to the regulation of medical devices, including the hip, knee and shoulder joint implant reclassification
- [Regulatory decisions & notices \(medical devices & IVDs\)](#)
Links to regulatory decisions about medical devices and in vitro diagnostic medical devices, e.g. advertising exemptions

Quick links

- [ARGMD](#)
- [IVD guidance documents](#)
- [Legislation](#)
- [eBusiness Services](#)
- [Fees & payments](#)
- [Manufacturing medical devices & IVDs](#)
- [Search the ARTG](#)
- [Report a problem](#)
- [Advisory Committee on Medical Devices](#)
- [Regulatory and Technical Consultative Forum](#)
- [Health Technology Assessment \(HTA\)](#)

PoCT Standard 1: Clinical governance

- > The practice uses clinical governance to establish and review clinical responsibility and accountability.
- > Effective clinical governance of PoCT ensures that:
 - each practice team member takes ownership of PoCT processes, models good practice, and challenges poor practice
 - each team member is jointly accountable for patient safety and quality care
 - roles, responsibilities and accountabilities for achieving agreed outcomes are clearly allocated to team members, according to each person's scope of practice
 - the practice uses what they have learnt to improve patient safety and quality of care

Indicators

PoCT1.1 ▶ A Our practice can describe the clinical and diagnostic purposes of PoCT based on best practice evidence, and how it can be applied.

PoCT1.1 ▶ B Our practice's specifications for the analytical performance of PoCT are determined by the relevant clinical and diagnostic purposes.

PoCT1.1 ▶ C Our practice uses reference data that is based on best practice evidence to interpret test results.

PoCT1.1 ▶ D Our practice applies quality improvement and risk management processes to PoCT to improve quality of care and to minimise risk to patients.

PoCT Standard 2: Education and training of PoCT practitioners

- > The practice team has the appropriate skills and knowledge to perform PoCT.
- > The quality of PoCT can be compromised by pre-analytical, analytical and post-analytical errors and issues, especially if performed by inadequately trained PoCT practitioners.
- > This is why team members performing and managing PoCT must be appropriately trained and educated, and must be able to demonstrate competency when assessed.

Indicators

PoCT1.1▶A Our practice can describe the clinical and diagnostic purposes of PoCT based on best practice evidence, and how it can be applied.

PoCT1.1▶B Our practice's specifications for the analytical performance of PoCT are determined by the relevant clinical and diagnostic purposes.

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PoCT1.1▶D Our practice applies quality improvement and risk management processes to PoCT to improve quality of care and to minimise risk to patients.

APPN - The Australian Point of Care Practitioner's Network

- > The APPN is an online platform that provides training, certification and professional development programs for all PoCT practitioners.
- > PoCT practitioners can also maintain an electronic record of their continuing professional development (CPD) on the APPN's portal.

appn.net.au/home.aspx

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WOULD YOU LIKE YOUR DEVICE LISTED ON THE APPN?

Register your Point of Care technology with the APPN to facilitate the access of service providers to your equipment.

The APPN will provide impartial advice and resources on your behalf that would meet guideline recommendations.

For more information please contact us by clicking this banner.

APPN News

New RACGP Standards for point-of-care testing 5th edition is now available
To download a copy of these standards, please visit the Resources section of the website, or [click here](#).

CRP Webinar now Available
Please click [here](#) to view our latest webinar: Use of CRP to Guide Antibiotic Prescription; The Role of Point of Care Testing. All of our webinars are available for viewing through our 'Events' section.

PoCT Standard 3: Implementation and performance

- > The practice ensures that the implementation and performance of PoCT is in accordance with manufacturers' recommendations and best practice.
- > The successful implementation and performance of a PoCT program includes:
 - conducting PoCT in a fit-for-purpose environment
 - conducting PoCT in accordance with the manufacturers' instructions
 - maintaining PoCT equipment in accordance with the manufacturers' instructions
 - maintaining PoCT records.

Criterion PoCT3.1 – Facilities for testing

Indicators

PoCT3.1▶A Our practice conducts testing in a safe environment that ensures patient privacy.

PoCT3.1▶B Our practice ensures that instruments and consumables are located and managed to optimise performance.

Criterion PoCT3.2 – Routine testing

Indicators

PoCT3.2▶A Our practice follows the manufacturers' instructions for PoCT.

PoCT3.2▶B Our practice identifies and reviews errors and deviations.

PoCT3.2▶C Our practice ensures that specimens remain positively identified with patients throughout the testing process.

PoCT3.2▶D Our practice documents its requirements for PoCT essential support services.

PoCT3.2▶E Our practice commissions and maintains our PoCT equipment in accordance with each manufacturer's instructions.

Criterion PoCT3.3 – Data management

Indicator

PoCT3.3▶A Our practice maintains records relating to PoCT that are readily accessible and secure.

PoCT Standard 4: Quality Outcomes

- > The practice performs PoCT using an established quality system to ensure the safety and quality of our patient care.
- > Quality control (QC) testing helps your practice to:
 - be confident that your PoCT is functioning properly
 - detect and manage sub-optimal performance.

Criterion PoCT4.1 – Quality manual

Indicators

PoCT4.1▶A Our practice maintains a quality manual for PoCT.

PoCT4.1▶B Our practice regularly assesses compliance with PoCT policies and procedures.

Criterion PoCT4.2 – Quality control procedures

Indicator

PoCT4.2▶A Our practice uses quality control procedures to ensure the PoCT is functioning optimally.

Criterion PoCT4.3 – External quality assurance program

Indicator

PoCT4.3▶A Our practice participates in an external quality assurance program.



rcpaqap.com.au/product/point-of-care-hiv-poct-only/

RCPAQAP

The Royal College of Pathologists of Australasia
Quality Assurance Programs

MYQAP ONLINE DATA ENTRY

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Home » Products » Point of Care – Human immunodeficiency virus (HIV)

Point of Care – Human immunodeficiency virus (HIV)

Clinical material provided (Stabilised Whole blood/ Inactivated viral culture lysate – 0.4 mL) to assess the detection of HIV using Point of Care Assays

Frequency / Number of samples

4 surveys / 2 samples per survey

Tests

HIV Antigen PoCT; HIV Antibody PoCT



SERVING REMOTE COMMUNITIES



"Bedside pathology and other technologies are revolutionising rural practice. The ability to diagnose a heart attack, monitor medication, check salts and kidney function and check the blood gases in a seriously ill patient means that rural generalists can make more informed decisions when they need to be made - here and now."



SMALL IN SIZE, BIG IN SCOPE: POINT OF CARE TESTING IN RURAL AND REMOTE QUEENSLAND

As you may have noticed Australia is a very big country. The tyranny of distance and its corresponding poor access to health services for people living in rural and remote communities is one of the biggest issues facing Australian medicine.

- > New Breakthroughs
- > Real Life Stories
- > Pathology Explained
- > People in pathology
- > Serving Rural Communities
- > The Doctor's Doctor

LATEST NEWS



Federal MP tours pathology lab after cancer diagnosis speech
August 30, 2019



Olympic athlete Jana Pittman learns about



While both tests are convenient and easy to read, neither is sufficiently sensitive nor specific to replace the gold standard of formal treponemal testing. This is especially true in areas with a low prevalence of disease. **Currently our recommendation is that all patients at high risk of infection should be assessed with gold standard testing, even in the presence of a negative point-of-care test.**



Obrigado! Merci!

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<http://www.nsf.org/services>