



# PathWay

THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA



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Issue #038

## In This Issue

- NPAAC PoCT Best Practice Guidelines and RCPA PoCT device Guidelines aim to ensure safe use of PoCT devices
- Point of Care Testing devices for diabetes - Caveat emptor!
- Point of Care Tests for infectious diseases can be a game changer
- Issues with Point of Care Testing for anticoagulant therapy are not that bleeding obvious

## Welcome to the July edition of ePathway

This is an exclusive Point of Care Testing (PoCT) edition that highlights the benefits and risks associated with this growing trend.

There's no doubt PoCT ticks a lot of boxes including the convenience of testing (almost) anywhere, anytime with faster results. But the results must be reliable or they're of little use. Two pathology associations are currently writing guidelines to help ensure PoCT is delivered safely in any testing situation or setting. Our article explains who is writing them and why.

PoCT is also used in many areas of medicine and we've chosen to highlight three: monitoring Warfarin therapy with an INR test, diagnosing and monitoring diabetes and early detection of infectious diseases.

Don't forget to check our [Facebook](#) page regularly and keep up-to-date with what's happening in pathology by following our CEO Dr Debra Graves (@DebraJGraves) or the College (@PathologyRCPA) on Twitter.

## Interesting Facts

### August 2013

The month the RCPA released their latest [position statement](#) on Point of Care Testing (PoCT)

### \$4.7 billion

The value of the global rapid tests and point of care market in 2010

## NPAAC PoCT Best Practice Guidelines and RCPA PoCT device Guidelines aim to ensure safe use of PoCT devices

# \$7.4 billion

The forecast value of the global rapid tests and point of care market in 2017

Source: RCPA, [Research and Markets](#)

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Point of Care Testing (PoCT) ticks all of the boxes of our modern mobile age including smaller and more portable testing devices delivering faster results. But there's one important box these tests always need to tick - quality of results. The Royal College of Pathologists of Australasia (RCPA) and the National Pathology Accreditation Advisory Council (NPAAC) are drafting PoCT guidance documents with the goal of ensuring the safe use of PoCT devices and delivery of quality results.

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## Point of Care Testing devices for diabetes - Caveat emptor!

Point of Care Testing (PoCT) devices for diabetes, called blood glucose meters or glucometers, have enabled blood glucose (sugar) levels to be monitored anytime, anywhere. Some of these devices, as well as other POCT devices, measure glycated haemoglobin (HbA1c)<sup>[1]</sup>. While they have an important role in the management of diabetes, PoCT devices can't completely replace tests performed in an accredited laboratory<sup>[2]</sup> for diagnosing and monitoring the disease.



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## Point of Care Tests for infectious diseases can be a game changer

Time has usually been on the side of an infectious disease. It can often make a person very ill very quickly and spread rapidly from host to host, while the laboratory often takes days to grow, identify and perform antibiotic sensitivity (resistance) tests on the causative organism. Advances in technology have put the shoe on the other foot with Point of Care Tests (PoCT) for infectious diseases making it a more even time match.

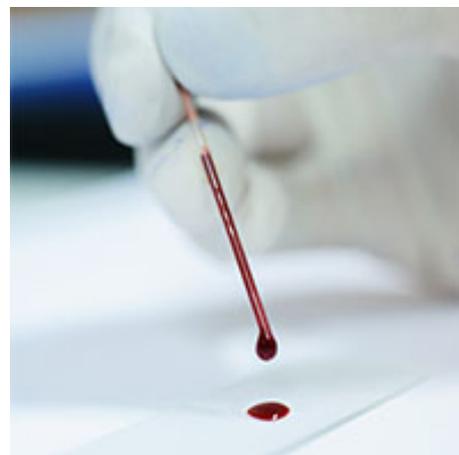


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## Issues with Point of Care Testing for anticoagulant therapy are not that bleeding obvious

There's no doubt Point of Care Testing (PoCT) is an attractive proposition for patients on Warfarin therapy who require frequent blood tests for dose control. But this type of test has limitations that must be factored into the equation.



Anticoagulant therapy is monitored through a test called an International Normalised Ratio (INR). This test measures how long it takes blood to clot and informs the dose of anticoagulant therapy. PoCT for INR can mean the test and any consequent dose adjustments can be accomplished during one doctor visit. On the other side of the equation, limitations associated with PoCT for INR include the collection technique.

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## Previous Editions



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### IN THIS ISSUE

- Know Pathology Know Healthcare campaign kicked off at Canberra's Parliament House with blood tests for our polities
- HPV test may renew Australia's National Cervical Screening Program
- Quality assurance processes are finally

### Introduction



2014

[033 - February 2014](#)

[034 - March 2014](#)

[035 - April 2014](#)

[036 - May 2014](#)

[037 - June 2014](#)

## 2013

[022 - February 2013](#)

[023 - March 2013](#)

[024 - April 2013](#)

[025 - May 2013](#)

[026 - June 2013](#)

[027 - July 2013](#)

[028 - August 2013](#)

[029 - September 2013](#)

[030 - October 2013](#)

[031 - November 2013](#)

[032 - Dec 2013/Jan 2014](#)

## 2012

[010 - Dec 2011/Jan 2012](#)

[011 - February 2012](#)

[012 - March 2012](#)

[013 - April 2012](#)

[014 - May 2012](#)

[015 - June 2012](#)

[016 - July 2012](#)

[017 - August 2012](#)

[018 - September 2012](#)

[019 - October 2012](#)

[020 - November 2012](#)

[021 - December 2012](#)

## 2011

[001 - March 2011](#)

[002 - April 2011](#)

[003 - May 2011](#)

[004 - June 2011](#)

[005 - July 2011](#)

[006 - August 2011](#)

[007 - September 2011](#)

[008 - October 2011](#)

[009 - November 2011](#)

[« Back to Home Page](#)

---

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## NPAAC PoCT Best Practice Guidelines and RCPA PoCT device Guidelines aim to ensure safe use of PoCT devices



Point of Care Testing (PoCT) ticks all of the boxes of our modern mobile age including smaller and more portable testing devices delivering faster results. But there's one important box these tests always need to tick - quality of results. The Royal College of Pathologists of Australasia (RCPA) and the National Pathology Accreditation Advisory Council (NPAAC) are drafting PoCT guidance documents with the goal of ensuring the safe use of PoCT devices and delivery of quality results.

Dr Bronwen Ross, Deputy CEO of the RCPA, is assisting the RCPA PoCT Taskforce in drafting a quality framework document to guide PoCT. The taskforce has been working on this document for 12 months with funding from a rural support initiative of the Commonwealth Specialist Training Program (STP).

"The RCPA recognises there is a lack of guidance about how to ensure the procedure for using PoCT devices is safe throughout the whole chain of practice to deliver an accurate result," she explains. "There are a lot of PoCT devices entering the market, and it's important that quality procedures for the whole test-request-report cycle are maintained when using these devices."

Dr Ross says manufacturers of PoCT devices are not required to take responsibility for the whole cycle even though errors can enter the process at any stage.

"One example is that if a reagent deteriorates because it isn't kept at the right temperature the machine may not pick this up. This can mean the error continues through the whole process and affect the results for a whole series of patients," she says.

Associate Professor Tony Badrick from the Faculty of Health Sciences and Medicine at Bond University is chairing the NPAAC committee developing *Guidelines for Point of Care Testing*<sup>[1]</sup>. The draft document was released for public consultation on June 12 and provides a quality framework for the appropriate safe operation of PoCT and delivery of quality

results in laboratories, other healthcare settings and community settings.

“NPAAC has developed guidelines for PoCT that provides guidance on minimum acceptable best practice for medical governance, staff training, quality management systems and specimen and result integrity,” he explains. “While they are mostly focussed on operators within pathology laboratories, the principles provide guidance on best practice regardless of where the test may be performed.”

While both the RCPA and NPAAC are developing PoCT guidance documents, Dr Ross says they will be complementary.

“NPAAC is providing the broader best practice guidelines and the RCPA is honing in on the finer practice details for PoCT devices and tests ranging from blood gas machines in intensive care units to PoCT devices delivering results to remote Aboriginal communities,” she explains.

[1] NPAAC's draft *Guidelines for Point of Care Testing* is accessible through the Australian Government Department of Health [website](#). The closing date for submissions is 23 July 2014.

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Most people with diabetes monitor their blood glucose levels daily with their own PoCT device, but it's important to remember the 'device isn't always right'. Results can be affected by such things as expired test strips, a low or flat battery or insufficient blood on the test strip. The issue of reliability of results escalates when it comes to diagnosing diabetes with an HbA1c test.

"PoCT for HbA1c is not deemed reliable or fit for purpose unless strict quality assurance practices are followed," says Dr Samarina Musaad, chemical pathologist at Labtests in New Zealand and Chair of the PoCT task force for the Royal College of Pathologists of Australasia (RCPA).

"Unfortunately, machines that are not properly calibrated and that do not give reproducible results for this test making them not fit for purpose are able to enter the system, and once they are in there they are difficult to identify and remove."

Dr Musaad says PoCT devices that measure HbA1c are fit for purpose if they are analytically correct with reproducible results that are clinically valid.

"Consumers and other health care professionals can't be expected to know if it's a 'good' or 'bad' machine. That takes the expertise of a pathologist or laboratory scientist. Other factors can affect the result including the patient's age and preexisting conditions. This is why the clinical interpretation of the result is also important."

Dr Musaad says another issue is accreditation of PoCT devices is encouraged by scientific and regulatory bodies, but it is not mandatory in the community. Guidelines produced by peak bodies such as the RCPA and the Australasian Association of

Clinical Biochemists (AACB), and Standards produced by the National Pathology Accreditation Advisory Council (NPAAC) are all available but the onus is on the service providing PoCT to follow them and opt for accreditation. Obstacles that stand in their way may be cost or lack of knowledge about its importance.

Dr Musaad says the RCPA supports the use of PoCT for HbA1c if there is no other choice, but if there is a choice, the test should always be performed in a National Association of Testing Authorities (NATA)/RCPA or International Accreditation NZ (IANZ) accredited laboratory.

It's also important that patients who purchase a POCT device for their own use receive adequate training from the provider (such as their doctor or pharmacist) about how to read the manufacturer's instructions, how to use it and to notify their health carer if they have any concerns regarding the results when they use it.

"A diagnosis of diabetes is for life, and monitoring its progress is for life, so the results must be accurate," says Dr Musaad.

[1] HbA1C is covered in the [September 2012](#) and [November 2013](#) editions of ePathWay

[2] Quality assurance is covered in the [June 2012](#) and [August 2012](#) editions of ePathWay

[« Back to Home Page](#)

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Time has usually been on the side of an infectious disease. It can often make a person very ill very quickly and spread rapidly from host to host, while the laboratory often takes days to grow, identify and perform antibiotic sensitivity (resistance) tests on the causative organism. Advances in technology have put the shoe on the other foot with Point of Care Tests (PoCT) for infectious diseases making it a more even time match.

Professor Joan Faoagali, microbiologist and Emeritus Physician in Infection Management Services at Brisbane's Princess Alexandra Hospital, says microbiologists traditionally receive a sample to examine for bacteria that are then cultured and identified, and their antibiotic sensitivities tested, before a final report is issued about three to four days later. PoCT's mean that some pathogens can be detected faster and a report produced in just hours.

"New technologies such as molecular testing allow us to provide information about the cause of an infection faster than waiting for an organism to grow, and this enables earlier and more specific treatment," she explains.

Prof Faoagali says PoCT tests are now available for Influenza viruses A and B, respiratory syncytial virus (RSV), *Clostridium difficile* toxin, pneumococcus and human immunodeficiency virus (HIV), and there are more in the pipeline.

"There are about 55 different companies working on PoCT for infectious diseases such as malaria, strep A, hepatitis and some sexually transmitted diseases."

The world market for infectious disease tests was estimated at \$14.5 billion in 2012 and is tipped to grow at a slightly higher rate than the rest of the diagnostics market. Timely identification of causative pathogens can also enhance investigation and timely treatment of epidemics and disease outbreaks.

"During the last influenza epidemic at the hospital where I work, we were able to do a quick PoCT on patients to indicate if

they were positive or negative for the circulating influenza virus,” explains Dr Faoagali. “In fact, PoCT are particularly useful for identifying viruses that can’t be easily grown in a laboratory.”

While PoCT for early identification and treatment of infectious diseases is a welcome trend, there are caveats. Prof Faoagali says they can produce false positive and false negative results making formal laboratory confirmation of the result important. There are quality assurance issues and the correct clinical interpretation of the result to consider as well.

“While we may be able to produce a quicker than normal result with these devices, confirmation and interpretation of the result through a pathology laboratory is still important,” she says.

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There's no doubt Point of Care Testing (PoCT) is an attractive proposition for patients on Warfarin therapy who require frequent blood tests for dose control. But this type of test has limitations that must be factored into the equation.

Anticoagulant therapy is monitored through a test called an International Normalised Ratio (INR). This test measures how long it takes blood to clot and informs the dose of anticoagulant therapy. PoCT for INR can mean the test and any consequent dose adjustments can be accomplished during one doctor visit. On the other side of the equation, limitations associated with PoCT for INR include the collection technique.

"The collection technique and the person collecting the sample can vary the result. Blood from a vein is used for a laboratory INR test, while blood from a finger prick is used for PoCT for INR," explains Dr Michael Harrison, CEO of Sullivan Nicolaides Pathology.

"This means tissue thromboplastins from the lancet damage to skin and underlying structures can contaminate a blood sample from a finger prick and influence the result. This is not usually a problem with a well-collected venous sample."

Thromboplastins are substances released from damaged tissues (as well as platelets and white blood cells) which initiate the blood clotting process. Dr Harrison says this issue can be assessed by occasionally collecting blood from a vein at the same time as a finger prick sample for PoCT, and sending the venous sample to a pathology laboratory to compare the INR results.

"Laboratory tests for INR are very precise with a Coefficient of Variation (CV) of around 3%, while PoCT for INR is much less precise with a CV in the PoCT trial of around 8%," explains Dr Harrison. "This means a laboratory INR result of 3 could actually be 2.8 or 3.2 when tested by PoCT, and this can be a problem if this variation isn't recognised and the dose of anticoagulant is changed based on the premise these are 'real' changes."

Dr Harrison says another limitation of PoCT for INR is that results over 4 are often very different when tested in the laboratory. He says if PoCT for INR returns a result of 4, then it could actually be 4 or 6 or 8 meaning any result over 3.5 or 4 should be confirmed by a pathology laboratory.

“Overall PoCT for INR is a good application of this technology because it is definitely more convenient for the patient, but there are issues associated with it,” explains Dr Harrison. “However, if these issues are managed well then it is a very good use of this technology.”

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