

MEDIA RELEASE

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RCPA updates advice surrounding rapid antigen tests

Due to limitations in sensitivity, the [Royal College of Pathologists of Australasia](https://www.rcpa.edu.au/) remains concerned over the uncontrolled use of rapid antigen tests (RATs) in Australia and New Zealand whilst the prevalence of SARS-CoV-2 remains generally low. However, the RCPA recognises that governments and public health authorities fighting localised outbreaks may need to use RATs for surveillance testing in defined circumstances, in addition to the more accurate mainstream molecular tests.

The RCPA is the leading professional organisation representing pathologists, medical specialists and scientists who provide pathology testing in Australasia. The College plays a key role in maintaining the quality and standards of pathology services in Australia and New Zealand.

Dr Michael Dray, President of the RCPA, says that by being informed of the limitations of RATs, the RCPA aims to assist authorities in making their limited use for surveillance testing in COVID-19 hotspots as effective as possible.

“RATs are less able to detect SARS-CoV-2 and therefore should never be used alone for diagnostic purposes in a symptomatic patient where a false-negative result may provide unwarranted reassurance and lead to ongoing community transmission. It is wrong to automatically assume that mass surveillance through frequent use of RATs may detect SARS-CoV-2 infection more (or as) quickly as infrequent use of the superior gold standard Polymerase Chain Reaction (PCR) molecular test. This strategy has some rationale in countries with high prevalence of the virus, such as in the US and UK, where they did not have the capacity to use the more sensitive PCR tests and where the implications of a false negative or false positive are not as serious.

“There is limited evidence supporting mass surveillance by RATs in Australia and New Zealand where only a small number of independent evaluations have been performed in populations with a low prevalence of COVID-19. This is why the RCPA continues to urge caution when using RATs and why the College is advocating for an initial limited rollout as part of well-supervised feasibility studies. Some studies have in fact shown that the sensitivity of RATs is poor in asymptomatic patients. Whilst the College is open to explore new possibilities, molecular tests remain the preferred method for COVID-19 diagnosis as they are highly sensitive and specific,” said Dr Dray.

Dr Lynette Waring, Chair of the RCPA’s Microbiology Advisory Committee says that RATs have several impracticalities that must be addressed.

“If RATs are to be used in Australia and New Zealand, there must be caveats in place around their use. Firstly, all positive RAT tests must be verified by an additional molecular test due to the high likelihood of false-positive results. As self-collected and self-administered RATs are not approved for use in Australia or New Zealand, a mid-nasal swab must still be collected, and the test performed by a trained operator. These operators must wear appropriate personal protective equipment (PPE) and have access to suitable waste disposal.

“It is imperative that we are still able to accurately track the spread of the virus, therefore results of RATs must be recorded in individuals’ medical records, and positive and negative results reported to public health authorities. In addition to isolating a RAT-positive individual while awaiting the result of the definitive molecular test, the appropriate interim response at the testing site must be pre-determined and acceptable to public health authorities. RAT kits

must be transported, stored and handled correctly at each non-clinical test site and each test site should participate in a registered quality assurance program (QAP) conducted at quarterly intervals,” said Dr Waring.

The Therapeutic Goods Administration (TGA) has updated its guidance regarding supply, training and supervision requirements for RATs. The RCPA agrees that health practitioners must ensure that anyone performing the test under their supervision (including sample collection and interpretation of test results) should be appropriately trained in all matters related to good testing practice. This includes training in infection control; collection of samples; correct use of the device and interpretation of test results; protocols for recording results and requirements for notification of positive results; protocols and referral processes for recollection and confirmatory testing; and protocols for reporting any problems or adverse events associated with performance of the test, including false negative or false positive results, to the TGA.

The RCPA recommends that, as applies to all other quality diagnostic tests, a RAT is chosen depending on demonstration of acceptable performance in independent validations conducted under local conditions, in addition to being feasible and the practical issues being addressed. These scenarios may include:

- Suspected outbreaks of COVID-19 in remote settings where PCR molecular testing is not readily accessible. Results would need to be confirmed by PCR molecular testing.
- To support PCR confirmed outbreak investigations. (i.e., closed or semi-closed groups including schools nursing homes, cruise ships, prisons etc). The RAT result could be used to quickly isolate positive cases and initiate contact tracing while awaiting definitive molecular testing.
- To monitor trends in disease incidence in communities particularly among essential workers such as healthcare workers during outbreaks or in regions of widespread community transmission.
- Where there is widespread community transmission, frequent antigen testing (daily or second daily) may be useful for early detection and isolation of positive cases in health facilities, nursing homes, prisons, other institutions and essential worksites, if regular, routine screening with PCR methods is not available.

“Pathologists have worked hard to achieve the high level of laboratory testing that has been a major contributor to the enviable COVID-19 position in Australia and New Zealand and we do not want to compromise that position by rolling RATs out too hastily. We have ample capacity for current methods of testing with laboratories in Australia and New Zealand continuing to provide reliable high-throughput molecular testing with over 100,000 COVID-19 tests performed daily in NSW alone,” said Dr Dray.

For further information on the RCPA, please visit www.rcpa.edu.au or see updates on Facebook - @PathologyRCPA, Twitter - @RCPAPresident, @PathologyRCPA, or Instagram - @the_rcpa #RCPA #pathology #MedicinesPathology.

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About the Royal College of Pathologists of Australasia:

The RCPA is the leading professional organisation representing pathologists, medical specialists and scientists who provide pathology testing in Australasia. Its mission is to train and support pathologists and to improve the use of pathology testing to achieve better healthcare.

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